No. 2010-1001

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

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US COURT OF APPEALS
FEDERAL CIRCUIT

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
CASE NO. 2:05-CV-40188, JUDGE AVERN COHN

COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for defendants-appellees Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. certifies the following:

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

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

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:

N/A

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

Caraco is publicly traded. Sun owns a majority of Caraco's shares.

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:

From Winston & Strawn LLP: James Hurst, Charles Klein, David Bloch, Scott Blackman, Steffen Johnson, Matthew Campbell, John Hsu, Julie Shin, and Andrew Nichols. From Barris, Sott, Denn & Driker, PLLC: Morley Witus. From Proskauer Rose: Charles Guttman and John Stellabotte.

Dated: MAY 14, 2010

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TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND REGULATIONS

OTHER AUTHORITIES

CIRCUIT RULE 35(B) STATEMENT

In my professional judgment, the petition presents a "precedent-setting question of exceptional importance" (Cir. R. 35(b)):

> When FDA approves a drug for more than one use, the Hatch-Waxman Act allows drug makers to market a generic version of the drug for any non-patented uses. Name-brand drug makers can block generic approval by submitting overbroad patent descriptions to FDA. Accordingly, the Act authorizes a "counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section 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).
>
> Does this statute apply where, as here, (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) the brand submits inaccurate "patent information" to FDA that should be "correct[ed]"?

James F. Hurst/SNJ, *Counsel of Record*

INTRODUCTION

Appellee Caraco seeks panel or en banc review of a splintered ruling raising issues of exceptional importance under the Hatch-Waxman Act—a ruling that each panel member recognized "tip[s] the [Act's] careful balance in the favor of pioneering manufacturers." Op. 12; Conc. 2; Diss. 23. Indeed, the majority's reading of the Act allows Novo to use its patent to block Caraco from marketing drugs that Novo *concedes* do not infringe. This extraordinary result compels review, particularly in the context of a law designed to expedite, not delay, generic competition.

Here is the problem. When a drug has multiple uses and "a patent claims at least one, but not all, approved methods of using [the] drug," section viii of the Act

expedites generic competition by allowing generics to "carve out" infringing uses from their product labels. Op. 4-5, 11. Caraco seeks FDA approval to market a generic version of Novo's drug for two uses that Novo admits do not infringe its patent. And every panel member agreed that Caraco has satisfied section viii.

Yet the majority held that Novo can block Caraco's product simply by providing FDA a description of its patent erroneously suggesting that it *does* cover Caraco's proposed use. After this suit began, and despite its repeated admissions in court, Novo did just that, submitting a newly broadened description of its patent to FDA. As the district court found, this submission "seriously misrepresents" the scope of Novo's patent. App. 4. But FDA does not independently determine the patent's scope; it relies on the brand's description of that scope, which is provided in the form of a "use code" and then listed in FDA's Orange Book. Thus, Novo's revised and admittedly overbroad use code led FDA to reject Caraco's "carve out" label, thwarting Caraco's effort to obtain FDA approval for non-infringing uses.

The issue is whether the Act provides a remedy for such abuse. It does. It authorizes counterclaims to "correct or delete the patent information submitted by the [patent] holder" when (1) there is "an approved method of using the drug" that "the patent does not claim" (here, Novo's patent does not claim *two* approved methods of use), and (2) the "patent information" is inaccurate (here, Novo's use code admittedly misrepresents its patent's scope). 21 U.S.C. § 355(j)(5)(C)(ii)(I).

But over Judge Dyk's dissent—and contrary to the Act's text, structure, legislative history, and interpretation by FDA—the panel said Caraco has no remedy. Under the majority's view, (1) no counterclaim is available because Novo's patent claims *one* approved use, even though it "does not claim" two other "approved method[s] of use"; and (2) the counterclaim is effectively limited to *delisting* wrongfully-listed patents, even though the Act also refers to *correcting* patent information. Op. 13. Therefore, brands are now free to submit use codes at the highest level of generality—*e.g.*, "a method for treating diabetes"—thus extending their patents to non-infringing uses. And because overbroad use codes will thwart useful "carve out" labels, the ruling effectively writes section viii out of existence.

As Judge Dyk recognized, this "cannot be what Congress intended." Diss. 27. And if the law is to permit "manipulation of the Orange Book"—leaving generics "without any remedy" (*id.*)—that decision should come from the full Court, not from a ruling that split three ways and threatens the congressionally-mandated balance between brands and generics. Further review should thus be granted.

STATEMENT OF THE CASE

A. Structure of Hatch-Waxman Act

If a generic seeks to market a drug covered by an unexpired patent listed in FDA's Orange Book, "the generic is generally required to certify that the patent . . . is invalid or will not be infringed by the sale or use of the [generic] drug."

Diss. 3. This is referred to as a Paragraph IV certification.

The Act also provides, however, an alternative means of obtaining generic approval—the "section viii" statement. "Section viii addresses scenarios where a patent claims at least one, but not all, approved methods of using a drug." Op. 11. This provision is applicable when the Orange Book lists a method patent that "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)-(2)(A)(viii). Along with its section viii statement making that representation, "the generic manufacturer must submit a proposed label to the FDA that does not contain [*i.e.*, carves out] the patented method of using the listed drug." Op. 4.

Importantly, FDA does not interpret the scope of patents. So "[w]hen considering approval of [section viii] requests, the FDA relies on the applicable patent's use code narrative to determine the scope of the patented method." Op. 4. The use code narrative for each listed method patent is provided by the brand. Op. 3. "FDA approves the section viii statement only where there is no overlap between the proposed carve-out label . . . and the [brand's] use code narrative." Op. 4. Thus, accurate use codes are "essential to the [Act's] operation." Diss. 6.

B. Counterclaim Provision

In 2003, aware of brands' efforts to "block generic competition by making unwarranted claims to patent coverage" (Diss. 4), Congress enabled generic drug makers "in a Paragraph IV suit to assert a counterclaim challenging the accuracy of

the 'patent information' submitted to the FDA." Op. 5. As Congress provided:

> [The ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I).

C. District Court Proceedings

In 2008, Caraco sought section viii approval for generic repaglinide, a diabetes drug that Novo markets as Prandin. "FDA has approved PRANDIN for three uses: (1) repaglinide by itself (*i.e.*, monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones ('TZDs')." Op. 5-6. Novo's patent claims repaglinide combined with metformin, but Novo "does not own patents claiming the other two approved methods." Op. 6.

Caraco's "section viii statement" thus "declar[ed] that Caraco was not seeking approval for the repaglinide-metformin combination therapy," and "FDA indicated that it would approve Caraco's proposed carve-out label." *Id.* But Novo then "updated its use code narrative for the '358 patent" (Op. 7) to indicate that its patent "encompass[ed] the use of repaglinide in monotherapy." Diss. 22. As a result, "FDA reversed itself and rejected Caraco's proposed labeling carve-out." *Id.*

Caraco thus filed a counterclaim, and the district court enjoined Novo to correct its use code, which was "so broad as to incorrectly suggest that [Novo's] pat-

ent generically covers three (3) different FDA-approved methods of use of repaglinide," when in fact "the first two (2) uses are not covered." App. 4.

D. The Divided Panel's Ruling

In a ruling that produced three opinions, the panel (Rader, Clevenger, Dyk, JJ.) reversed. First, reading the phrase "*an* approved method of use" to mean "*any* approved method of use," the majority (per Rader, J.) held that a counterclaim is available "only if the listed patent does not claim *any* approved methods of using the listed drug." Op. 10 (emphasis added). Second, the majority held that the term "patent information" in the provision is limited to "an erroneous patent number or expiration date" and "does not extend to the use code narrative." Op. 13.

In Judge Rader's view, a generic can use a Paragraph IV suit to prove that its "use will not overlap with . . . the patented use." Op. 11. But Judge Clevenger was "not as certain" of this "clean[]" result. Conc. 2. And although he blamed FDA for purportedly creating the confusion, he recognized that the outcome here risked "upset[ting] the careful balance of interests" reflected in the Act. *Id.*

Judge Dyk dissented, explaining that "the text is clear" in light of "the overall operation of the statute." Diss. 18. "[I]nterpreting 'an approved method' . . . to mean 'any' approved method," he noted, is "fundamentally inconsistent with the Supreme Court's admonition . . . that '[u]ltimately, context determines meaning.'" Diss. 16. And on the "patent information" issue, he explained that the majority's

view was contrary to the text, "FDA's interpretation," and *Chevron*. Diss. 15.

Judge Dyk also disagreed with the notion that FDA caused "Caraco's predicament," citing Novo's admission that "FDA did not require [a change in the use code]." Diss. 23-24. But he agreed with Judge Clevenger that generics are "left without any remedy to correct an erroneous Orange Book listing" for a method patent, concluding that this "cannot be what Congress intended." *Id.* at 27.

POINTS OF LAW MISAPPREHENDED BY THE PANEL

The panel should grant rehearing. The lead opinion correctly notes that the context for this dispute is the "balance" that Congress sought to "strike" between "the pioneering and generic manufacturing interests." Op 12. But when concluding that its statutory construction did no violence to that balance, the lead opinion incorrectly assumed generics would still have a remedy, even without a counterclaim, via the "dispute resolution mechanism" of "Paragraph IV" litigation. Op. 11-12. That was an outright mistake, and the other panel members rightly took issue. Conc. 1; Diss. 26. FDA will *not* permit "carve out" labels unless it can determine, based on the brand's use code, that the revised label avoids an infringing use. Diss 22 n.17 (citing regulations). So where an overbroad use code precludes that determination, FDA requires the original, *infringing* label—thus eliminating the non-infringement defense and forcing the generic to prove *invalidity* to reach the market early. *Id.* And even more basically, Congress did not intend for Para-

graph IV to be a substitute for section viii—it enacted both. Rehearing is needed to correct this point of law, which the panel misapprehended.

REASONS FOR GRANTING PANEL OR EN BANC REHEARING

I. Rehearing is warranted because the panel's splintered decision rewrites a key provision of the Hatch-Waxman Act, in contravention of its text, structure, purpose, legislative history, and interpretation by FDA.

