UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

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

Plaintiffs,

-vs-

Case No. 05-40188
Hon: AVERN COHN

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

Defendants.
_____/

MEMORANDUM

This memorandum explains the reasons for denying plaintiffs' motion (Doc. 337) to dismiss defendants' Count IV of the Third Amended Answer and Counterclaim (Doc. 309) (for an order requiring correction of a "use code"), and to Strike Defendants' Sixth Affirmative Defense (Doc. 309) (for an order requiring correction of a "use code") in an order entered on August 20, 2009 (Doc. 369). The order is not a decision on the merits. The order means only that the Counterclaim states a cognizable cause of action and that the Affirmative Defense states a cognizable position.

I.

A.

This is a Hatch-Waxman[1] case, Pub. L. No. 98-417, 98 Stat. 1585 (1984), 21 USC § 355, *et seq*. Defendant, Caraco Pharmaceutical Laboratories, Ltd. (Caraco), a generic

[1] *See* CONG. RES. SERV., CRS REPORT FOR CONGRESS, No. RL 30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") (Updated 2005).

drug manufacturer, has pending before the Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) for repaglinide, a diabetes control drug. Repaglinide was first brought to market by plaintiffs, Novo Nordisk A/S and Novo Nordisk, Inc. (Novo), proprietary drug manufacturers, under the trade name Prandin. Novo processed the New Drug Application (NDA) for repaglinide under NDA Number 20-741, and claimed patent protection for it under U.S. Patent No. RE37,035E (the '035 patent). The '035 patent expired on March 14, 2009.

B.

In anticipation of the expiration of the '035 patent, Caraco filed an ANDA for approval to market repaglinide. After receiving notice of Caraco's ANDA, Novo sued Caraco for infringement of U.S. Patent No. 6,677,358B1 (the '358 patent) claiming that if Caraco marketed repaglinide it would contributorily infringe the '358 patent, and particularly claim 4 which reads:

> 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.

Caraco responded by asserting that the '358 patent was invalid and unenforceable because of misconduct before the Patent Office. Caraco also asserted that its sale of repaglinide would not infringe the '358 patent.

C.

The '358 patent was intended by Novo to cover a new product, Prandimet, a combination of repaglinide with metformin. Novo filed a NDA for Prandimet which was processed by the FDA under NDA 22-386. As part of the application process Novo filed two (2) Forms FDA 3546, Patent Information Submitted Upon And After Approval Of An

NDA Or Supplement.[2]

The first FDA 3546, dated February 05, 2004, in pertinent part reads:

NDA NUMBER:	NDA 20-741
TRADE NAME:	Prandin
ACTIVE INGREDIENT:	Repaglinide
United States Patent Number:	U.S. 6,677,358 B1
Patent Claim Number:	4

(Continued on next page)

[2] Form FDA 3542 is designed to elicit the patent information called for by 21 U.S.C. § 355(b)(1)(G), 21 C.F.R. § 314.53(b)(1) and 68 Fed. Reg. 36,683. *See* Exhibit A; *see also* Orange Book preface *infra* fn 4, at 30 (Exhibit B).

If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use:[3] (Submit the description of the approved indication or method of use that you propose FDA include as the "Use Code" in the Orange Book[4]. . . .) Use of repaglinide in combination with metformin to lower blood glucose.

[3] Form FDA 3542 instructions state in part:

> 4. Method of Use
>
> 4.2) For each approved use of the drug claimed by the patent, identify by number the claim(s) in the patent that claim the approved use of the drug. An applicant may list together multiple claim numbers and information for each approved method of use, if applicable. However, each approved method of use must be separately listed within this section of the form.
>
> 4.2a) Specify the part of the approved drug labeling that is claimed by the patent.
>
> 4.2b) The answer to this question will be what FDA uses to create a "use code" for Orange Book publication. The use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method of use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. . . .

[4] The Orange Book, an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, lists products approved by the FDA. The Use Code is a code designating numerically and in narrative the approved use of a drug product, and is intended to alert ANDA applicants to the existence of a patent that claims an approved use. The narrative is supplied by the applicant seeking approval of a new drug as will be explained. For an overall description of the Orange Book, see the Orange Book preface at http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm. See http://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071436.pdf for the full text of the Orange Book.

