UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

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

PRE-TRIAL ORDER EXHIBIT 3
ELI LILLY'S STATEMENT OF CONTESTED FACTS

TABLE OF CONTENTS

Page

[redacted]

TABLE OF CONTENTS
(continued)

Page

Pursuant to Local Rule 16.3(c)(4), Defendant Eli Lilly and Company ("Lilly") submits the following statement of the issues of fact that remain to be litigated. This statement is not exhaustive, and is based on Lilly's current understanding of the arguments Plaintiffs Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH (collectively, "Sanofi") are likely to make at trial, based on the pleadings, discovery, and expert reports to date. To the extent Sanofi introduces different or additional facts or alleged facts in support of any claim or defense it asserts in this case, Lilly reserves the right to contest such facts or alleged facts, and to present any and all rebuttal evidence in response.

I. THE ASSERTED FORMULATION PATENTS

A. Specifications of the Asserted Formulation Patents

1. It is undisputed that the specifications of the '652 and '930 patents describe the invention of the patents as being directed to "a pharmaceutical formulation".

2. The specifications of the '652 and '930 patents describe the invention of the patents as being directed to "the addition" of non-ionic surfactants to "increase the stability" of acidic insulin preparations.

3. The specifications of the '652 and '930 patents describe the concentration of surfactant present in the pharmaceutical composition to be 5-200 µg/mL.

4. The specifications of the '652 and '930 patents do not describe [redacted] in the context of stabilizing protein or insulin formulations.

5. The specifications of the '652 and '930 patents do not describe [redacted] in the context of stabilizing protein or insulin formulations.

6. The specifications of the '652 and '930 patents do not describe [redacted] in the context of stabilizing protein or insulin formulations.

7. The specifications of the ’652 and ’930 patents do not describe the use of surfactant concentrations below 5 µg/mL as stabilizing protein or insulin formulations.

8. The specifications of the ’652 and ’930 patents do not describe surfactant concentrations below 1 µg/mL.

9. The specifications of the ’652 and ’930 patents do not describe experimental results with any non-ionic surfactant besides polysorbate 20 and polysorbate 80.

B. Asserted Claims of the Formulation Patents

10. It is undisputed that the asserted claims of the ’652 patent are all directed to a “pharmaceutical formulation” comprising insulin glargine and either: (1) “at least one chemical entity chosen from polysorbate 20 and polysorbate 80” or (2) “at least one chemical entity chosen from polysorbate and poloxamers,” amongst other ingredients.

11. It is undisputed that the asserted claims of the ’930 patent are all directed to a “pharmaceutical formulation” comprising insulin glargine and “at least one chemical entity chosen from esters and ethers of polyhydric alcohols”, amongst other ingredients.

12. The asserted claims of the ’652 and ’930 patents all describe the addition of certain non-ionic surfactants to a pharmaceutical formulation.

13. The specifications of the ’652 and ’930 patents do not support claims asserted to cover trace levels of polysorbates (including polysorbate 20 or 80), poloxamers, or esters or ethers of polyhydric alcohols alleged to be [redacted]

14. The specifications of the ’652 and ’930 patents do not contain language to support claims to trace levels of polysorbates (including polysorbate 20 or 80), poloxamers, or esters or ethers of polyhydric alcohols that do not provide a stabilizing effect.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.