In addition to encouraging the gaming of Hatch-Waxman, the panel opinion rests on two key errors. *First*, it defies the text of § 355(j)(5)(C)(ii), which allows a counterclaim if there is "an approved method of using the drug" that the listed patent "does not claim." *Second*, it ignores FDA's reading of "patent information," which Congress ratified, and which warrants *Chevron* deference. These errors—on a recurring issue "essential to the [Act's] operation" (Diss. 6)—warrant review.

A. The majority misconstrued the Act's plain language and ignored the cardinal rule that statutory language must be read in context.

1. As countless decisions hold, "there is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has . . . specifically enacted." *Lamie v. United States Trustee*, 540 U.S. 526, 538 (2004). Yet the panel changed the Act's text by "read[ing] 'an approved method' as 'any approved method.'" Op. 10 (quoting § 355(j)(5)(C)(ii)). That was simply wrong.

Novo admits there is "an approved method of using the drug" that its patent "does not claim." Yet the majority ignored this sensible reading of the plain text. Instead, it "detect[ed] no ambiguity" because, "[w]hen an indefinite article is pre-

ceded and qualified by a negative, standard grammar generally provides that 'a' means 'any.'" Op. 10. But the fact that "an," when qualified by a negative, *can* mean "any" does not mean it *generally* means "any." Diss. 18 (citing *Webster's Third Int'l Dictionary* 1 (2002) and noting that the majority relies on secondary definitions of "an"). Congress instead chose "an," the meaning of which depends on what it is "followed by"—by its context. Diss. 18.

2. This is the deeper problem with the majority's decision: it ignores the "cardinal rule that statutory language must be read in context" (*Hawkins v. United States*, 469 F.3d 993, 1001 (Fed. Cir. 2006)), because "[u]ltimately, context determines meaning" (*Johnson v. United States*, 130 S. Ct. 1265, 1270 (2010)). Thus, "contextual indications may point clearly to one dictionary definition among conflicting alternatives." *Smith v. Brown*, 35 F.3d 1516, 1523 (Fed. Cir. 1994). By ignoring this possibility, the majority rewrote a vital provision of the Act.

First, the phrase "an approved method" appears in a provision entitled "[c]ounterclaim to infringement action," which places the burden of proof on the generic to show that "the patent does not claim" a certain method of use. By design, this provision asks not whether the *brand* can show that its patent *claims* "an approved method," but whether the *generic* can point to "an approved method" the patent "*does not* claim." "Only by such full reference to the context of the whole can [this] [C]ourt find the plain meaning" of the statute. *Smith*, 35 F.3d at 1523.

An illustration confirms this. Suppose A writes to B with news that she had a third child. In relating the challenges of having three children, A adds that "my taxes are higher than they should be because I did not claim *an exemption*." Read in context, this statement does not suggest that A did not claim *any* exemptions—only that she did not claim an exemption *for the third child*. If B ignored the context and concluded that A did not claim *any* exemptions, we would not say A's use of the phrase "did not claim an exemption" was ambiguous. We would say B read it in isolation. The same is true of the panel's reading of "an approved method."

Second, to read "an" as "any" is particularly problematic given that "any" appears elsewhere in the same provision. *See* § 355(j)(5)(C)(ii)(II) ("any civil proceeding"). So "Congress knew how" to express other meanings. *See Central Bank v. First Interstate Bank*, 511 U.S. 164, 176-77 (1994). And as the bill's sponsor noted: "[T]o close the loopholes . . . the devil is in the details. . . . Change an 'and' to an 'a,' to a 'the' and you go from huge savings to huge costs." *Hrg. Before Cmte. on Judiciary*, 108 Cong. 15 (Aug. 1, 2003) (Sen. Schumer).

Third, section viii and the counterclaim provision work together and use similar statutory language—one refers to a patent that does "not claim *a* use" and the other refers to a patent that does "not claim *an* approved method." There is no reason to read these provisions inconsistently, as the majority did, such that one provision means "*any*" method (counterclaim) and the other refers to "*a*" use (viii).

Fourth, the Act allows counterclaims "to *correct or* delete patent information," § 355(j)(5)(C)(ii)(I), but the majority "render[ed] superfluous" the term *correct*. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). That is, brands may list only patents that claim the drug or an approved method of using it. § 355(b)(1), (c)(2). And in the majority's view, a counterclaim is available only where the patent claims neither one. But in those cases, the patent should not have been listed at all, and the only remedy is *deleting* all patent information. Indeed, under the majority view, even an incorrectly listed expiry could not be "correct[ed]," so long as the patent claimed the drug or any approved use. Op. 10.[1]

Fifth, the majority misread the counterclaim's legislative purpose—*i.e.*, to "close loopholes in the law and end abusive practices. . . by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to . . . *correct the patent information*." 149 Cong. Rec. 31200 (2003) (Sen. Schumer) (emphasis added). In the panel's view, the counterclaim was enacted only to fix the precise problem presented in *Mylan Pharm. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). But as Judge Dyk showed (at 10), the patent there did not belong in the Orange Book at all—a problem, as noted, that could have been solved by providing only for *deleting* patent information. In sum, "the majority's crabbed view of the

[1] At argument, Novo asserted that a generic could file a counterclaim to "correct" typographical errors in a listed patent number. But a brand would typically have an incentive to fix such typos, and there is no reason to think Congress would create a *counterclaim for generics* to do so.

statute sanctions an unjustified manipulation of the Orange Book." *Id.* at 27.

B. In violation of *Chevron*, the majority further erred in overriding the FDA's interpretation of "patent information."

The majority's ruling that the Act's reference to "patent information" is limited to "the patent number and expiration date," not "use codes," is also contrary to FDA's well-supported statutory interpretation—and thus violates *Chevron.*

As the majority noted, before Congress created counterclaims, "FDA promulgated a regulation [entitled '*Submission of Patent Information*'] . . . requir[ing] a [brand] to submit not only the patent number and the expiration date, but also the use code narratives." Op. 13-14. Congress thus acted "with full awareness of [FDA's] interpretation," and the majority's view ignores this "compelling evidence of legislative adoption of the agency's interpretation." Diss. 14-15, & n.11.

FDA's interpretation is correct. By filing a counterclaim, what a generic can "correct or delete" is "patent information submitted by the holder under [§ 505] (b) or (c)." § 355(j)(5)(C)(ii)(I). Because § 505(b) and (c) expressly mention only the patent number and expiry, the majority read "patent information" as limited to those items. But this rewrites the text by replacing the phrase "patent information *submitted . . . under* subsection (b) or (c)" with "patent information *referenced in* subsection (b) or (c)." In all events, the majority's ruling violates *Chevron v. NRDC*, 467 U.S. 837 (1984), which requires sustaining FDA's sensible reading of an undefined term: "patent information." Diss. 11-14.

In sum, the majority failed to see that "[s]licing a statute into phrases while ignoring their contexts—the surrounding words, the setting of the enactment, the function a phrase serves in the statutory structure—is a formula for disaster." *Smith*, 35 F.3d at 1523. En banc review is needed to avert that disaster.

II. Left unaddressed, the majority's ruling will encourage Orange Book abuse, upsetting the Act's balance between brands and generics.

Contrary to the core purpose of the counterclaim, the panel's ruling invites "manipulation of the Orange Book." Diss. 27. Brands can now stymie marketing of admittedly non-infringing drugs by filing admittedly overbroad use codes. It is no overstatement to say that such brazen Orange Book abuse guts section viii, which allows FDA to approve generic entry "[i]f a method of using the approved drug is patented and is listed in the Orange Book, but the [generic] is not seeking approval for the patented use." *Allergan, Inc. v. Alcon Labs, Inc.*, 324 F.3d 1322, 1326 (Fed. Cir. 2003). The full Court's review is needed to prevent that result.

Judge Rader recognized that "a broad use code covering all uses of a pharmaceutical could require generic manufacturers to prove specifically that their use will not overlap with and infringe the patented use," dismissing this danger on the theory that Paragraph IV suits provide an "efficient dispute resolution mechanism" to resolve such issues. Op. 11-12. The other panel members rightly disagreed. Conc. 1 ("I am not as certain as Judge Rader that the ongoing Paragraph IV litigation will cleanly resolve the dispute between the parties."); Diss. 26 ("[T]he con-

currence doubts that there is a remedy in the infringement suit, and I agree.").

A. As both the dissent and concurrence acknowledged, Paragraph IV litigation is ill-suited to resolve section viii issues.

First, it makes no sense to force generics to invoke Paragraph IV rather than section viii—the point of which is to *avoid* protracted litigation. "Paragraph IV certifications and section viii statements have quite different consequences. Applicants submitting section viii statements have no obligation to provide notice, nor must they wait thirty months for FDA approval." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). Moreover, unlike Paragraph IV certifications, section viii statements are not an act of infringement and they are not subject to the 180-day exclusivity period for Paragraph IV applicants. *See Apotex, Inc. v. FDA*, 393 F.3d 210, 214 (D.C. Cir. 2004). Under the panel's 2-1 ruling, brands can force generics to make certifications they would not have to make—often delaying competition for 30 months—just by submitting overbroad use codes.

Second, if a generic cannot use a section viii carve-out label due to an overbroad use code, its label must discuss the patented use—inviting an infringement claim. This leaves just two paths to market, awaiting patent expiration or using a Paragraph IV certification to challenge the patent's *validity*. But neither option allows generics to litigate whether a carve-out label infringes, because FDA will not permit a carve-out label that raises any infringement issue. § 355(j)(2)(A)(v), (j)-(4)(G); 21 C.F.R. § 314.94(a)(8)(iv); Diss. 22 n.17. Thus, as Judges Clevenger and

Dyk recognized, Paragraph IV suits provide no remedy for Novo's misconduct.

