

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,

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**DECISION RE: DOC. 318**

This is a patent case involving the drug repaglinide marketed by Novo Nordisk (Novo) under the trade name Prandin. Now before the Court is Caraco Pharmaceutical Laboratories' (Caraco) Motion for Summary Judgment on Count IV of Its Third Amended Counterclaim and Sixth Affirmative Defense for Patent Misuse (Dkt. 318). The background of the case as well as Caraco's motion is described in the Court's decisions reported at 450 F. Supp. 2d 757 (E.D. Mich. 2006) (finding allegations of complainant sufficient to state a claim against Sun) and 2009 WL 2768955 (E.D. Mich. Aug. 31, 2009) (holding that Caraco can challenge an alleged incorrect use code narrative and the Hatch-Waxman Act allows for the affirmative defense of patent misuse in such circumstances).

For the reasons which follow, the Court finds that Novo has improperly filed with the FDA for listing in the Orange Book the use code narrative for the method of use of claim 4 of the '368 patent relating to Prandin, and Caraco is entitled to a mandatory

injunction requiring Novo to request the FDA to delist the U-968 listing for Prandin, and reinstate its former U-546 listing for Prandin. Novo's defense to Caraco's motion is a farrago of misstated and irrelevant facts and misstated law.

Novo's patent on repaglinide, RE37,035, expired on March 14, 2009. Caraco's ANDA covers repaglinide. The '358 patent which is the subject of this patent action does not cover repaglinide; it covers repaglinide only in combination with metformin. The U-968 use code narrative for the '358 patent states "a method for improving glycemic control in adults with type 2 diabetes mellitus." It is so broad as to incorrectly suggest that the '358 patent generically covers three (3) different FDA-approved methods of use of repaglinide:

- monotherapy treatment
- treatment in combination with thiazolidinediones
- treatment in combination with metformin

However, Novo admits that the first two (2) uses are not covered by claim 4 of the '358 patent. Caraco seeks FDA approval only to market a generic version of repaglinide; it does not seek approval to market repaglinide in combination with metformin, the only use covered by claim 4 of the '358 patent.

Novo filed the new U-968 use code on May 6, 2009, shortly after the '035 patent expired, as a significantly broadened replacement for use code U-546 that it previously submitted for the '358 patent.<sup>1</sup> As a result of the revised use code, the FDA will no longer permit Caraco to file a "section viii statement" carving out the patented repaglinide-metformin combination therapy as a predicate for securing approval of

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<sup>1</sup> U-546 specified "use of repaglinide in combination with metformin to lower blood glucose."

Caraco’s ANDA to market its generic repaglinide for non-infringing uses.

Because the FDA does not review use code narratives as explained in the August 31, 2009, decision, it has required Caraco as part of its ANDA to “submit an updated patent certification addressing the 6,677,358 patent and its associated Use Code 968.” Fax from William Peter Rickman, Director of the Division of Labeling and Program Support, FDA, to Veeranna Lolla, Caraco Pharmaceutical Laboratories (Aug. 3, 2009). Caraco has therefore been seriously disadvantaged by the improper U-968 use code narrative.

Novo acknowledges that monotherapeutic use of repaglinide is not covered by the ‘358 patent: “[T]he ‘358 patent contains 5 claims one of which (claim 4) is directed to a method of treatment of NIDDM with a combination of repaglinide and metformin.” Letter from Rosemarie R. Wilk-Orescan, Senior Counsel, Novo Nordisk, to the FDA (June 9, 2008).

This limitation is reiterated in the Novo’s Amended Complaint: “In the ‘358 patent claim. . .a method for treating NIDDU by administering to a patient in need of treatment repaglinide in combination with metformin (claim 4).” Amended Complaint at ¶ 10, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. Sept. 14, 2005). The Orange Book listing of Prandin reads:

<u>Proprietary Name</u>		PRANDIN		
<u>Patent Data</u>				
Appl. No.	Prod. No.	Patent No.	Patent Expiration	Patent Use Code

020741	001	6,677,358	06/12/2018	U-968 <sup>2</sup>
020741	001	RE37,035	03/14/2009	

The FDA has made clear that a use code description must be “accurate and detailed.” 68 Fed. Reg. 36,682 (June 18, 2003).

FDA regulations state that the use code must properly describe in sufficient detail the scope of the patented method covering an approved use of the referenced drug. 21 C.F.R. § 314.53(c)(2)(ii). The Patent Information submitted by Novo on its May 6, 2009 Form FDA 3542 for Prandin did not comply with the applicable FDA regulations and instructions, resulting in the U-968 use code that seriously misrepresents the approved method of use covered by claim 4. The Memorandum of August 31, 2009 summarized the clear legislative intent behind the 2003 amendments to Hatch-Waxman that added the counterclaim provision, § 355(j)(5)(C)(ii), namely, to curb Orange Book abuses arising from misinformation regarding listed patents. As provided for by the statute Caraco is entitled to “an order requiring [Novo] to correct . . . the patent information submitted” to the FDA in Form 3542. 21 U.S.C. § 355(j)(5)(C)(ii).

Caraco is correct when it says:

Novo . . . asserts . . . that the following accurately and completely describes the scope of the ‘358 patent’s method claim: “a method for improving glycemic control in adults with Type 2 diabetes mellitus.” This new use code is . . . vague on its face because it does not provide, as [the regulations] require[ ], “[t]he description of the patented method of use” in a manner that is both “accurate and detailed.” 21 C.F.R. §314.53(c)(2)(ii)(P); 68 Fed. Reg. at 36682. On the contrary, this. . .use code fails to identify with any specificity whatsoever the patented method and, read literally, suggests that [the ‘358] patent covers any method of improving glycemic control in adults with Type 2 diabetes

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<sup>2</sup> Patent Use Code U-968: A method for improving glycemic control in adults with type 2 diabetes mellitus.

mellitus. [One cannot] tell from this use code description alone which of the three repaglinide uses purportedly falls within the scope of the '358 patent.

Brief of Caraco Pharmaceutical Laboratories at 10, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. June 19, 2009).

Lastly, Novo proposed the new use code narrative not to more accurately describe the method of use of Prandin covered by claim 4 of the '358 patent, but "as part of its longstanding efforts to ensure that information about the predominant approved use of repaglinide – *i.e.*, in combination therapy with metformin – is provided to repaglinide consumers." Brief of Novo Nordisk. at 25, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. Sept. 10, 2009).

Novo is not a private FDA. Novo, by the change in the use code narrative is attempting to extend the life of an expired patent. The FDA is fully equipped to ensure that the label for Caraco's generic version of repaglinide is adequate to inform the public.

Caraco shall submit an order implementing this decision on notice to Novo.

Dated: September 24, 2009

s/Avern Cohn  
U.S. District Court Judge

#### CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, September 24, 2009, by electronic and/or ordinary mail.

s/Julie Owens  
Case Manager (313) 234-5160