UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

Case No. IPR2018-01676
U.S. Patent No. 8,603,044

PATENT OWNER'S SUR-REPLY IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit #	Description
2001	Press Release, "Mylan Enhances Partnership with Biocon through Strategic Collaboration for Insulin Products", Feb. 13, 2013 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=122834
2002	Press Release, "Mylan Commences Phase III Clinical Trials for its Generic Version of Advair Diskus® and Insulin Analog to Lantus®", Sept. 16, 2014 (PR Newswire), available at http://newsroom.mylan.com/press-releases?item=123251
2003	Press Release, "Mylan and Biocon Present Clinical Data on Insulin Glargine at the American Diabetes Association's 77th Scientific Sessions", June 10, 2017 (PR Newswire), available at http://newsroom.mylan.com/2017-06-10-Mylan-and-Biocon-Present-Clinical-Data-on-Insulin-Glargine-at-the-American-Diabetes-Associations-77th-Scientific-Sessions
2004	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH v. Eli Lilly and Company*, C.A. No. 1-14-cv-00113-RGA (D. Del), Dkt. No. 1
2005	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie v. Merck Sharp & Dohme Corp.*, C.A. No. 1-16-cv-00812-RGA (D. Del), Dkt. No. 1
2006	Stipulation and Proposed Order, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.,* Civil Action No. 17-9105-SRC-SLW (D.N.J. Feb 5, 2018), Dkt. No. 45
2007	Complaint for Patent Infringement, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J. Oct. 24, 2017), Dkt. No. 1
2008	Excerpts from Defendants' Invalidity Contentions, dated Jan. 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2009	Excerpts from Mylan GMBH's Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2010	Excerpts from Mylan GMBH's Exhibit C to Amended Invalidity Contentions, dated April 25, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)

Exhibit #	Description
2011	Aug. 13, 2018 Service of Sanofi's Responses to Mylan's Amended Contentions, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2012	MP4 file of Sanofi's Patented Pen animation
2013	Excerpt from Defendants' opening claim construction brief, dated October 12, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2014	Memorandum Opinion, *Sanofi-Aventis U.S. LLC v. Merck Sharp & Corp.*, Case No. 16-cv-812-RGA (D. Del.), Dkt. No. 192
2015	International Patent WO 99/3855
2016	Excerpt from Joint claim construction statement, Ex. A, dated October 8, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2017	Animation depicting Møller's first embodiment
2018	Animation depicting Møller's second embodiment
2019	Defendants' Opposition to Plaintiffs' Motion to Stay dated Nov. 22, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 44
2020	Joint Proposed Discovery Plan dated Dec. 14, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.)
2021	Letter from A. Calmann to Judge Waldor dated Apr. 24, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17-cv-09105-SRC-CLW (D.N.J.), Dkt. No. 90
2022	Motion to Expedite Defendants' Motion Requesting an Expedited Scheduling Conference dated Nov. 22, 2017 , *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 46
2023	Initial Planning Meeting Report and Discovery Proposals dated Dec. 22, 2017, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 61
2024	Transcript of Motion / Scheduling Conference dated Jan. 3, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 1:17-cv-00181-IMK (N.D. W. Va.), Dkt. No. 64

Exhibit #	Description
2025	Excerpts from Transcript, Conference Call dated Aug. 2, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, Case No. 2:17-cv-09105-SRC-CLW (D.N.J.) (confidentiality designation removed)
2026	Report of the Local Patent Rules Committee, Explanatory Notes for 2016 Amendments
2027	Transcript, Conference Call for Case IPR2018-01675, -01676, -01678, -01680 (P.T.A.B. Feb. 5, 2019)

Patent Owner respectfully submits this sur-reply on the issue of whether the Board should exercise discretion under 35 U.S.C. § 314(a) and deny institution. As detailed below and in Patent Owner's Preliminary Response, the specific facts of this case warrant the exercise of that discretion.