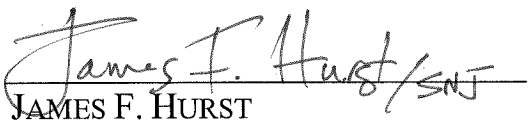
B. As the dissent correctly observed, the abuse enabled by the panel decision was not caused by the FDA.

Every panel member recognized that, in effect, this result "tip[s] the [Act's] careful balance in the favor of pioneering manufacturers." Op. 12; Conc. 2; Diss. 23. Judge Clevenger blamed FDA for the problem, evidently on the understanding that a change in the "approved labeling" for repaglinide required a change in its use code. Conc. 2. That is incorrect. The use code describes the patent, not the label. "[A]s Novo admitted," "FDA did not direct or request that Novo change its use code," "nor was [this] required under FDA regulations." Diss. 24. Rather, FDA "accepts at face value the use claimed by the patent holder." *Purepac*, 354 F.3d at 885. Thus, Caraco cannot ask FDA to correct Novo's overbroad use code.

CONCLUSION

By sanctioning Novo's conduct and leaving generics "without any remedy," the panel's split ruling invites the "true manipulation" of the Orange Book listings "the counterclaim provision was designed to avoid" Diss. 19, 27. Caraco is seeking to market a generic drug only for non-infringing uses. But Novo blocked that effort by broadening its use code and misrepresenting its patent's scope. This conduct renders section viii a dead letter, eviscerates the counterclaim's text and structure, and "cannot be what Congress intended." Diss. 27. Rehearing is needed to prevent that extraordinary result.

Respectfully submitted,



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MAY 14, 2010

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing *Combined Petition for Panel Rehearing or Rehearing En Banc* were caused to be served on May 14, 2010, on counsel listed below by Federal Express, next-day delivery, and by electronic mail:

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Dated: MAY 14, 2010

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DECLARATION OF AUTHORITY PURSUANT TO
28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(D)

I, Steffen N. Johnson, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

I am an attorney of WINSTON & STRAWN LLP in the Washington, D.C. Office. Because of time constraints and the distance between counsel, James F. Hurst is unavailable to provide an original signature, in ink, on this document to the court. Pursuant to 28 U.S.C. § 1746 and Federal Circuit Rule 47.3(d), I signed the document for Mr. Hurst, with actual authority on his behalf as an attorney appearing for the party.

May 14, 2010

Steffen N. Johnson

ADDENDUM

United States Court of Appeals for the Federal Circuit

2010-1001

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

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

Mark A. Perry, Gibson, Dunn & Crutcher LLP, of Washington, DC, argued for plaintiffs-appellants. With him on the brief were Josh A. Krevitt, of New York, New York; Wayne Barsky, of Los Angeles, California; and Michael A. Sitzman, of San Francisco, California.

James F. Hurst, Winston & Strawn LLP, of Chicago, Illinois, argued for defendants-appellees. With him on the brief were Charles B. Klein and Scott H. Blackman, of Washington, DC; David S. Bloch, of San Francisco, California. Of counsel was Andrew Nichols, of Washington, DC.

Appealed from: United States District Court for the Eastern District Michigan

Senior Judge Avern Cohn

United States Court of Appeals for the Federal Circuit

2010-1001

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, Senior Judge Avern Cohn.

DECIDED: April 14, 2010

Before RADER, CLEVENGER, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Concurring opinion filed by Circuit Judge CLEVENGER. Dissenting opinion filed by Circuit Judge DYK.

The United States District Court for the Eastern District of Michigan entered an injunction directing Novo Nordisk A/S and Novo Nordisk, Inc. (collectively, "Novo") to request the U.S. Food and Drug Administration ("FDA") to replace Novo's patent use code U-968 listing for Prandin® in the Orange Book with the former U-546 listing. Because Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") does not have a statutory basis to assert a counterclaim requesting such injunctive relief, this court reverses and vacates the injunction.

I.

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the "Hatch-Waxman Act"). The Hatch-Waxman Act strikes a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term. See Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Title 21 prohibits sale of a new drug without FDA approval. 21 U.S.C. § 355(a). To obtain that approval, a pioneering manufacturer must file a new drug application ("NDA"), containing clinical studies of the drug's safety and efficacy. 21 U.S.C. § 355(b)(1). As part of the NDA process, the manufacturer must also identify all patents that claim the drug or a method of use:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application 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)(G) (emphases added).

> 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.

21 U.S.C. § 355(c)(2) (emphases added).

The FDA has authority to promulgate regulations for the efficient enforcement of these provisions. 21 U.S.C. § 371. Under those regulations, a pioneering manufacturer files with the FDA the patent number and the expiration date of any applicable patents by submitting Form 3542a ("Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement") or Form 3542 ("Patent Information Submitted Upon and After Approval of an NDA or Supplement"). 21 C.F.R. § 314.53 (2009). If the patent claims one or more methods of using the NDA drug, Forms 3542a and 3542 require a description of each of those processes. Id. This description is commonly known as the "use code narrative." The FDA assigns a unique number, known as a "use code," to each description. The FDA publishes a list of drugs, along with the applicable patents and their associated use codes, in its Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

A manufacturer that seeks to market a generic copy of these listed drugs may submit an abbreviated new drug application ("ANDA"). 21 U.S.C. § 355(j). The ANDA process streamlines FDA approval by allowing the generic manufacturer to rely on the safety and efficacy studies of a drug already listed in the Orange Book upon a showing of bioequivalence. 21 U.S.C. § 355(j)(2)(A)(iv).

As part of the ANDA process, a generic manufacturer must make a certification addressing each patent identified in the Orange Book pertaining to its drug. 21 U.S.C. § 355(j)(2)(A)(vii). Specifically, the generic manufacturer must select one of four

alternatives permitting use of the patented product or process: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii).

Often pharmaceutical formulations have multiple uses and applications. After expiration of the patent on the composition itself, only some of those uses may enjoy continued protection as patented methods. If a generic manufacturer wishes to seek FDA approval for a use not covered by a method-of-use patent for a listed drug, it must make a "section viii statement." 21 U.S.C. § 355(j)(2)(A)(viii). Along with the section viii statement, the generic manufacturer must submit a proposed label to the FDA that does not contain the patented method of using the listed drug. When considering approval of these requests for a use not covered by a patent, the FDA relies on the applicable patent's use code narrative to determine the scope of the patented method. Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36676, 36682 (June 18, 2003). The FDA approves the section viii statement only where there is no overlap between the proposed carve-out label submitted by the generic manufacturer and the use code narrative submitted by the pioneering manufacturer. Id.

The Hatch-Waxman Act facilitates early resolution of disputes between pioneering and generic manufacturers. To achieve this objective, the Act makes a Paragraph IV certification into an act of patent infringement. 35 U.S.C § 271(e)(2). A generic manufacturer that files a Paragraph IV certification must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B)(i). The patentee then has forty-five

days to sue the generic manufacturer for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the FDA may approve the ANDA. If the patentee sues, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iii). The court entertaining this suit has discretion to order a shorter or longer stay if "either party to the action fail[s] to reasonably cooperate in expediting the action." Id.

The Hatch-Waxman Act enables a generic manufacturer in a Paragraph IV suit to assert a counterclaim challenging the accuracy of the "patent information" submitted to the FDA:

> [The ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either–
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I). This counterclaim provision was not part of the original Hatch-Waxman Act. Rather the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) added this counterclaim provision to permit challenges to patent information at the FDA. The interpretation of this counterclaim provision is the central issue in this case.

II.

Novo markets and distributes the drug repaglinide under the brand name PRANDIN. PRANDIN is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (non-insulin dependent diabetes mellitus). The FDA has approved PRANDIN for three uses: (1) repaglinide by itself (i.e., monotherapy); (2)

repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones ("TZDs"). Novo Nordisk, Inc. holds the approved NDA for PRANDIN.

The Orange Book lists two patents for PRANDIN. U.S. Patent No. RE 37,035 (the "'035 patent") claims, inter alia, the chemical composition of repaglinide. The '035 patent expired on March 14, 2009. U.S. Patent No. 6,677,358 (the "'358 patent") claims, inter alia, repaglinide in combination with metformin:

> A method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin.

'358 patent, claim 4. The '358 patent expires on June 12, 2018. Novo Nordisk A/S owns the '358 patent. Novo does not own patents claiming the other two approved methods of using repaglinide to treat type 2 diabetes. The FDA initially assigned the '358 patent the use code "U-546–Use of repaglinide in combination with metformin to lower blood glucose."

On February 9, 2005, Caraco filed an ANDA for the drug repaglinide. The ANDA initially contained a Paragraph III certification for the '035 patent and a Paragraph IV certification for the '358 patent. On June 9, 2005, Novo initiated an infringement action against Caraco. In April 2008, Caraco stipulated that its ANDA would infringe the '358 patent if it included a label that discussed the combination of repaglinide and metformin. At around the same time, Caraco submitted an amended ANDA with a Paragraph IV certification for the '358 patent and a section viii statement declaring that Caraco was not seeking approval for the repaglinide-metformin combination therapy. The FDA indicated that it would approve Caraco's proposed carve-out label. Novo moved for

reconsideration on the ground that allowing the carve-out would render the drug less safe and effective.

On May 6, 2009, Novo submitted an amended Form 3542 for PRANDIN in which Novo updated its use code narrative for the '358 patent. The FDA removed the use code U-546 from the Orange Book for PRANDIN and substituted the new use code "U-968–A method for improving glycemic control in adults with type 2 diabetes mellitus." The FDA then denied Novo's request for reconsideration as moot in light of the new use code. According to the FDA, the factual predicate on which the FDA's permissive carve-out determination had rested no longer applied. The FDA then disallowed Caraco's section viii statement, because its proposed carve-out label overlapped with the use code U-968 for the '358 patent. As a result, Caraco's current label now includes the repaglinide-metformin combination therapy, which is stipulated to infringe claim 4 of the '358 patent.