The second Form FDA 3546, dated October 01, 2008, in pertinent part reads:

NDA NUMBER:	22-386
TRADE NAME:	Prandimet (repaglinide/metformin HCl) tablets
ACTIVE INGREDIENT:	repaglinide/metformin HCl
United States Patent Number:	U.S. 6,677,358
Patent Claim Number:	4

If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (Submit the description of the approved indication or method of use that you propose FDA include as the "Use Code" in the Orange Book. . . .) Use of repaglinide in combination with metformin to lower blood glucose.

The Use Code narrative for each of the two (2) Form 3546 reads: U-546 - USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE.

D.

On May 06, 2009, Novo filed an amended FDA 3542, in pertinent part as follows:

NDA NUMBER:	20-741
TRADE NAME:	Prandin
ACTIVE INGREDIENT:	Repaglinide
United States Patent Number:	U.S. 6,677,358
Patent Claim Number:	4

If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (Submit the description of the approved indication or method of use that you propose FDA include as the "Use Code" in the Orange Book. . . .) A method for improving glycemic control in adults with type 2 diabetes mellitus.

As part of this filing, Novo wrote the FDA as follows:

> Re: TIME SENSITIVE PATENT INFORMATION
> NDA 20-741, Prandin® (repaglinide)
>
> To the Orange Book Staff:
>
> In accordance with Section 314.53(c) and (d) of FDA regulations, please find an original and two copies of Form FDA 3542, containing an AMENDMENT to the patent information for the above-referenced NDA. The information being submitted is to amend the use code relating to U.S. Patent No. 6,677,358 to correspond with the change in labeling required by FDA in November 28, 2007 (and to correct an unrelated inadvertent error in the original Form 3542.) This amendment is not applicable to NDA 22-386, PrandiMet® (metformin hydrochloride/repaglinide), which will retain its present use code relating to U.S. Patent No. 6,677,358.
>
> Applicant believes the use code should be changed. Therefore, please remove use code U-546 from the Orange Book for the listed drug (Prandin) and substitute with the use code contained in this form.[5]

NDA 20-741 is the NDA number under which Novo originally processed its NDA for repaglinide under the '035 patent.

The Use Code narrative following the change reads:

> U-968 - A METHOD FOR IMPROVING GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.

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[5] Plaintiffs' reasons for the new Form FDA 3542 were described by Novo during a hearing on July 15, 2009, as follows:

> MR. SITZMAN [Novo's counsel]: . . .the change in use code was designed to do two things. One is to make it consistent with the indication that the FDA required.
>
> The other reason that the use code was changed in May 2009 was as a result of several different things.
>
> * * *
>
> . . .and two, that it would prevent Caraco from carving out of its label the most critical and vital information to this drug.

II.

The filing of the new Form FDA 3542 by Novo on May 06, 2009, and the new Use Code, U-968 narrative for repaglinide, prompted the filing by Caraco of the Counterclaim and the Affirmative Defense, at which Novo's motion is directed, and which the Court has denied.

A.

The Counterclaim reads:

> 97. Under 21 USC § 355(j)(5)(C)(ii), Caraco seeks an order requiring Plaintiffs to correct the use code information submitted by plaintiffs.
>
> 98. Plaintiffs' original Prandin use code for the '358 patent was: "U-546: use of repaglinide in combination with metformin to lower blood glucose."
>
> 99. On or about May 6, 2009, Plaintiffs changed the use code for the '358 patent in reference to Prandin to one with a much broader scope: "U-968: a method for improving glycemic control in adults with Type 2 diabetes mellitus." This new use code does not purport to specifically or accurately describe the patented method of use found in claim 4 of the '358 patent, as required by FDA regulations.
>
> 100. Novo's revised use code could be read as suggesting that the '358 patent covers all approved methods of using repaglinide (including monotherapy and combination with TZDs). But the '358 patent cannot possibly be construed to cover any method of use other than "repaglinide in combination with metformin."
>
> 101. Caraco is entitled to an Order requiring Plaintiffs to correct the patent information submitted by Plaintiffs for the '358 patent's method claim on the ground that the patent does not claim the approved methods of using repaglinide as monotherapy or in combination therapy with TZDs. In particular, Plaintiffs must correct the use code for the '358 patent in reference to Prandin, submitted on or about May 6,

> 2009, from "U-968: a method for improving glycemic control in adults with Type 2 diabetes mellitus" to the original use code: "U-546: use of repaglinide in combination with metformin to lower blood glucose."

