IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, | ) | |
| *Plaintiffs*, | ) | C.A. No. 14-113-RGA-MPT |
| v. | ) | [redacted] |
| ELI LILLY AND COMPANY, | ) | |
| *Defendant*. | ) | |

**PRE-TRIAL ORDER PURSUANT TO L.R. 16.3(D)(1)**

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Dated: September 15, 2015

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## NATURE OF THE ACTION [L.R. 16.3(C)(1)]

### Parties and Patents

This is an action alleging patent infringement arising under the patent laws of the United States, Title 35, United States Code based on Defendant's filing of a New Drug Application ("NDA") with the Food and Drug Administration ("FDA").

Plaintiffs are Sanofi-Aventis U.S. LLC ("Sanofi U.S.") and Sanofi-Aventis Deutschland GmbH ("Sanofi GmbH") (collectively "Sanofi" or "Plaintiffs"). Sanofi is represented by Steven J. Balick, Andrew Mayo, and Tiffany Geyer Lydon of Ashby & Geddes. Sanofi is also represented by Mark A. Perry, Frederick Brown, Tracey Davies, Joseph Evall, Ernest Hsin, and R. Scott Roe of Gibson, Dunn & Crutcher LLP.

Sanofi U.S. is the holder of approved NDA No. 21-081 for insulin glargine [rDNA origin] for injection to treat diabetes, which is prescribed and sold in the United States under the trademarks Lantus® and Lantus® SoloSTAR®.

Sanofi asserts five patents asserted in this litigation (collectively, "Patents-in-Suit"). United States Patents Nos. 8,556,864 ("the '864 Patent"), 8,603,044 ("the '044 Patent"), and 8,679,069 ("the '069 Patent") are referred to herein by Sanofi as the "Asserted Device Patents." U.S. Patent Nos. 7,476,652 ("the '652 Patent") and 7,713,930 ("the '930 Patent") are referred to herein by Sanofi as the "Asserted Formulation Patents." Sanofi U.S. has listed the Patents-in-Suit in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

On or about February 10, 2009, Sanofi submitted the '652 patent for listing in the Orange Book. On or about May 13, 2010, Sanofi submitted the '930 patent for listing in the Orange Book. On or about October 25, 2013, Sanofi submitted the '864 patent for listing in the Orange Book. On or about January 6, 2014, Sanofi submitted the '044 patent for listing in the Orange

Book. On or about March 25, 2014, Sanofi submitted the '069 patent for listing in the Orange Book. The Orange Book provides the following expiration dates for the Patents-in-Suit:

a) '864 Patent: March 3, 2024

b) '044 Patent: March 2, 2024

c) '069 Patent: April 12, 2025

d) '652 Patent: July 23, 2023

e) '930 Patent: June 13, 2023[1]

By assignment, Sanofi GmbH owns all right, title, and interest in and to the Patents-in-Suit. Sanofi U.S. is an exclusive licensee of the Patents-in-Suit with exclusive rights, including the rights to sell and offer to sell in the United States the technologies, products, or services claimed by the Patents-in-Suit, further including the right to sue and recover for the infringement of the Patents-in-Suit.

Defendant is Eli Lilly and Company ("Eli Lilly" or "Defendant"). Eli Lilly is represented by Joseph J. Farnan, Jr., Brian E. Farnan and Michael J. Farnan of Farnan LLP. Eli Lilly is also represented by Bruce M. Wexler, Gerald J. Flattmann, David M. Conca, Steven L. Park, and Nicholas A. Tymoczko of Paul Hastings LLP.

**Commencement of Civil Action No. 1:14-cv-00113-RGA-MPT**

On or about [redacted], Eli Lilly submitted NDA No. 205-692 to the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), seeking the approval to manufacture commercially and sell its proposed product—

[redacted]

[1] The '652 and '930 Patents are subject to an additional six months of pediatric exclusivity.

[redacted]

On or about December 18, 2013, Eli Lilly sent Sanofi a "Notice of Paragraph IV Certifications" pursuant to § 505(b)(2)(A)(iv) and (b)(3) of the FFDCA, which discloses that its NDA No. 205-692 contained Paragraph IV certifications for the patents listed in the Orange Book as of the time of the Notice, including, *inter alia*, the '864, '652, and '930 Patents. Sanofi U.S. received Eli Lilly's Notice of Paragraph IV Certifications on December 19, 2013, and Sanofi GmbH received Eli Lilly's Notice of Paragraph IV Certifications on December 20, 2013.

On or about January 23, 2014, Eli Lilly sent Sanofi an amendment to its "Notice of Paragraph IV Certifications" pursuant to § 505(b)(2)(A)(iv) and (b)(3) of the FFDCA, disclosing that Eli Lilly amended its Paragraph IV certifications contained in NDA No. 205-692 to include the '044 Patent. Sanofi U.S. received Eli Lilly's amendment to its Notice of Paragraph IV Certifications on January 24, 2014, and Sanofi GmbH received Eli Lilly's amendment to its Notice of Paragraph IV Certifications on or about January 27, 2014.

Sanofi commenced case number 1:14-cv-00113-RGA-MPT (the "Action") within 45 days after receiving Eli Lilly's Notice of Paragraph IV Certifications by filing a Complaint on January 30, 2014. Sanofi asserted that Eli Lilly was infringing under 35 U.S.C. § 271(e)(2)(A) by its submission of NDA No. 205-692 prior to the expiration of the '864, '044, '652, and '930 Patents. *See* No. 14-113-RGA-MPT, D.I. 1. Sanofi also asserted that if Eli Lilly's NDA No. 205-692 were to be approved, then Eli Lilly's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Product would infringe the '864, '044, '652, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c), literally and/or under the Doctrine of Equivalents. *Id.* On or about February 19, 2014, Lilly filed its Answer

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