On June 11, 2009, Caraco amended its answer and counterclaim. Caraco added a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii), requesting an order requiring Novo to change the use code for the '358 patent in reference to PRANDIN from U-968 to U-546. Caraco claimed that the use code U-968 was overbroad because it incorrectly suggested that the '358 patent covered all three approved methods of using repaglinide even though it claimed only one approved method. Caraco also added a patent misuse defense, asserting that Novo misrepresented the scope of the '358 patent in its use code narrative.

On June 29, 2009, Novo moved to dismiss Caraco's new counterclaim and to strike the patent misuse defense. The district court denied Novo's motions. Caraco

then moved for summary judgment on both the new counterclaim and the patent misuse defense. On summary judgment, the district court granted Caraco's motion on the counterclaim and declined to address the patent misuse defense. The district court found that Novo had improperly filed an overbroad use code narrative for the '358 patent. On September 25, 2009, the district court entered the following injunction:

> Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended Form FDA 3542 that reinstates its former U-546 listing for Prandin and describes claim 4 of the '358 patent in section 4.2b as covering the "use of repaglinide in combination with metformin to lower blood glucose."

Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., Case 2:05-cv-40188, slip. op. 1-2 (E.D. Mich. Sept. 25, 2009).

Given the urgency of Novo's situation, Novo filed a motion in this court for an expedited appeal from the district court's order. This court granted Novo's motion to expedite briefing. Novo also filed a motion for a stay of the injunction pending appeal and a stay of trial court proceedings. This court ordered a stay of the injunction pending disposition of this appeal but declined to stay trial court proceedings. Because the district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(e), this court has jurisdiction under 28 U.S.C. § 1292(c)(1).

III.

This court reviews the grant of an injunction for an abuse of discretion. Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1301-02 (Fed. Cir. 2005). To the extent that an injunction is premised upon an issue of law, such as

statutory interpretation, this court reviews that issue without deference. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1374 (Fed. Cir. 2006).

Statutory construction "begins with 'the language of the statute.'" Hughes Aircraft Co. v. Jacobson, 525 U.S. 432, 438 (1999) (quoting Estate of Cowart v. Nicklos Drilling Co., 505 U.S. 469, 475 (1992)). This court derives the plain meaning of the statute from its text and structure. Electrolux Holdings, Inc. v. United States, 491 F.3d 1327, 1330 (Fed. Cir. 2007) (citation omitted). If the statutory language is unambiguous, the inquiry ends. Id. Nevertheless, this court may "look at the legislative history 'only to determine whether a clear intent contrary to the plain meaning exists.'" Sharp v. United States, 580 F.3d 1234, 1238 (Fed. Cir. 2009) (quoting Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 396 (Fed. Cir. 1990)). To overcome the plain meaning of the statute, the party challenging it must establish that the legislative history provides "an 'extraordinary showing of contrary intentions.'" Id. (quoting Garcia v. United States, 469 U.S. 70, 75 (1984)).

IV.

The Hatch-Waxman Act provides a limited counterclaim to a generic manufacturer in a Paragraph IV infringement action. The Act authorizes the generic manufacturer to assert a counterclaim "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I) (emphases added).

Novo and Caraco agree that the '358 patent claims only one of the three approved methods of using PRANDIN (i.e., repaglinide in combination with metformin). Novo asserts that the counterclaim is available only if the '358 patent does not claim

any approved methods. Caraco argues that it is entitled to the counterclaim because the '358 patent does not claim two of the approved methods of PRANDIN use. In other words, Novo reads "an approved method" in the counterclaim statute as "any approved method" while Caraco reads it as "all approved methods."

This court detects no ambiguity in the statutory language. When an indefinite article is preceded and qualified by a negative, standard grammar generally provides that "a" means "any." See, e.g., American Heritage Dictionary of the English Language 1 (4th Ed. 2006) (defining "a" as "[a]ny" in the example "not a drop to drink"); Random House Webster's Unabridged Dictionary 1 (2d ed. 2001) (defining the indefinite article "a" as "any" or "a single" in the example "not a one"); see also Barnhart v. Thomas, 540 U.S. 20, 26 (2003) (adopting a construction that is "quite sensible as a matter of grammar") (citation omitted).

The rest of the counterclaim provision also does not support Caraco's interpretation. In the context of this case, the statutory language "an approved method of using the drug" refers to the approved methods of using the listed drug, PRANDIN. This language cannot refer to the methods of using Caraco's generic drug, because the FDA has not yet approved Caraco's ANDA. Therefore, the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug.

Although the statutory language on its face presents no ambiguities, this court nonetheless examines the legislative history to make sure that it does not contain any clear intent to the contrary. Before the amendment to the Hatch-Waxman Act in 2003, private litigants could not challenge FDA submissions at all. Buckman Co. v. Plaintiffs'

Legal Comm., 531 U.S. 341, 349 (2000). Novo and Caraco agree that the counterclaim provision responded to this court's decision in Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2002). In Mylan, the Orange Book listed a patent as covering the FDA-approved drug BuSpar. Id. at 1330-31. Mylan, a generic manufacturer, asserted that the patent "did not claim BuSpar or an approved method of using BuSpar." Id. at 1331. This court held that Mylan did not have a private cause of action to delist the allegedly irrelevant patent from the Orange Book. Id. The 2003 amendment used exact language from Mylan in the new counterclaim provision. This choice of legislative language suggests that the 2003 Amendment sought to correct the specific issue raised in Mylan, i.e., to deter pioneering manufacturers from listing patents that were not related at all to the patented product or method. Thus, the language selected for this Amendment supports this court's interpretation that "an approved method" means "any approved method." A patent listing that covers one amongst several approved methods of using a formulation protects that patented method and thus bears a direct relation to the purpose of Orange Book listings. This court does not detect a situation such as the one occurred in Mylan.

This case also suggests that this court should address the relationship between section viii and the counterclaim provision. Section viii addresses scenarios where a patent claims at least one, but not all, approved methods of using a drug. See 21 U.S.C. § 355(j)(2)(A)(viii). This court recognizes that a broad use code covering all uses of a pharmaceutical could require generic manufacturers to prove specifically that their use will not overlap with and infringe the patented use. This proof, under Hatch-Waxman procedures, will take the form of a Paragraph IV lawsuit. In that context, the

generic may provide proof that their use will not cause infringement of the patented use. This court perceives that the Hatch-Waxman Act will thus ensure that a generic drug for non-patented purposes will not be used for patented purposes via a simple section viii certification. Instead, the generic manufacturer will need to alleviate the risk of infringement or induced infringement in a proceeding that fully tests for infringement and its implications, including potential health and safety risks. Thus, the Act again facilitates efficient resolution of disputes concerning potential overlapping of protected and unprotected uses. The Act seeks to strike a balance of the pioneering and generic manufacturers' interests.

As Judge Clevenger points out, Caraco's real complaint should lie with the FDA, not with Novo. Had it not been for the FDA's regulatory action, Caraco could have asserted in a Paragraph IV lawsuit that its proposed labeling did not infringe the '358 patent. It was the FDA, not Novo, that tipped the careful balance in the favor of pioneering manufacturers.

V.

As further indication of balancing interests and creation of an efficient dispute resolution mechanism, this court notes that the Act, by its terms, does not allow generic manufacturers to counterclaim unless the listed patent bears no relation to the listed drug. To be more specific, the terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative. The counterclaim provision states that a generic manufacturer can request an order compelling "the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c)." 21 U.S.C. § 355(j)(5)(C)(ii)(I) (emphasis added). Subsection (b)

requires a pioneering manufacturer to submit "the patent number and the expiration date of any patent . . . which claims a method of using such drug." 21 U.S.C. § 355(b)(1) (emphases added). Subsection (c) states that "[i]f the patent information described in subsection (b) of this section could not be filed with the submission of an application," the holder "shall file with the Secretary the patent number and the expiration date of any patent . . . which claims a method of using such drug." 21 U.S.C. § 355(c)(2) (emphases added).

Thus, the Act defined the term "patent information" as "the patent number and the expiration date." See Valley Drug Co. v. Geneva Pharms. Inc., 344 F.3d 1294, 1296-97 (11th Cir. 2003) (referring to the patent number and the expiration date as "this patent information"). The reference in subsection (c) to "the patent information described in subsection (b)" could only mean the patent number and the expiration date, because no other "patent information" appears in the statute. Therefore, to maintain consistency in the statutory terms, "the patent information" in the counterclaim provision must also mean the patent number and the expiration date. Envtl. Def. v. Duke Energy Corp., 549 U.S. 561, 574 (2007) (noting that the identical words used in the same act are presumed to have the same meaning). Thus, the counterclaim provision only authorizes suits to correct or delete an erroneous patent number or expiration date. The authorization does not extend to the use code narrative. Once again, this careful use of language suggests that the Act facilitates efficient resolution of disputes over the potential overlap of patented and unpatented uses in the form of a Paragraph IV suit.

Approximately six months before the 2003 Amendment, the FDA promulgated a regulation concerning the "Submission of Patent Information" in which it requires a

pioneering manufacturer to submit not only the patent number and the expiration date, but also the use code narratives and other patent-related information on Forms 3542a and 3542. See 21 C.F.R. § 314.53. This regulation appeared to include the use code narrative under the broader heading of "patent information." Although this regulation preceded the 2003 Amendment, it did not change the meaning of the statutory use of the term "patent information." As this court has clarified, "[s]uch opaque timing observations hardly amount to a 'most extraordinary showing of contrary intentions,' especially when the language of the statute trumpets its meaning by itself." Wyeth v. Kappos, 591 F.3d 1364, 1372 (Fed. Cir. 2010). The counterclaim provision does not mention the FDA regulations or in any way suggest adoption of a meaning for "patent information" broader than the express statutory definition. Moreover, this court owes "no deference is due to agency interpretations at odds with the plain language of the statute itself." Pub. Employees Ret. Sys. v. Betts, 492 U.S. 158, 171 (1989). As discussed above, this broader definition would upset the careful balance that requires a full resolution of the potential infringement issues involved in overlapping patented and unpatented uses.