B.

The Affirmative Defense reads:

> 31. The claims of the '358 patent are unenforceable due to patent misuse.
>
> 32. Plaintiffs have misused their rights under the '358 patent, including by providing FDA with a materially inaccurate and fraudulent use code description for that patent. Plaintiffs have improperly and illegally expanded the legitimate scope of the '358 patent to delay or prevent FDA approval of Caraco's ANDA, and in this fashion also have illegally extended the life of Novo's U.S. Patent No. RE37,035, which expired on March 14, 2009.

C.

Novo takes issue with Caraco's right to file the Counterclaim and Affirmative Defense as follows:

> Caraco's Fourth Counterclaim "seeks an order requiring Plaintiffs to correct the use code information submitted" to the Food and Drug Administration ("FDA"). Third Amended Answer and Counterclaims, ¶97. Even assuming the truth of Caraco's allegation of inaccuracy, no cause of action has ever been authorized by Congress, or recognized by any court, to correct an inaccurate use code. Hatch-Waxman authorizes only two specific counterclaims by an ANDA filer for correction of the patent information submitted by an NDA holder. Caraco's Fourth Counterclaim is not even remotely within the narrow scope of either of the *two permissible counterclaims*. Hatch-Waxman expressly rules out all claims and counterclaims "other than" the *two permissible counterclaims* (emphasis added).
>
> Caraco's Sixth Affirmative Defense and other allegations of "patent misuse" based on the use code information submitted to the FDA should be stricken. The Federal Circuit has made

> clear that neither a defense to patent infringement, nor a claim of patent misuse, can be based on the propriety of the patent information submitted for inclusion in the Orange Book. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001); *Schwarz Pharrma, Inc. v. Teva Pharms. USA, Inc.*, 2005 WL 4158850 (D.N.J. Feb. 4, 2005).

The "two permissible counterclaims" according to Novo are limited to correction of the patent number and the patent expiration date.

III.

A.

1.

21 U.S.C. § 355(j)(5)(C)(ii), on which Caraco relies reads in part

> (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.
> >
> > (II) No independent cause of action. – Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

2.

Section 355(j)(5)(C)(ii) was not part of Hatch-Waxman, Pub. L. No. 98-417,[6] as initially enacted. It came into the statute with enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

B.

The scope of a counterclaim under § 355(j)(5)(C)(ii) allows for Caraco's challenge to the Use Code U-968 narrative which comes from the Form FDA 3542 filed by Novo on May 06, 2009 (*see supra* p. 5). This conclusion is illustrated by first an analysis of the Federal Circuit's decision in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), then the legislative history of § 355(j)(5)(C)(ii), and finally post-enactment commentary.

1.

The Federal Circuit's decision in *Mylan* was a reversal of the district court's decision, 139 F. Supp. 2d 1 (D.D.C. 2001). In *Mylan*, a generic drug applicant brought a declaratory judgment action challenging an Orange Book Use Code narrative associated with a particular patent. The district court held that the Use Code narrative was improperly listed. The Federal Circuit, after describing the regulatory framework reversed. Novo says of *Mylan*:

> On appeal the Federal Circuit looked to the Hatch-Waxman Amendment to determine whether this created a misuse defense

It goes on to say:

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[6] The Drug Price Competition and Patent Term Restoration Act of 1984, Title I, Abbreviated New Drug Applications, Pub. L. No. 98-417, 98 Stat. 1585, in turn was an amendment to the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

> The Federal Circuit concluded that "a view of the amendment shows no explicit provisions allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent."

While this is a correct description of the decision in *Mylan*, it misreferences the "amendment." The reference to "amendment" is to the original 1984 enactment of Hatch-Waxman, which was an amendment to the Federal Food, Drug and Cosmetic Act. *See supra* page 9. Novo seems to ignore subsequently-enacted Pub. L. No. 108-173, which, as described, added the counterclaim provision, § 355(j)(5)(C)(ii), as an amendment to Hatch-Waxman in 2003. *Scwartz Pharma, Inc. V. Teva Pharmaceuticals USA, Inc.*, 2005 WL 4158850 (D.N.J. Feb. 4, 2005) is not to the contrary. There the issue was an improper use code narrative for a patent. The fact of listing the patent was not contested.

