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The Honorable Colm F. Connolly
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

REDACTED - PUBLIC VERSION

Re: *Novo Nordisk Inc. et al. v. Sandoz Inc.*, C.A. No. 20-747-CFC

Dear Chief Judge Connolly:

We represent the Novo Nordisk Plaintiffs in this matter. We write in response to Defendant Sandoz's October 4 letter (D.I. 123) seeking leave to move for summary judgment of non-infringement of Novo Nordisk's '833 patent. Novo Nordisk opposes that request.

There is no pressing need to divert the Court and the parties from other matters with summary judgment proceedings on the '833 patent. A bench trial in this Hatch-Waxman case is scheduled for April 2022, and the 30-month stay extends to October 21, 2022. [redacted] There is therefore no urgency to Sandoz's request. The parties can address the '833 patent as part of the pretrial process.

Moreover, on October 4, Novo Nordisk provided Sandoz a covenant not-to-sue on the '833 patent, which eliminated any controversy between the parties concerning that patent. After granting the covenant, Novo Nordisk asked Sandoz to stipulate to the dismissal of the parties' claims and counterclaims concerning the '833 patent, the easiest and most efficient way to remove it from the case. Sandoz declined and instead asked the Court to initiate summary judgment proceedings. With no infringement issue, the only remaining issue regarding the '833 patent is whether the Court has subject matter jurisdiction to rule on it.

According to Sandoz, Novo Nordisk's covenant is insufficient because only a judgment on the '833 patent can "trigger" a third-party "first ANDA filer's" 180-day generic exclusivity, which might someday block Sandoz from "enter[ing] the generic market" for the product-in-question.

[redacted]

See D.I. 123 at 2. Sandoz contends that it needs to pursue this hypothetical "trigger" to cause the third party to forfeit its exclusivity and ensure that Sandoz can launch promptly in [redacted] Otherwise, Sandoz's theory goes, the first-filer's exclusivity might prevent FDA from finally approving Sandoz's ANDA product, delaying Sandoz's launch. *Id.* In other words, Sandoz is asking the Court to hear summary judgment on a patent that Novo Nordisk cannot assert against Sandoz, in hopes of targeting a third-party generic competitor's hypothetical statutory exclusivity [redacted]

Settled precedent establishes that the Court does not have subject matter jurisdiction over Sandoz's demand for a judgment on the '833 patent because there is no justiciable "case or controversy." Novo Nordisk's covenant eliminates any potential injury to Sandoz relating to infringement of the '833 patent. The only injury Sandoz complains of—potential delay in launching its generic product—is of Sandoz's own making. [redacted] That delay was Sandoz's choice, and therefore any launch delay injury is traceable to Sandoz itself, not to Novo Nordisk or the '833 patent. Under these circumstances, no justiciable controversy exists. *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361-62 (Fed. Cir. 2008).

Moreover, whether Sandoz will *ever* experience any launch delay is *highly* speculative. For that delay to occur, the first-filer would need to have generic exclusivity [redacted] Both of these conditions are remote possibilities at best. There is no evidence that the first-filer for the product-in-question has retained exclusivity, given its apparent inability to meet certain statutory prerequisites. [redacted], *and* FDA were to conclude that the first-filer had somehow maintained unexpired generic exclusivity, Sandoz would *also* need to convince the Federal Circuit that *yet another* Novo Nordisk patent asserted in this case (the '893 patent) is invalid or not infringed *before* Sandoz could trigger the first-filer's hypothetical exclusivity.

Thus, the injury Sandoz claims it urgently needs summary judgment to address—delayed launch of its generic product—is impossible until [redacted] at the very earliest due to Sandoz's own actions, and is highly speculative after that, as it is contingent on several other events that may never occur. That contingent, future alleged injury is far from the sort of real, immediate, and concrete controversy that this Court has jurisdiction to hear. *Janssen*, 540 F.3d at 1363. Novo Nordisk respectfully submits that the Court may defer a decision on the '833 patent until the pretrial phase of this case, rather than initiating summary judgment proceedings not contemplated in the Scheduling Order. If, however, the Court wishes to hear Sandoz's request for summary judgment, Novo Nordisk requests that the Court first consider the critical threshold issue of whether the Court retains subject matter jurisdiction over the '833 patent to decide the issue.[2] *See*

[2] Specifically, if the Court wishes to address the '833 patent at this time, Novo Nordisk would seek dismissal of the '833 patent for lack of subject matter jurisdiction. But rather than burden the

Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1123 (Fed. Cir. 2018) ("We must first address whether the district court properly exercised [subject matter] jurisdiction . . . .").

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

cc: All Counsel of Record (via CM/ECF and electronic mail)

Court with motion practice on dismissal, this too can be deferred until the pretrial phase for the same reasons that summary judgment can be deferred. Both forms of relief rise and fall on whether the Court retains subject matter jurisdiction over the '833 patent.