The legislative history does not add any clarity to the meaning of "patent information." During the floor debate, Senators occasionally referred to the need to correct "patent information." See, e.g., 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) (The counterclaim provision may "delist the patent or correct the patent information in FDA's Orange Book."). This court must read these statements to use the term "patent information" consistent with the express statutory definition. Accordingly, to preserve the Act's careful balance and to enforce the

language of the statute, the explicit definition of "the patent information" as "the patent number and the expiration date" controls.

VI.

Caraco argues that in case this court does not find that Caraco is entitled to a counterclaim, this court should affirm the district court's injunction under the doctrine of patent misuse. Because the judicial doctrine of patent misuse creates an unusual circumstance where an infringer can escape the consequences of its infringing conduct because the victim of that tort may have used its patent rights to gain an unfair competitive advantage against an unrelated third party, this court examines such allegations with particularity. See, e.g., C.R. Bard v. M3 Sys., 157 F.3d 1340, 1372-73 (Fed. Cir. 1998) ("Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce."). For instance, the doctrine may apply where the patentee's misconduct toward unrelated parties amounted to unfair market benefits beyond the scope of the patent. See Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992). In any event, in this case, the district court, apparently recognizing the rarity of this situation, expressly declined to address the doctrine of patent misuse. Without any finding to review, this court declines to adjudicate this issue in the first instance. See Ecolab, Inc. v. FMC Corp., 569 F.3d 1335, 1352 (Fed. Cir. 2009).

VII.

This court therefore reverses the district court's grant of summary judgment on Caraco's attempted, but unsuccessful, counterclaim and vacates the injunction ordering Novo to correct its use code for the '358 patent listed in the Orange Book for PRANDIN.

REVERSED and VACATED.

United States Court of Appeals for the Federal Circuit

2010-1001

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, Senior Judge Avern Cohn.

CLEVENGER, Circuit Judge, concurring.

I agree with Judge Rader's analysis of the relevant statutory provisions in this case and therefore join the opinion he writes for the court. I am not as certain as Judge Rader that the ongoing Paragraph IV litigation will cleanly resolve the dispute between the parties.

The dissent masks the cause for the dispute between the parties. Novo did nothing that was illegal or forbidden. FDA voluntarily requested a change to the approved indications for PRANDIN® which required Novo to use FDA's new approved labeling. The change also permitted Novo to revise its use code as the relevant FDA form, "Patent Information Submitted Upon and After Approval of an NDA or Supplement," expressly 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." Novo changed its use code to match the new PRANDIN® indication. Nothing in the record suggests that Novo is responsible for the labeling change, which, given the statutory and regulatory framework, happens to benefit Novo at Caraco's expense.

If not for FDA's request that Novo change its labeling to the present broad indication, everything would have worked properly under the relevant statutes. As Judge Rader notes, the "efficient dispute resolution mechanism" was in play. Caraco filed its ANDA for repaglinide, and by making its Paragraph IV certification had committed the statutory act of infringement. Novo followed with its infringement suit. Caraco was prepared to defend on the grounds that its proposed use of repaglinide would not induce infringement of the '358 patent. Caraco also filed a section viii statement in light of the then-approved labeling and use code for PRANDIN®, and proposed carve-out language in its labeling to signify its proposed noninfringing use of repaglinide. Caraco was thus set to get FDA approval to bring its generic drug to market and to defend itself in Novo's Paragraph IV suit.

But FDA, acting independently, gummed up the works. By requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the '358 patent. It remains to be seen what impact FDA's action will have on Caraco's ability to defend itself in the ongoing Paragraph IV litigation, but FDA's regulatory action threatens to impair Caraco's ability to disprove infringement. FDA thus may have inadvertently upset the careful balance of interests represented by the efficient dispute resolution mechanism Congress created in the Hatch-Waxman Act.

The dissent's fix would be to have United States District Courts dictate to FDA what indications should be used on the prescribed labeling for approved drugs, even though there is nothing illegal, or even incorrect, about Novo's current use code. There is no basis for a counterclaim to correct or delete the patent information submitted by Novo. If a fix is in order under the circumstances of this case, it lies with the FDA and Congress to understand the consequences of changing the approved repaglinide labeling to a single broad indication, and corresponding use code, and to remedy the situation. Laying blame on Novo is wrong.

The counterclaim statute, which the dissent would expand beyond its literal reach, was designed to cure the situation presented in Mylan. Congress has not addressed the fact situation presented in this case. Congress is the appropriate entity to readjust, if necessary, the delicate balance it has struck between original drug manufacturers and their generic counterparts.

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DYK, Circuit Judge, dissenting.

In 2003, Congress enacted the counterclaim provision of the Hatch-Waxman Act in order to prevent manipulative practices by patent holders with respect to the Orange Book listings. These practices were designed to delay the onset of competition from generic drug manufacturers. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(C), 117 Stat. 2066, 2452 (codified at 21 U.S.C. § 355(j)(5)(C)(ii)) ("the counterclaim amendment"). In my view, the majority, in reversing the district court, now construes the statute contrary to its manifest purpose and allows the same manipulative practices to continue in the context of method patents. The amendment was designed to permit the courts to order correction of information published in the Orange Book, yet under the majority's opinion, erroneous Orange Book method of use information cannot be corrected. I respectfully dissent.

I

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act." Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and scattered sections of 35 U.S.C.). Under the Hatch-Waxman Act, Congress required the Food and Drug Administration ("FDA") to maintain and publish a list of patents associated with approved drugs and methods of use. See id. § 102(a)(1). The FDA has implemented this provision by publishing this list in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). See 21 C.F.R. § 314.53(c)(2)(i)(O).[1] The statute is complicated, but its operation in the present context is not.

A

Under the Food, Drug, and Cosmetic Act ("FDCA"), a drug manufacturer must secure approval from the FDA for the sale of any drug in interstate commerce. 21 U.S.C. § 355(a). To do so, the manufacturer files a New Drug Application ("NDA") with the FDA to secure approval for a "new drug," 21 U.S.C. § 355(b)(1), a term which encompasses a new use for an existing drug, see 21 C.F.R. § 310.3(h)(4). The application requires that the manufacturer specify the drug (or drugs) in question and the proposed method (or methods) of use. See 21 C.F.R. § 314.53(b)-(c). The drug cannot be sold until the FDA has approved the drug for the particular method of use, 21 U.S.C. § 355(a), (b)(1), and the method of use is required to appear on the label, 21

[1] See also Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,686 (June 18, 2003) (codified at 21 C.F.R. pt. 314) ("Report and Order Accompanying the Patent Listing Rule").

U.S.C. § 352(f); 21 C.F.R. pt. 201, id. § 314.125(b)(8). Section 355(b) also requires the NDA filer to list all patents "with respect to which a claim of patent infringement could reasonably be asserted" by patent number and expiration date with its NDA application, 21 U.S.C. § 355(b)(1), while section 355(c)(2) requires NDA applicants to provide the same information with respect to patents issuing after the NDA application was approved, id. § 355(c)(2). This information, referred to as "information submitted . . . under subsection (b) or (c)" or "patent information," is published in the Orange Book. Id. § 355(b)(1), (c)(2).

A generic manufacturer may piggyback on the safety and efficacy data the original drug manufacturer submitted in its NDA, and may seek approval for an identical method of use for its identical generic product by submitting an "Abbreviated New Drug Application," or "ANDA." See id. § 355(j). If a patent is listed in the Orange Book for a drug or method of use covered by the NDA, the generic is generally required to certify that the patent has expired or is invalid or will not be infringed by the sale or use of the drug for which the ANDA is submitted. Id. § 355(j)(2)(A)(vii). In what is called a "paragraph IV" certification regarding noninfringement and invalidity, approval is stayed pending the outcome of court litigation to determine infringement and validity.[2] Recognizing that some NDAs would cover both uses covered by a patent and uses not

[2] Where the applicant makes this paragraph IV certification, the patentee has forty-five days to bring suit for infringement of the patent that is the subject of the generic manufacturer's certification, and the approval of the ANDA is stayed for a period of thirty-months (or until the resolution of the infringement suit, whichever is shorter). See 21 U.S.C. § 355(j)(5)(B)(iii). The first ANDA applicant to make a paragraph IV certification benefits from a 180-day period of marketing exclusivity, id. § 355(j)(5)(B)(iii)(IV)(iv), a provision intended encourage generic manufacturers to undertake challenges to patents claimed to cover brand drugs. See Teva Pharms. USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

covered by a patent, Congress enacted "section viii," which allows the ANDA applicant to limit its application to unpatented uses, and to secure approval for those unpatented uses. Id. § 355(j)(2)(A)(viii); H.R. Rep. No. 98-857 pt. 1, at 22 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2655.

Some NDA filers realized that they could block generic competition by making unwarranted claims to patent coverage, for example, by listing in the Orange Book a patent for a drug or method of use when in fact the patent was clearly inapplicable. The FDA repeatedly declined to police the Orange Book listings,[3] and before the enactment of the counterclaim provision in 2003, we held that the courts could not do so through declaratory judgments. See Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1332-33 (Fed. Cir. 2001).

Congress responded by enacting the counterclaim amendment as part of the "Greater Access to Affordable Pharmaceuticals Act" ("Gregg-Schumer Bill"), enacted in 2003. S. 1225, 108th Cong. (2003). The counterclaim amendment provides:

> (ii) Counterclaim to infringement action.—
> (I) In general.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—
> (aa) the drug for which the application was approved; or
> (bb) an approved method of using the drug.

[3] The FDA has consistently held the position that its role in listing patents in the Orange Book is "ministerial," and that establishing an administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are beyond its expertise and authority. See, e.g., Report and Order Accompanying the Patent Listing Rule, 68 Fed. Reg. at 36,683.

21 U.S.C. § 355(j)(5)(C)(ii) (emphases added). Thus, the amendment allows an ANDA applicant, who is defending against a patent infringement suit brought by the holder of the NDA, to assert a counterclaim to correct or delete the Orange Book "patent information submitted . . . under subsection (b) or (c)" on the ground that the patent does not claim "the drug for which the application was approved" or "an approved method of using the drug." We have not previously construed this provision. The majority now holds that the counterclaim provision is unavailable to correct erroneous method of use information in the Orange Book—on two separate grounds.