I. THE DISTRICT COURT CASE WILL CONCLUDE BY MARCH 2020

Petitioner's assertion that the "district-court timeline is speculative" can be rejected out of hand. From the outset of the District Court case in October 2017, Petitioner has demanded an expeditious trial of all issues of validity and infringement well in advance of March 2020, when the 30-month stay in the District Court case expires and when a so-called "transition date" occurs. This "transition date" is unique to the insulin space and is the date in March 2020 when insulins will be governed by the biologics statute (BPCIA) and no longer by the Hatch-Waxman Act. Indeed, Petitioner has repeatedly asserted that "the transition date makes the timeline in this case ***more urgent than in a typical Hatch-Waxman case***." Ex. 2019 at 1 (emphasis added); *see also* Ex. 2020 at 19 ("[i]n view of the unique issues in this case relating to regulatory approval and the BPCIA, the timeline in this case is more urgent than in a typical Hatch-Waxman case."); Ex. 2021 at 1 ("[T]his case presents a unique timing issue that requires diligent adherence to litigation timelines sufficient to allow the Court plenty of time to issue a decision prior to the expiration of the FDA's 30-month stay.").

Thus, at the outset of the case, Petitioner sought to have the case resolved in West Virginia rather than New Jersey, asserting that "[i]t is vital to Defendants' interests that this case proceed as quickly as possible." Ex. 2022 at 1; Ex. 2023 at 7-8 ("[T]here is a heightened need to efficiently litigate this case to allow the Court sufficient time to issue a decision prior to the expiration of the stay in this matter."); *id*. at 12 ("[T]he timeline in this case is more urgent than in a typical Hatch-Waxman case").

In deciding to stay the West Virginia action and allow the case to proceed in New Jersey, the District Court Judge in West Virginia specifically recognized that the District of New Jersey and Judge Chesler were known to resolve Hatch-Waxman cases expeditiously and in advance of stay expiration:

> I really would be out of my league to suggest that the judges—the district judges in New Jersey can't efficiently handle a pharmaceutical patent case like this and in my years on the Bench, I have bowed to their knowledge and experience in patent work generally. . . . [T]he court has a long standing history of experience trying these cases. ***I have no reason to believe that the District Judge in New Jersey, Judge Chesler, will not make a decision on this as quickly as is reasonable***.

Ex. 2024 at 31:15-32:3 (emphasis added). Petitioner thus agreed to proceed in New Jersey on the condition that the parties jointly propose a trial date in October 2019. Ex. 2006, ¶ 8.

The Magistrate Judge in the New Jersey Action has recognized the importance of resolving Petitioner's validity challenges well before the 30-month stay ends. *See, e.g.*, Ex. 2025 at 6:17-24 (encouraging parties to resolve their disputes to maintain the October trial date). The District Court Judge—Judge Chesler—in the New Jersey Action, has presided over 50 Hatch-Waxman cases and is the Chair of the Local Patent Rules Committee for the District of New Jersey. Ex. 2026 at 2. In 2016, that committee amended New Jersey Local Patent Rule 2.1 to require parties in Hatch-Waxman cases to address the 30-month stay in their case planning conference and joint discovery plan, explaining that the amendment was made "in order to expedite matters." *Id*. at 1. Thus, even if the trial date shifts to later in 2019, there is simply no basis to suggest that the District Court will not resolve all of the issues in this case, including validity, before the March 2020 transition date and expiration of the stay.