2.

In the lead up to enactment of § 355(j)(5)(C)(ii), *Mylan* was cited more than once as an example of the inability to challenge a Use Code narrative, and the need for corrective legislation.

A CRS Report stated:

> In *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), an ANDA applicant contended that its cause of action arose under the patent laws. The ANDA applicant observed that listing in the Orange Book was a necessary element of the patent infringement charge brought by the NDA holder. Therefore, an argument the patent should be delisted was effectively a defense to patent infringement, reasoned the ANDA applicant. As a result, the ANDA applicant concluded that it could simply rely upon the patent laws as a basis for jurisdiction in the federal courts.
>
> The Federal Circuit disagreed, however. According to the Federal Circuit, the 1984 Act did not provide a private cause of action for delisting patents from the Orange Book. Following

> *Mylan Pharmaceuticals, Inc. v. Thompson*, an ANDA applicant could not request that a patent be removed from the Orange Book merely as a defense to patent infringement.

Congressional Research Services, CRS Report for Congress, No. 31379, *The "Hatch Waxman" Act: Selected Patent Related Issues* 11 (2002).

In a Congressional Hearing, the Acting Commissioner of the Food and Drug Administration, in a prepared statement said:

> FDA does not undertake an independent review of the patents submitted by the NDA sponsor. Issues of patent claim and infringement are matters of patent law, and FDA does not have the authority as well as the resources or capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug. FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information. The statute requires FDA to publish patent information upon approval of the NDA and, therefore, the Agency's role in the patent-listing process is ministerial. The Agency relies on the NDA holder or patent owner's signed declaration stating that the patent covers an approved drug, product's formulation, composition or use. Generic and innovator firms may resolve any disputes concerning patents in private litigation.[2]
>
> _____
>
> [2] *Mylan v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) – A generic's claim of improper listing "is not a recognized defense to patent infringement."

Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcommm. on Health of the House Com. on Energy and Commerce, 107th Congress 32 (Oct. 9, 2002) (statement of Lester M. Crawford, Acting Commissioner, FDA).

At the same hearing, the Chairman of the Federal Trade Commission, in prepared

testimony, citing *Mylan*, said:

> One of the first potential abuses the Task Force considered was the improper listing of the patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA [fn omitted]. Instead, the FDA takes at face value the declaration of the NDA filer that the listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause.
>
> In January of this year, lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its brand-name drug BuSpar[38] presented the Commission with an opportunity to clarify the *Noerr* doctrine in a way that might have a significant impact on the Commission's ongoing pharmaceutical cases. Specifically, plaintiffs alleged that, through fraudulent filings with the FDA, Bristol-Myers caused that agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act [fn omitted].
>
> [38] *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) ("*In re Buspirone*"). Some of the same plaintiffs previously had brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to de-list the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. *See Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001).

Id. at 41-42 (statement of Timothy J. Muris, Chairman, FTC).

3.

The legislative history of § 355(j)(5)(C)(ii) discusses the intended scope of the counterclaim-authorizing language.

a.

A CRC Report Summary states:

> The Congress is currently debating changes to the Medicare program. H.R. 1, the Medicare Prescription Drug and Modernization Act, and S. 1, the Prescription Drug and Medicare Improvements Act, as passed by each respective body on June 27, 2003, contain provisions that would amend P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). The Hatch-Waxman Act made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. The two bills currently under consideration would address Hatch-Waxman related issues of drug patents listed in the Orange Book. . . . This report provides a thematic side-by-side comparison of the proposed changes contained in H.R. 1 and S. 1 that would affect the Hatch-Waxman legislation.

