

**UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

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

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

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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  $\mu\text{g/mL}$ .

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

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

6. The specifications of the ’652 and ’930 patents do not describe [REDACTED] [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  $\mu\text{g}/\text{mL}$  as stabilizing protein or insulin formulations.

8. The specifications of the '652 and '930 patents do not describe surfactant concentrations below 1  $\mu\text{g}/\text{mL}$ .

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.

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