II. EXERCISING DISCRETION IN THIS CASE WILL NOT BROADLY IMPACT HATCH-WAXMAN LITIGANTS

Petitioner claims that Patent Owner's arguments would create a "sector-specific nullification of § 315(b) for ANDA suits" by purportedly preventing all Hatch-Waxman defendants from using the full one-year statutory period to file an IPR. Reply at 6. This argument is refuted by Petitioner's own repeated assertions in District Court that "the unique issues in this case relating to regulatory approval and the BPCIA, the timeline in this case is more urgent than in a typical Hatch-Waxman

case." Ex. 2020 at 19. These "unique issues" are the transition date and the commitment by the parties and the court to resolve the case in advance of the March 2020 stay expiration and transition date. Other facts specific to this case make it appropriate for denial under § 314(a). Petitioner asserts the same invalidity grounds in the Petition and the District Court, which results in unnecessary duplicative litigation in two forums. *See NHK Spring*, IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12, 2018). These case-specific circumstances arise from Petitioner's selection of invalidity grounds and the timing of the petitions relative to the District Court case. Moreover, these factors are not unique to Hatch-Waxman cases, as evidenced by *NHK Spring*, which was not such a case. Thus, it is Petitioner that improperly seeks "sector-specific" treatment for Hatch-Waxman cases by asking the Board to exempt such cases from the Board's discretion under § 314 and *NHK Spring*.

III. PETITIONER IS ASSERTING DUPLICATIVE GROUNDS IN THIS IPR AND THE DISTRICT COURT CASE

The invalidity grounds in the Petition are also asserted in Petitioner's District Court invalidity contentions. *See* Paper 10 at 11. Nonetheless, Petitioner apparently contends that because its District Court invalidity positions have not "been developed" to the same degree as its IPR arguments, it is not clear that the District Court ultimately will decide the same issues. Ex. 2027 at 13:10-14:3. Not once, however, has Petitioner affirmed to the Board that it will *not* continue to assert the same grounds against the challenged claims in the District Court case. Nor has

Petitioner affirmed that it will ultimately present a *different* theory of obviousness based on the same prior art references to the District Court, or even suggested how it *could* present different, non-overlapping theories of obviousness to the Board and the District Court based on the same prior art. Thus, even accepting *arguendo* Petitioner's claim that the invalidity arguments in the District Court case are not fully developed, Petitioner has provided no assurances that it will not invite the District Court to adjudicate the same invalidity grounds after receiving an institution decision in this proceeding.[1] It therefore remains that the invalidity grounds asserted in the Petition are still asserted in the District Court case, and instituting a trial would result in duplicative litigation over the same grounds, with the District Court case resolving before the Board's final written decision is due.

* * *

For these reasons and those set forth in Patent Owner's Preliminary Response, Patent Owner respectfully requests that the Board exercise its discretion under § 314 to deny institution.

[1] Given that Petitioner can still tailor its District Court invalidity grounds to address weaknesses identified in the Patent Owner's Preliminary Response or the institution decision, the potential tactical advantage also merits denial.

Dated: February 12, 2019	Respectfully submitted, */Elizabeth Stotland Weiswasser/* Elizabeth Stotland Weiswasser (Reg. No. 55,721) Anish R. Desai (Reg. No. 73,760) Sudip K. Kundu (Reg. No. 74,193) Kathryn M. Kantha (Reg. No. 70,371) Weil, Gotshal & Manges LLP 767 Fifth Avenue New York, NY 10153 Phone: 212-310-8000 elizabeth.weiswasser@weil.com anish.desai@weil.com sudip.kundu@weil.com kathryn.kantha@weil.com William S. Ansley (Reg. No. 67,828) Matthew D. Sieger (Reg. No. 76,051) Weil, Gotshal & Manges LLP 2001 M Street NW, Ste. 600 Washington, D.C. 20036 Phone: 202-682-7000 sutton.ansley@weil.com matthew.sieger@weil.com Adrian C. Percer (Reg. No. 46,986) Brian C. Chang (Reg. No. 74,301) Weil, Gotshal & Manges LLP 201 Redwood Shores Parkway Redwood Shores, CA 94065 Phone: 650-802-300 adrian.percer@weil.com brian.chang@weil.com Sanofi.IPR.Service@weil.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 12, 2019, the foregoing **PATENT OWNER'S SUR-REPLY IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE** and **EXHIBITS 2019 – 2027** were served via electronic mail upon the following:

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