Congressional Research Services, CRS Report for Congress, No. 32003, *Hatch-Waxman Related Provisions of the Medicare Prescription Drug Bills (H.R. 1 and S. 1): A Side-by-Side Comparison* (Updated 2003). In a side-by-side comparison of H.R.1 and S.1 (the pending bills), the report states:

H.R. 1	S. 1
Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of notification. However, if sued, the generic firm may file a counter claim to require the patent holder make changes to the Orange Book listings. No damages are to be awarded in either case.	If a patent owner does not file an infringement suit within 45 days of notification of a paragraph IV ANDA, the ANDA applicant may request a declaratory judgment regarding the validity of the patent. However, if sued, the generic firm may file a counter claim to require the patent holder make changes to the Orange Book listings. No damages are to be awarded in either case.

Id. at 5.

b.

In the floor debate in the Senate on November 24, 2003, this view of the scope of a counterclaim is discussed: 149 Cong. Rec. S 15746:

> The Gregg-Schumer amendments to the Hatch-Waxman Act would put an end to the practice of brand companies listing frivolous patents for the sole purpose of automatically delaying generic approval.
>
> * * *
>
> Third, the provisions enforce the patent listing requirements at the FDA by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand drug company delist the patent or correct the patent information in FDA's Orange Book.

149 Cong. Rec. 51546 (2003) (statement of Sen. Schumer).

c.

The broad scope of the counterclaim provision is discussed in a commentary on Greater Access to Affordable Pharmaceutical Act, S. 1225, 108th Cong. – a precursor to Pub. L. No. 108-173. Sec. 2(a)(C)(iii)(II) of the bill contained a provision reading:

> (II) COUNTERCLAIM TO INFRINGEMENT ACTION
> (aa) IN GENERAL – if the owner of the patent brings a

> patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the patent owner to correct or delete patent information filed by the patent owner under subsection (b) or (c) on the ground that the patent does not claim –
> (AA) the drug for which the application was approved; or
> (BB) an approved method of using the drug.
> (bb) NO DAMAGES – An applicant shall not be entitled to damages on a counterclaim under item (aa)
> (cc) NO INDEPENDENT CAUSE OF ACTION – Item (aa) does not authorize the assertion of a claim described in item (aa) in any civil action or proceeding other than a counterclaim described in item (aa)

Sarah Eurek, in explaining the subsection, says:

> Provisions Regarding Orange Book Listings:
>
> Unlike the FDA regulations, the GAAP does not specify which patents may or may not be listed in the Orange Book. However, it does create a new mechanism for challenging improper Orange Book listings. If a name-brand company lists a questionable patent and sues a generic applicant for violating that patent in order to trigger the 30-month stay, the GAAP allows the generic company to file a counterclaim, arguing that the patent should not have been listed. Subsequently, an order may be entered requiring the patent owner to correct or delete the patent information in the Orange Book. This provides an official mechanism for unlisting improper patents from the Orange Book, one which previously did not exist under current law or FDA regulations.

Sarah E. Eurek, Note, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 Duke L. & Tech. Rev. 0018.

d.

Post-enactment of Pub. L. No. 108-173 the Congressional Research Service said:

> Under the original act, the role of the FDA in adjudicating Orange Book listing disagreements is limited. If a generic pharmaceutical company disputes the accuracy of an Orange Book listing, that enterprise must present the grounds for disagreement to the FDA in writing. The FDA will then request that the NDA holder confirm the propriety of the listing. Unless

> the NDA holder withdraws or amends the listing, the FDA will not alter the patent information in the Orange Book.

Congressional Research Service, CRS Report for Congress, No. RL 32377, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents* 5 (2004). It went on to say:

> If sued, the generic firm may file a counter claim to require the patent holder make changes in the Orange Book listings. The generic firm may request that certain patents be delisted because they do not claim the drug to which they are attached. No monetary damages are to be awarded.

Id. at 9.

IV.

A.

Novo's assertion that the counterclaim provisions of Pub. L. No. 108-173, § 355(j)(5)(C)(ii) are limited solely to a correction of the patent number and the expiration date of the patent linked to an incorrect Use Code narrative in the Orange Book are belied by what has been discussed above.

As quoted above, FDA's Form 3542 requires that a Use Code narrative accurately describe each approved method of use *claimed* by a patent listed in the Orange Book. The narrative is limited to those approved uses of the drug product that the patent claims. *See also* 68 Fed. Reg. 36,682 (attached Exhibit A) and 21 C.F.R. § 314.53(c)(2)(ii)(P). In expanding the required patent information beyond the patent number and expiration date, FDA cited as its authority section 701(a) of the act which provides, "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary." 21 U.S.C. § 371(a).