II

A

In my view, the majority has misconstrued the term "patent information submitted . . . under subsection (b) or (c)." Id. § 355(j)(5)(C)(ii)(I). In the majority's view, 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 term 'patent information' as 'the patent number and the expiration date.'" Majority Op. at 13. There is, in fact, no definition of "patent information" in the statute, and in reaching this construction, the majority ignores critical statutory language. The statute requires the NDA applicant to

> file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application 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) (emphases added). Thus, the statute requires the NDA applicant to list patents claiming a drug or method of use "with respect to which a claim of patent

infringement could reasonably be asserted." In other words, the statute on its face contemplates that the scope of the patent must be accurately described and that the patent must be related to the drug or method of use for which the NDA application is submitted.[4] The statute does not require the listing of patent numbers and expiration dates in the abstract. It contemplates the description of the scope of the patent and of the relationship between the patent and the drug or the method of use; the description of that scope and relationship is itself "patent information." The statute requires that this information be published, stating that the Secretary "shall publish information submitted under the two preceding sentences." Id.

Other provisions of the statute also contemplate that the ANDA filer will be able to understand the scope of the patent and to relate the patent information to the drug or drugs being claimed and the method or methods of use being claimed. See id. § 355(b)(1). Describing the scope of the patent and relating the listed patents to the drug or method of use is essential to the operation of the statute, as the basic idea of the

[4] Subsection (b) refers to patent information submitted with an NDA application; subsection (c) describes the requirements for the submission of patent information after an NDA has already been filed. The patent listing and publication requirements of 21 U.S.C. § 355(c)(2) parallel those in § 355(b)(1):

> 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 because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, 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. . . . Upon the submission of patent information under this subsection, the Secretary shall publish it.

patent listings in the Orange Book is to put ANDA applicants on notice regarding which listed drugs and methods of use may be copied and which drugs or method of use are patent protected, and to enable the ANDA filer to submit an appropriate certification as required by law. The statute requires an ANDA applicant to provide, as part of the application,

> (vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .

Id. § 355(j)(2)(A)(vii) (emphases added). Similarly, the section viii certification provision also appears to contemplate that information submitted under subsection (b) or (c) will encompass information regarding the patented method of use. The statute directs the ANDA applicant to submit,

> if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

Id. § 355(j)(2)(A)(viii). The statute plainly contemplates that "patent information" will include information that describes the scope of the patent and that relates the patent to the drug or method of use.

B

Quite apart from the fact that the majority's limiting interpretation is inconsistent with the statutory language and structure, the majority's interpretation is in my view untenable for other reasons.

First, the majority agrees that the counterclaim amendment was designed to overrule our decision in Mylan. Majority Op. at 11. In overruling Mylan, Congress viewed erroneous information as to the scope of the patent and its relationship to an approved drug or method of use as "patent information" that could be ordered corrected. The majority appears to suggest that the overruling of Mylan is limited to the precise facts of Mylan, namely, the situation in which correction of the error would require that the patent number be deleted entirely from the Orange Book. See id. The overruling would not apply to a situation in which other erroneous Orange Book information is involved, for example, where the patent is erroneously listed with respect to a particular drug or method of use, but is properly listed elsewhere in the Orange Book. This ignores the context of the Mylan decision.

The first thing to understand is that the majority's description of the Orange Book likely bears no relationship to the actual document. The Orange Book is not a list of patents from which a particular patent could be excised. The Orange Book is a list of NDAs that associates particular patents with approved drugs or methods of use. Correction of an Orange Book listing does not strike a patent from a list, it strikes (or corrects) the listing that associates the patent with a particular NDA, approved drug, or method of use.

The problem in Mylan was that the Orange Book improperly described the scope of the patent and improperly related the patent to a drug and method of use not covered by the patent. In Mylan, Bristol-Myers Squibb ("Bristol") owned U.S. Patent No. 4,182,763 ("the '763 patent") directed to the treatment of anxiety through the administration of buspirone hydrochloride. 268 F.3d at 1327. The '763 patent was listed in the Orange Book in connection with that use but was about to expire. Id. Eleven hours before the patent's expiration, Bristol delivered to the FDA copies of U.S. Patent No. 6,150,365 (the "'365 patent"), which included a single method claim directed to the treatment of anxiety using a "metabolite" of buspirone.[5] Id. at 1327-28. Bristol sought to have the '365 patent listed in the Orange Book as covering buspirone and a method of using buspirone. Id. at 1328. Mylan and other ANDA applicants challenged the listing of the '365 patent on the ground that it only covered a metabolite of buspirone, and a method of using a metabolite of buspirone to treat anxiety. Id. After the FDA refused to correct the listing, Mylan filed suit for a declaratory judgment that Bristol improperly listed the '365 patent in the Orange Book as covering buspirone and the use of buspirone, and a preliminary injunction requiring Bristol to delist the '365 patent. Id. Reversing the district court, we held that there was no declaratory relief available to correct an erroneous Orange Book listing. Id. at 1332-33.

Thus, in Mylan, the accused infringer challenged the accuracy of the listing associating the patent with the approved method of use. Congress acted to provide a

[5] A metabolite is "[a] product of intermediary metabolism." McGraw-Hill Dictionary of Scientific and Technical Terms 1319 (6th ed. 2003). We held in Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (1997), that a patent claiming either the active ingredient of a drug or a method of using that ingredient does not also cover metabolites of that ingredient.

counterclaim action to correct such errors. Congress' concern with the proper listing of the patent in the Orange Book does not remotely suggest a myopic congressional focus on situations where the patent belonged nowhere in the Orange Book, as the majority suggests. Most significantly, viewing the overruling of Mylan as limited to complete delisting would be inconsistent with the explicit statutory language, which provides for correction of Orange Book information "on the ground that the patent does not claim . . . the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I). The statute thus must allow correction of a misdescription of patent scope that includes a drug not covered by the patent and erroneous information about the relationship between the patent and the drug, even if the patent is properly listed elsewhere in the Orange Book. In other words the scope of the patent and its relationship to the drug must be "patent information."

Moreover, if "patent information" includes information as to the scope of the patent with respect to the drug and the relationship between the patent number and the drug, it must also include Orange Book information describing the scope of a method of use patent and linking the method of use to the patent. There is no basis in the statutory language or statutory purpose for distinguishing between drug information and method of use information. Either both must be "patent information," or neither must be patent information. In my view, all Orange Book information is "patent information."

Second, at the time the counterclaim provision was enacted in 2003, the FDA had adopted the Patent Listing Rule,[6] making clear that the agency had adopted a broad interpretation of "patent information submitted . . . under subsection (b) or (c)." That interpretation is entitled to Chevron deference even if the language of the statute is ambiguous, and not (as I urge) plainly contrary to the majority's interpretation. See Chevron U.S.A. Inc. v. Natural Res. Def. Council, 467 U.S. 837, 843-44 (1984). By the time of the counterclaim amendment in 2003, the FDA had adopted detailed requirements for the submission of "patent information" for both drugs and methods. The 2003 rule, published as a proposed rule in the Federal Register in late 2002[7] and finalized six months before the counterclaim amendment, includes a section entitled "Submission of patent information" on the requirements for the listing of a patent in the Orange Book. See 21 C.F.R. § 314.53. The report accompanying the regulatory revision makes clear that the FDA is defining what constitutes "patent information" for

[6] The full title of the final rule was: "Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not Be Infringed," 68 Fed. Reg. 36,676.

[7] See Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 67 Fed. Reg. 65,448 (Oct. 24, 2002) ("Proposed Rule").

purposes of subsections (b) and (c).[8] Additionally, the report accompanying the Proposed Rule in 2002 confirms that the FDA's authority for the 2003 rule arises from not only the FDA's general authority to enforce the FDCA under 21 U.S.C. § 371, but also its authority to implement section 505 of the Hatch-Waxman Act, "including the patent listing and patent certification requirements" in section 505(b). See Proposed Rule, 67 Fed. Reg. at 65,457. The regulation itself provides that "patent information" includes 1) "[i]nformation on the drug substance (active ingredient) patent including . . . [w]hether the patent claims the drug substance that is the active ingredient in the drug product described in the new drug application or supplement," 2) "[i]nformation on the drug product (composition/formulation) patent including . . .

[8] The Report explains why it is promulgating the regulation, and in fact this is because of the existence of subsections (b) and (c):

> To explain why we (FDA) issued the proposal, we first describe how Federal law requires NDA applicants to file patent information and how that patent information can affect the approval of ANDA and 505(b)(2) applications. . . .
>
> Section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application 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." Section 505(c)(2) of the act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application.
>
> Under section 505(b)(1) of the act, we publish patent information after approval of an NDA application in our approved drug products list entitled "Approved Drug Products With Therapeutic Equivalence Evaluations." This list is known popularly as the "Orange Book" because of its orange-colored cover. If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

Report and Order Accompanying the Patent Listing Rule, 68 Fed. Reg. at 36676.

[w]hether the patent claims the drug product for which approval is being sought,"[9] and 3) "[i]nformation on each method-of-use patent including . . . [w]hether the patent claims one or more methods of using the drug product for which approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted."[10]

The NDA applicant is thus not only required to submit the patent number and the expiration date as part of its application, but is also required to describe the scope of the patent and relate the drug substance, drug product, or method of use in question to the particular patent. Furthermore, the regulation requires an NDA holder or applicant to complete FDA Form 3542, which requires the applicant to identify whether the submitted patent claims a "drug substance," "drug product," or "method of use," and link such information to each patent for which information is being submitted. See J.A. 918-20. The information in this form provides the basis for the Orange Book listing. See 21 C.F.R. § 314.53(c)(2)(ii).

Congress was well aware of this regulatory interpretation of "patent information" when it enacted the counterclaim provision. As Senator Schumer, one of the original sponsors of the amendment, stated, "The bill provides a critical complement to the work

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[9] A "drug product" is a "finished dosage form . . . that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." See 21 C.F.R. § 314.3. A "drug substance" is "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body." Id.

