

*Handwritten notes*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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NOVO NORDISK INC. and  
NOVO NORDISK A/S,

Plaintiffs,

v.

ACTAVIS PHARMA MANUFACTURING  
PVT. LTD. LLC and ACTAVIS INC.,

Defendants.  
----- X

No. 09 Civ. 8939 (PGG)

**STIPULATION AND ~~PROPOSED~~ ORDER OF DISMISSAL**

WHEREAS, on May 11, 2009, Actavis Pharma Manufacturing Pvt. Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 91-400 to the Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, and sale of certain proposed generic products;

WHEREAS, on September 10, 2009, Novo Nordisk Inc. received from Actavis Inc. a letter dated September 9, 2009, stating that Actavis Pharma Manufacturing Pvt. Ltd. had submitted ANDA No. 91-400 to FDA and that ANDA No. 91-400 contained a certification to FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") asserting that the claims of United States Patent No. 6,677,358 ("the '358 patent") are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of its proposed generic products;

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**WHEREAS**, within the 45-day period set forth in 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively “Novo Nordisk”) brought the above-captioned action against Defendants Actavis Pharma Manufacturing Pvt. Ltd. LLC and Actavis Inc. (collectively “Actavis”) for infringement of the '358 patent;

**WHEREAS**, after the filing of the above-captioned action, Actavis submitted to FDA an amendment to ANDA No. 91-400 that withdrew its Paragraph IV Certification as to the '358 patent;

**WHEREAS**, Actavis has represented to Novo Nordisk that Actavis has submitted to FDA an amendment to ANDA No. 91-400 and received from FDA a receipt of that submission;

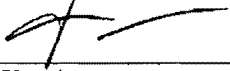
**WHEREAS**, ANDA No. 91-400, as amended, contains no Paragraph IV Certification relating to the '358 patent, and thus, subject matter jurisdiction no longer exists;

**IT IS HEREBY STIPULATED AND AGREED**, by and between the undersigned counsel for the parties, that:

1. The above-captioned action and all claims and counterclaims are hereby dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1).
2. Actavis will provide undersigned counsel for Novo Nordisk copies of all future submissions to FDA relating to the '358 patent, including any amendments to its certification to the '358 patent under 21 U.S.C. § 355(j)(2)(A)(vii) or 21 U.S.C. § 355(j)(2)(A)(viii), within five (5) business days of each such submission, except that Actavis will provide the notice required by 21 U.S.C. § 355(j)(2)(B)(ii)(II) at the time Actavis submits an amendment to its application with a certification to the '358 patent described at 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
3. The Court will retain jurisdiction to enforce the provisions of this Stipulation.

Dated: November 4, 2010

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Dated: November 4, 2010

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Attorneys for Defendants  
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**SO ORDERED:**

\_\_\_\_\_  
Honorable Paul G. Gardephe  
United States District Judge

Dated: November 4, 2010

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Attorneys for Plaintiffs  
Novo Nordisk Inc. and Novo Nordisk A/S

*The Clerk of Court is directed to close this case.*

**SO ORDERED:**

*Paul G. Gardephe*  
\_\_\_\_\_  
Honorable Paul G. Gardephe  
United States District Judge

*Nov. 5, 2010*

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Dated: November 4, 2010

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