The FDA's administration of the Orange Book is strictly ministerial. The FDA makes no judgment on whether or not a Use Code narrative comports to the use of the drug

product covered by the patent. The FDA accepts what the application for approval of the drug product states the patent covers. *See aaiPharma Inc. v. Thompson*, 296 F.3d 227, 234 (4th Cir. 2002).

Mylan pointed up a flaw in Hatch-Waxman: the fact that an applicant for ANDA could be seriously disadvantaged by an incorrect Use Code narrative because of a lack of an opportunity to challenge it. Senator Schumer in his floor comments quoted above described how the counterclaim provision would give a generic drug manufacturer processing an ANDA the opportunity to challenge a Use Code narrative improperly impeding the processing of the ANDA.

Novo's position that only the fact of the patent's listing in the Orange Book and its expiration date could be challenged by a generic drug manufacturer is undercut not only by the history of § 355(j)(5)(C)(ii), but also by the fact that nowhere in that history is there mention of just striking the patent or compelling a change in its expiration date discussed. What was discussed regarding the Use Code narrative was the difficulty a generic drug manufacturer faced in any effort to challenge an improper use code narrative. Hobbled by an improper use code narrative, the generic drug manufacturer was given its day in court. Only a court could offer it relief if its position was correct, and denial of Novo's motion does just that. Caraco is entitled to its day in court on its claim that the May 06, 2004, filing by Novo was improper and a misuse of its rights under Hatch-Waxman.

B.

As is the case of its reliance on *Mylan* to support its challenge to Caraco's Counterclaim, Novo again relies on that 2001 decision to supports its motion to strike Caraco's Sixth Affirmative Defense (patent misuse). Novo quotes pages 1331-32 of that

decision to the effect that the Hatch-Waxman Act neither explicitly provides for, nor points to any intent to provide, such a defense based on improper Orange Book listing. *Mylan* was not an infringement action where the defense of patent misuse was raised, but rather a declaratory judgment in the form of an attempted private cause of action against the FDA and the patent owner.

The Counterclaims sections of a conference report accompanying the Medicare, Prescription Drug, Improvement and Modernization Act of 2003 directly contradicts Novo's reliance on the earlier *Mylan* decision:

> Section 1101 of the Conference agreement prohibits the recovery of damages resulting from a successful counterclaim in a paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book. *It is not the intent of Congress to prohibit recovery by a counterclaimant in a paragraph IV suit of anti-trust or any other damages as a result of the improper listing of a patent in the Orange Book*. The language found in this section simply means that *in the absence of any other cause of action*, a ruling in favor of the counterclaimant resulting in the removal of the patent does not entitle the countercliamant to recover damages. (emphasis added)

H.R. Rep. No. 108-391, at 836 (2003).

In *Astra Aktiebolag v. Kremers Urban Development Co.*, 61 U.S.P.Q.2d 1767 (S.D.N.Y. 2001), the court denied a motion to dismiss portions of the defendant's Answer and Counterclaim alleging misuse as to the asserted '499 patent. The allegation was that the patent owner falsely certified to the FCA that such patent covered the approved product and that such false certification forced defendant to file a Paragraph IV certificate. The court stated that "the elements of an allegation of patent misuse include a patentee's impermissible use of its patent to broaden the physical or temporal scope of its patent with

an anticompetitive effect." *Id.* at 1768. It held that "these allegations are sufficient to state a claim of patent misuse with respect to the '499 patent." *Id.*

The *Astra* decision, rather than the *Schwarz Pharma, Inc v. Teva Pharmaceuticals USA, Inc.*, 2005 WL 4158850 (D.N.J. Feb. 4, 2005) decision cited by Novo, is the better reasoned decision. *Schwarz* misconstrues *Mylan* and fails to distinguish the nature of the suit. Caraco's Sixth Affirmative Defense alleges sufficient facts and theory of defense to survive Novo's Motion to Strike under Rule 12(f).

s/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: August 31, 2009

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, August 31, 2009, by electronic and/or ordinary mail.

s/LaShawn R. Saulsberry
Case Manager, (313) 234-5160