[10] These listing requirements are described in 21 C.F.R. § 314.53(c)(2), while § 314.53(c)(1) provides: "An [NDA] applicant . . . shall submit the required patent information described in paragraph (c)(2) of this section for each patent that meets the requirements described in paragraph (b) of this section."

the FDA has done in clarifying its regulations on patent listing, but it goes much further." 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) (emphasis added). Additionally, in several places in the legislative history the FDA regulation is cited approvingly. See 149 Cong. Rec. S8690 (daily ed. June 26, 2003) (statement of Sen. Hatch, then-chairman of the Senate Committee on the Judiciary); 149 Cong. Rec. S8197 (daily ed. June 19, 2003) (statement of Sen. Frist, then Senate Majority Leader).

Quite apart from Chevron, it is well established that where, as here, Congress was specifically aware of the agency's interpretation of a statutory term at the time the statute was enacted, this is compelling evidence of legislative adoption of the agency's interpretation. This principle has been recognized by the Supreme Court for decades, both in the context of reenactment of existing statutes where statutory terminology had been construed by the agency before the reenactment,[11] and in the context of new

[11] See United States v. Bd. of Comm'rs of Sheffield, Ala., 435 U.S. 110, 131-35 (1978) (adopting the Attorney General's interpretation of "state[s] and political subdivision" to include all political units in a designated jurisdiction where Congress was aware of the Attorney General's interpretation when it reenacted the Voting Rights Act without change in 1975); Cammarano v. United States, 358 U.S. 498, 510 (1959) (adopting IRS' construction of "ordinary and necessary" business expenses as excluding sums spent to persuade the public of the desirability of proposed legislation affecting the taxpayer's business, as Congress reenacted the Internal Revenue Code without substantive change to the business expense deduction); Hartley v. Comm'r, 295 U.S. 216, 220 (1935) (adopting IRS' construction of "basis" for the purposes of a decedent's estate to be the property's value at the time of decedent's death, as Congress reenacted the pertinent Internal Revenue Code provisions without substantive change).

legislation utilizing terminology that the agency had previously construed.[12] Here, Congress utilized the FDA's interpretation of "patent information" by enacting the Gregg-Schumer Bill with full awareness of the agency's interpretation of the term, and the FDA's interpretation is binding on us in construing the statute.

Third, the legislative history makes clear that Congress was concerned with correcting Orange Book information generally. The legislative history suggests a broad concern with preventing brand manufacturers from manipulating the patent listing system in the Orange Book in order to delay entry of generics into the market. See 149 Cong. Rec. 31,200 (2003) (statement of Sen. Schumer) ("The [new] 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.").[13] The purpose of the statutory provision as reflected in the legislative history refers broadly to correction of Orange Book information, not just to correction of patent numbers and expiration dates. As Senator Schumer described it, "[T]he 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

[12] See Traynor v. Turnage, 485 U.S. 535, 546 (1988) (adopting Veterans' Administration's construction of "willful misconduct" as including alcoholism, where Congress enacted GI Bill using the same "willful misconduct" language previously construed by the Veterans' Administration).

[13] See also 149 Cong. Rec. at S8191 (daily ed. June 19, 2003) (statement of Sen. Schumer) ("A lot of blockbuster drugs were on the market. Their patents were about to expire. The drug industry . . . 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. That was never the concept of Hatch-Waxman.").

company delist the patent or correct the patent information in the FDA's Orange Book." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (emphases added).

Under the circumstances, it seems to me that we must interpret the phrase "patent information submitted . . . under subsection (b) or (c)" to include Orange Book information that describes the scope of the patent and relates the patent number and expiration date to the drug or method of use and, in particular, that "patent information" submitted under subsections (b) and (c) must be interpreted to include the patent information required by the 2003 regulation, including method of use information.

III

In my view, the majority also errs by interpreting "an approved method of using the drug" in 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb) to mean "any" approved method of use approved in the patentee's NDA. The majority's approach here is fundamentally inconsistent with the Supreme Court's admonition, in a recent opinion by Justice Scalia, that "[u]ltimately context determines meaning," Johnson v. United States, No. 08-6925, slip op. at 5 (U.S. Mar. 2, 2010), and the Court's repeated instruction that "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy," U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc., 508 U.S. 439, 455 (1993) (quoting United States v. Heirs of Boisdoré, 49 U.S. (8 How.) 113, 122 (1849)).

The evident purpose of the counterclaim provision is to allow for the correction of "patent information submitted . . . under (b) or (c)." In other words, as discussed above, the provision is designed to provide for correction of erroneous Orange Book information submitted by the NDA applicant or holder, including information with respect

to patent coverage of both drugs and methods of use. That purpose is reflected in the language of the statute, which allows an ANDA applicant defending against an infringement action to "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I) (emphases added). In other words, if the submitted Orange Book information claims patent coverage for an approved drug not covered by the patent or a method of use not covered by the patent, that information may be corrected.

Thus, the reference to "an approved method of using the drug" in subsection (bb) must refer to information in the Orange Book concerning "an approved method of using the drug." The majority's error lies in focusing on the relationship between the patent and the NDA (which is not Orange Book information), rather than the relationship between the patent and the Orange Book listing. Under the majority's view, no correction of erroneous Orange Book information is permitted so long as the patent covered any approved method of use covered by the NDA. The patent can be listed in the Orange Book as erroneously covering approved use A, despite the fact that the patent actually covers approved use B, and the counterclaim provision provides no mechanism for correction. This cannot be what Congress intended.[14]

[14] The majority suggests that Congress borrowed the statutory language from our decision in Mylan and that this shows that "an" means "any," because in Mylan the patent did not relate to any approved use. Majority Op. at 11. I have demonstrated above that Congress could not have intended to limit the counterclaim provision to the particular facts in Mylan.

Moreover, the statutory language referring to "an approved method of using the drug" obviously refers, once again, to the terminology used in the 2003 Patent Listing Rule. That regulation required that for "each method of use patent" the NDA applicant submit certain information, including "[w]hether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted." 21 C.F.R. § 314.53(c)(2)(ii)(P)(1) (emphasis added). In other words, the regulation requires the patentee to relate the patent to the approved method of use. Subsection (bb) is directly concerned with correction of the Orange Book patent information relating the patent to the approved method of use.

Once the overall operation of the statutory scheme is understood, the text is clear. Webster's Third New International Dictionary describes "a" as being "used as a function word before a singular noun followed by a restrictive clause or other identifying modifier <*a* man who was here yesterday>." Webster's Third New International Dictionary 1 (2002) (emphasis added). This definition appears before the definition of "a" as "any." See id. As the example illustrates, "an" in this case may be the function word before the singular noun ("approved method of using the drug") conveying a particular identity through the use of a restrictive clause. The restrictive clause here is implicit—"an approved method of using the drug" logically refers to an approved method of use listed by the NDA holder in the Orange Book, as associated with the listed patent. Thus, "an" refers to a particular method of using the drug, that is, the particular approved method listed by the NDA holder in the Orange Book. This is the only interpretation of the statutory language that yields a result that is not plainly at variance

with the purpose of the legislation as a whole. See Nixon v. Mo. Mun. League, 541 U.S. 125, 138 (2004) (citing United States v. Am. Trucking Ass'n, 310 U.S. 534, 543 (1940)). "As in all cases of statutory construction, our task is to interpret the words of these statutes in light of the purposes Congress sought to serve." Chapman v. Houston Welfare Rights Org., 441 U.S. 600, 608 (1979).

In short, the statute must be construed to read as follows:

> (ii) Counterclaim to infringement action.—
> (I) In general.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—
> (aa) the [associated] drug for which the application was approved; or
> (bb) an [associated] approved method of using the drug.

An error in an Orange Book use code, which covers an unpatented method of use, is subject to correction under a proper reading of the counterclaim provision.

IV

The facts in this case well illustrate the true manipulation that the counterclaim provision was designed to avoid. Here Novo Nordisk ("Novo") was originally the owner of the patent on the chemical composition of repaglinide, U.S. Patent No. RE37,035 ("the '035 patent"), which expired on March 14, 2009. See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 656 F. Supp. 2d 729, 730 (E.D. Mich. 2009). Novo is also the owner of a patent covering the use of repaglinide in monotherapy to treat diabetes, U.S. Patent No. 5,312,924 ("the '924 patent"), which expired in September of 2006. The expiration of these patents meant that Novo could not claim any patent protection for

monotherapy use of PRANDIN. However, Novo acquired an additional patent in 2004 (the patent in suit) claiming 1) a chemical composition of repaglinide and metformin; and 2) a method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient repaglinide in combination with metformin. See U.S. Patent No. 6,677,358 col.10 ll.42-43, 48-51 ("the '358 patent"). The '358 patent is not set to expire until June 12, 2018.

Following issuance of the '358 patent on January 13, 2004, Novo submitted an FDA Form 3546, dated February 5, 2004, associated with NDA 020741 (for PRANDIN). Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 649 F. Supp. 2d 661, 663 (E.D. Mich. 2009). The use code narrative was limited to claiming a use of PRANDIN in combination therapy. It read: "U-546—USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE." Id. at 664. Thus, the Orange Book entry in 2004 included the following:

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)
020741 001	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546
020741 002	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546
020741 003	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546

See J.A. 1235.

Caraco Pharmaceutical Laboratories, Limited ("Caraco") filed an ANDA seeking approval to market repaglinide for the treatment of diabetes in anticipation of the expiration of the '035 patent. Novo Nordisk, 649 F. Supp. 2d at 662. In June 2005, Novo sued Caraco, claiming that if Caraco marketed repaglinide, it would infringe.

Complaint at 3, Novo Nordisk, 649 F. Supp. 2d 661 (No. 05-cv-40188).[15] Novo did not claim that Caraco would infringe the '924 patent or the '035 patent; nor could Novo make such a claim since Caraco sought approval to market repaglinide only after both patents expired. Rather, Novo claimed that Caraco would induce infringement of the '358 patent, apparently because the Caraco label would suggest the use of repaglinide together with metformin.

