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October 4, 2021

Via CM-ECF
The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31
Room 4124
Wilmington, DE 19801

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Re: *Novo Nordisk v. Sandoz*, 20-cv-747 (D. Del.)

Dear Chief Judge Connolly,

I write as counsel to Defendant Sandoz Inc., along with Steptoe & Johnson LLP, to respectfully request permission to file a motion for partial summary judgment only as to non-infringement of U.S. Patent No. 8,114,833 (the "'833 patent") in the above-referenced matter. Good cause for such a motion exists for the following reasons:

(1) Plaintiffs are not asserting infringement of the '833 patent and there is no genuine dispute of material fact;

(2) Resolving the '833 patent on summary judgment will conserve judicial resources, particularly at trial; and,

(3) Sandoz requires a judgment (as opposed to dismissal) to protect its ability to launch its generic product as early as possible in view of Hatch-Waxman law and related FDA procedures.

First, there is no infringement dispute in this litigation as to the asserted claims of the '833 patent, which relate to formulation. Therefore, the motion for summary judgment may be resolved with little expenditure of the Court's and the parties' resources. Plaintiffs did not provide an opening expert report as to infringement of the '833 patent. Their expert stated that "I understand that, based on the formulation of Sandoz's Product as currently described in Sandoz's ANDA, Novo Nordisk is not asserting infringement of the '833 patent, and I have not been asked to opine on infringement of the '833 patent." Thus, there is no genuine dispute as to infringement of the '833 patent and Sandoz is entitled to summary judgment.

Second, the filing of the requested motion is the most expedient, economical way to proceed, given that Plaintiffs have twice refused to enter into a consent judgment on the '833 patent despite their clear intention not to pursue a claim of infringement.[1] [redacted] Thus, only the '833 patent, which relates to formulation, and U.S. Patent No. 9,265,893 ("'893 Patent"), which relates to the injection device, remain in this litigation. Judgment of non-infringement as to the '833 formulation patent will reduce this case to the one remaining patent – the '893 device patent, significantly narrowing the issues and time of trial for the Court. For example, the formulation and device patents involve different inventors and different expert witnesses. Narrowing the case to the device patent will avoid future expert discovery on formulation and composition patent issues, significantly reduce the number of witnesses presented at trial, and generally narrow the issues to be decided .

Third, Sandoz is not the first ANDA filer against the drug product that is the subject of this litigation. Under FDA provisions of forfeiture of exclusivity granted to the first ANDA filer, Sandoz must obtain a judgment of non-infringement as to the '833 patent to avoid risks of the FDA refusing to provide final approval of the Sandoz drug product. For example, under Hatch-Waxman law, a judgment of no infringement is required to trigger the forfeiture of the first ANDA filer exclusivity period in the event that the first ANDA filer does not launch or is otherwise not eligible to launch for various reasons. Without a judgment, Hatch-Waxman law precludes Sandoz from triggering that exclusivity period and thus will prevent Sandoz from gaining final approval to enter the generic market for an undetermined time. *See, e.g., Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc.*, 527 F.3d 1278, 1287, 1297 (Fed. Cir. 2008). Plaintiffs have offered to dismiss their claims of infringement via a stipulated dismissal and a covenant not to sue but have refused to enter a consent judgment of no infringement by Sandoz. Thus, Sandoz now seeks Court intervention to obtain a judgment of no infringement. *See id.* at 1297 (subsequent ANDA filer can trigger exclusivity only with a judgment; a covenant not to sue is insufficient).

Sandoz has worked diligently for the past several months in an effort to resolve this issue without Court intervention. Plaintiffs have offered to dismiss their claims of infringement via a stipulated dismissal and a covenant not to sue, but have refused to enter into a consent judgment. However, as discussed above, a covenant not to sue is insufficient; a judgment is required. *See id*. at 1297 (subsequent ANDA filer can trigger

[1] Provided the Court enters summary judgment of non-infringement of the '833 patent, Sandoz will not

exclusivity only with a judgment; a covenant not to sue is insufficient). Thus, the Court's judgment of no infringement will efficiently reduce this case to the sole remaining '893 device patent.

Counsel for Sandoz are available at the convenience of the Court if Your Honor would find a status conference helpful.

Respectfully,

/s/ Dominick T. Gattuso

Dominick T. Gattuso (# 3630)

DTG/ram

cc: All Counsel of Record (via CM-ECF)