IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PRETRIAL ORDER EXHIBIT 1:
SANOFI AND ELI LILLY'S JOINT STATEMENT OF ADMITTED FACTS

{01044336;v1 }

I. TABLE OF CONTENTS

I. THE PARTIES

1. Plaintiffs and Counterclaim Defendants in this lawsuit are Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH. Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH, as well as their predecessors-in-interest, are referred to herein as "Sanofi."

2. Sanofi U.S. is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Sanofi GmbH is a German corporation, with its principal place of business located at Industriepark Hoechst, Bldg. K607, Frankfurt Am Main, Germany D-65926.

4. Defendant and Counterclaim Plaintiff Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly conducts business operations in the United States, including in the State of Delaware.

II. THE PATENTS-IN-SUIT

5. Sanofi asserts that Lilly infringes certain claims of five United States patents in this litigation (collectively, "Patents-in-Suit"), which are U.S. Patent No. 7,476,652 ("the '652 Patent"), U.S. Patent No. 7,713,930 ("the '930 Patent"), U.S. Patent No. 8,556,864 ("the '864 Patent"), , U.S. Patent No.8,603,044 ("the '044 Patent"), and , U.S. Patent No. 8,679,069 ("the '069 Patent") The Asserted Claims of the Patents-in-Suit are as follows: Claims 7, 10, 20 and 24 of the '652 Patent; claims 7 and 17 of the '930 Patent; claim 2 of the '864 Patent; claims 1, 5, 7 and 10 of the '044 Patent; and claim 1 of the '069 Patent.

6. Lilly asserts, among other things, that the Asserted Claims of the Patents-in-Suit are not infringed and invalid, and further that the Asserted Devices Patents are unenforceable due to prosecution laches.

A. <u>The ’652 and ’930 Patents</u>

7. Each of the ’652 and ’930 Patents names Anette Brunner-Schwarz and Norbert Lill as inventors.

8. On January 13, 2009, U.S. Patent Application No. 11/089,777 issued as the ’652 Patent.

9. On May 11, 2010, U.S. Patent Application No. 12/328,208 issued as the ’930 Patent.

10. Both the ’652 Patent and the ’930 Patent claim ultimate priority to U.S. Provisional application 60/409,338 (filed June 13, 2003) and German Patent Application No. 10/227,232 (filed June 18, 2002).

B. <u>The’864, ’044, and ’069 Patents</u>

11. Each of the ’864, ’044, and ’069 Patents names Robert Veasey, Robert Perkins, and David Plumptre as inventors.

a. The ’044 and ’069 Patents

12. On March 25, 2014, U.S. Patent Application No. 12/944,544 issued as the ’069 Patent.

13. The ’069 Patent claims ultimate priority to GB Patent Application No. 0304822.0, filed March 3, 2003.

14. On December 10, 2013, U.S Patent Application No. 13/909,649 issued as the ’044 Patent.

15. The ’044 Patent claims ultimate priority to GB Patent Application No. 0304822.0, filed March 3, 2003.

b. The ’864 Patent

16. On October 15, 2013, U.S. Patent Application No. 13/075,212 issued as the ’864 Patent.

17. The ’864 Patent claims ultimate priority to GB Patent Application No. 0304822.0, filed March 3, 2003.

III. New Drug Applications (“NDAs”)

A. Sanofi’s NDA

18. Sanofi holds the approved new drug application (“NDA”) No. 21-081 for Lantus® (insulin glargine [rDNA origin] for injection) products, including Lantus® supplied in 10 mL vials and in 3 mL cartridges for use with Lantus®OptiClik® and Lantus® SoloSTAR®.

19. Sanofi submitted its original NDA 21-081 to the United States Food and Drug Administration (“FDA”) on April 9, 1999.

20. The Lantus® label approved by the FDA on April 20, 2000 states: “LANTUS is indicated for once-daily subcutaneous administration at bedtime in the treatment of adult and pediatric patients with type l diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.”

21. The active ingredient in Lantus® is insulin glargine.

22. Insulin glargine’s long-acting effect for 24 hours with no pronounced peak as a basal insulin has been one of the primary clinical benefits for patients treated with Lantus®.

23. As approved by the FDA on April 20, 2000 and originally marketed in the United States in May 2001, each milliliter of the Lantus® formulation consisted of: 100 IU (3.6378 mg)

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