Following the FDA's suggestion, Caraco sought a section viii certification, making clear that it was not seeking approval to market the use of repaglinide in combination with metformin (by limiting its label to the monotherapy use).[16] Based on the existing U-546 use code description for PRANDIN (limiting the description of the patent to combination therapy), the FDA permitted Caraco to move forward with its label carving out information pertaining to use of repaglinide in combination with metformin. See J.A. 625-43.

Several months later, Novo then broadened the use code for PRANDIN associated with the '358 patent, changing the use code to read: "U-968—A METHOD

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[15] In particular, Novo asserted that marketing of repaglinide would infringe claim 4 of the '358 patent, which claimed:

> A method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin.

'358 patent col.10 ll.48-51.

[16] Caraco initially made a paragraph IV certification with respect to Claim 4 of the '358 patent and a paragraph III certification with respect to the '035 patent on repaglinide. Opposition to Plaintiffs-Appellants' Emergency Motion to Stay Mandatory Injunction Pending Appeal at exh. 7, at 3, Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., No. 2010-1001 (Fed. Cir. Oct. 7, 2009). However, at the FDA's urging it sought a "split certification," a paragraph IV certification as to the drug product claims of the '358 patent, and a section viii certification as to the method claim. See J.A. 635.

FOR IMPROVING GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS." Novo Nordisk, 649 F. Supp. 2d at 664. The Orange Book listing for PRANDIN then included the following:

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES
REPAGLINIDE – PRANDIN			
N020741 001	6677358	Jun 12, 2018	DS DP U-968
N020741 002	6677358	Jun 12, 2018	DS DP U-968
N020741 003	6677358	Jun 12, 2018	DS DP U-968

See U.S. Dep't of Health & Human Servs., Approved Drug Products with Therapeutic Equivalence Evaluations add. A, at 157 (30th ed. 2010). Since U-968 appeared to encompass the use of repaglinide in monotherapy to treat diabetes, the FDA reversed itself and rejected Caraco's proposed labeling carve-out, requiring Caraco to include the information regarding the patented repaglinide-metformin combination therapy in its generic label.[17]

Novo acknowledges that monotherapeutic use of repaglinide is not covered by the '358 patent. See, e.g., Majority Op. at 9 ("Novo and Caraco agree that the '358 patent claims only one of the three approved methods of using PRANDIN (i.e., repaglinide in combination with metformin)."). But the use code claims that the patent

[17] With the exception of the carve-out to avoid the infringing use, the language of the generic label must otherwise match that of the original drug label. See 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 314.94(a)(8)(iv). Thus, in this case, without the section viii carve-out, Caraco would be required to include information regarding the combination therapy included in PRANDIN's label (in the "Dosage and Administration" and "Clinical Pharmacology" sections) in its own label. See J.A. 637. The inclusion of information regarding the combination therapy would likely cause Caraco to induce infringement of the '358 patent.

does cover the monotherapy use. In my view, this is precisely the type of situation that Congress intended the counterclaim provision to address.

The concurrence blames the FDA for Caraco's predicament, adopting Novo's disingenuous argument that the FDA, and not Novo, was responsible for the change in the use code. The concurrence accuses the FDA of "gumm[ing] up the works. By requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the '358 patent." Concurring Op. at 2. First, the FDA did not require a change in the use code. The FDA does not interpret patents or police the Orange Book listings, the very source of the problem that led to the counterclaim provision. The FDA role in administering the Orange Book is ministerial: it simply lists the patent information that it receives from brand manufacturers, expecting those parties to abide by the statutory and regulatory mandates. See Apotex, Inc. v. Thompson, 347 F.3d 1335, 1349 (Fed. Cir. 2003) (upholding the FDA's position that the FDA's duties with respect to the Orange Book are ministerial and that the Hatch-Waxman Act does not require the FDA to police the Orange Book listings to ensure compliance with regulatory and statutory requirements).

Second, while the FDA did require a general change in oral diabetes drug labeling in November of 2007 that required a corresponding change in the PRANDIN label, there is absolutely nothing in the statute or regulations that required Novo to

change the use code to track this new indication.[18] The FDA did not direct or request that Novo change its use code to reflect the new indication, nor was Novo required under FDA regulations to make such a change. Indeed, in response to questioning at oral argument, Novo admitted this. Oral Arg. at 1:40-1:46 ([The FDA directive of 2007] did not require [a change in the use code] . . .").

However, Novo argues that the labeling change required by the FDA in the "Indication" part of the label made the use code change appropriate. Novo argues that FDA Form 3542 allows them to submit either the method of use or the indication for the use code. Appellant's Br. 36 ("FDA's guidance is expressly written in the alternative: An applicant may describe either the indication or the method of use."). That is partially correct,[19] but the form also requires that the use code information refer to that portion of the label that relates to a patented use. See J.A. 919. An approved label, as in this case, may cover both patented uses and unpatented uses. Nothing in the FDA regulations or FDA Form 3542 suggests that the patentee may derive Orange Book use code information from that portion of the label referring to unpatented uses. Quite the contrary, the applicable regulations and FDA Form 3542 are clear that the patentee is required to utilize those portions of the label that refer to the patented use. See 21 C.F.R. § 314.53(c)(2)(ii)(P)(2) (requiring the NDA holder to identify "the specific section

[18] In November of 2007, as part of an ongoing reevaluation of the professional labeling of all oral antidiabetic drugs, the FDA required Novo to replace all separate indications with the following sentence: "PRANDIN is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." See J.A. 667-68.

[19] The form provides alternatives with respect to submission of a proposed use code—it directs the NDA holder to "provide the information on the indication or method of use for the Orange Book." J.A. 920.

of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted"); J.A. 919.

Here, the patentee did exactly what was expressly forbidden. For the proposed use code description submitted on the FDA Form 3542, Novo submitted the following: "A method for improving glycemic control in adults with type 2 diabetes mellitus." J.A. 673. It thus utilized that portion of PRANDIN's label that refers to the use of repaglinide standing alone to treat diabetes (an unpatented use), not to the use of repaglinide together with metformin (a patented use).[20] There is no justification for using a portion of the label referring to an unpatented use to describe a patented use.

The 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. At oral argument, Novo conceded that the decision to change the use code was in part "a response to the section viii ruling . . . in December '08 from FDA." Oral Arg. at 3:43-4:03.

V

Finally, the majority opinion suggests that the court's restrictive interpretation of the counterclaim provision is not so bad because it does not leave Caraco without a remedy to correct the erroneous Orange Book listing. The majority is sanguine about the outcome, believing that forcing Caraco to defend the paragraph IV infringement suit

[20] Various other parts of the current PRANDIN label reference the combination therapy, such as the "Clinical Pharmacology" and "Dosage and Administration" sections of the label.

will "facilitate[] efficient resolution of disputes concerning potential overlapping of protected and unprotected uses." Majority Op. at 12. In contrast, the concurrence doubts that there is a remedy in the infringement suit, and I agree. As the concurrence notes, "[b]y requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the '358 patent." Concurring Op. at 2. Indeed, Novo's adoption of a broad use code for PRANDIN likely prevents Caraco from being able to disprove infringement in the paragraph IV lawsuit, because Caraco is now compelled to include information regarding the patented combination therapy in its label.

Nor would there be a remedy in a suit under the Administrative Procedure Act ("APA"). To be sure, we have held that an APA action could be brought to challenge FDA action in refusing to police use codes in the Orange Book, but at the same time we expressed no view as to whether such an action would succeed. See Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1379 (Fed. Cir. 2002). To succeed in such an action, the ANDA applicant would have to establish that the FDA's refusal to police use codes was arbitrary and capricious, or contrary to the statute. 5 U.S.C. § 706(2)(A). We have subsequently held that the FDA is under no statutory obligation to determine the correctness of particular patent listings in the Orange Book, and that nothing in the Hatch-Waxman Act requires the FDA to screen Orange Book submissions by NDA applicants and refuse those that do not satisfy the statutory requirements for listing. See Apotex, 347 F.3d at 1349; see also aaiPharma Inc. v. Thompson, 296 F.3d 227, 238-40 (4th Cir. 2002). Moreover, the very enactment of the counterclaim provision assumed that no alternative remedy was available to an ANDA applicant challenging an

Orange Book listing. Today's decision strikingly limits the counterclaim provision with the consequence that, in all likelihood, the ANDA applicant is left without any remedy to correct an erroneous Orange Book listing with respect to a method of use patent. This cannot be what Congress intended.

* * *

In summary, the majority's crabbed view of the statute sanctions an unjustified manipulation of the Orange Book. In this suit, Caraco seeks to compel Novo to correct the use code for PRANDIN, and to reinstate the earlier U-546 use code describing the '358 patent as covering the "USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE." Under the correct construction of the counterclaim provision, the district court properly held that Caraco was entitled to an order reinstating the former U-546 use code. See Novo Nordisk, 656 F. Supp. 2d 729.

In holding that the counterclaim provision is unavailable, the majority's approach is notably inconsistent with the approach adopted by our sister circuit in another recent Hatch-Waxman Act case, Teva Pharmaceuticals USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010). There the court construed another provision of the 2003 amendments concerning the NDA holder's withdrawal of "patent information submitted under subsection (b) or (c)." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). The statute provided that if such information were "withdrawn by the holder of the application," the period of exclusivity of the ANDA first filer would be forfeited. See id. The court held that only the withdrawal resulting from a successful counterclaim suit triggered a forfeiture and not a voluntary withdrawal. Teva, 595 F.3d at 1317. This was so because there was "not a single cogent reason why Congress might have permitted brand manufacturers to

trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario," id. (emphasis in original), and because of the strong policy of the statute favoring the 180-day marketing exclusivity period. Id. at 1318. Here the majority reaches a result that is unsupported by any cogent reason for leaving an ANDA applicant without a remedy to correct an erroneous Orange Book listing with respect to a method of use patent, and is directly contrary to the congressional purpose. I respectfully dissent.