IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, et al., Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	Civil Action No. 14-113-RGA-MPT

MEMORANDUM OPINION

Steven J. Balick, Esq., Tiffany Geyer Lydon, Esq., Andrew C. Mayo, Esq., ASHBY & GEDDES, Wilmington, DE; Mark A. Perry, Esq., GIBSON, DUNN & CRUTCHER LLP, Washington, D.C.; Joseph Evall, Esq. (argued), R. Scott Roe, Esq. (argued), GIBSON, DUNN & CRUTCHER LLP, New York, NY; Tracey Davies, Esq. (argued), GIBSON, DUNN & CRUTCHER LLP, Dallas, TX; Frederick Brown, Esq., GIBSON, DUNN & CRUTCHER LLP, San Francisco, CA; Y. Ernest Hsin, Esq. (argued), GIBSON, DUNN & CRUTCHER LLP, Palo Alto, CA.

Attorneys for Plaintiffs Sanofi-Aventis U.S. LLC, et al.

Brian E. Farnan, Esq., Michael J. Farnan, Esq., FARNAN LLP, Wilmington, DE; Bruce M. Wexler, Esq. (argued), Joseph M. O'Malley, Jr., Esq., David M. Conca, Esq. (argued), Young Park, Esq., Nicholas A. Tymoczko, Esq., PAUL HASTINGS LLP, New York, NY.

Attorneys for Defendant Eli Lilly and Company.

April 27, 2015

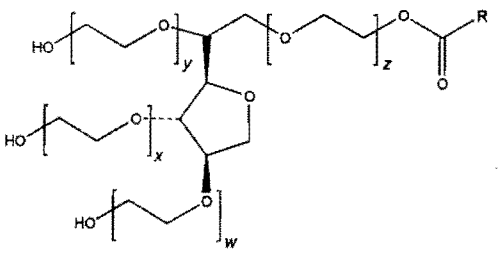
ANDREWS, U.S. DISTRICT JUDGE:

This opinion supplements the *Markman* opinion issued by this Court on January 20, 2015. (D.I. 192). Knowledge of the prior opinion is presumed. The parties submitted declarations by expert witnesses on January 16, 2015 (D.I. 189 & 191), and appeared for an evidentiary hearing on January 23, 2015. (D.I. 198). The following terms are in dispute:

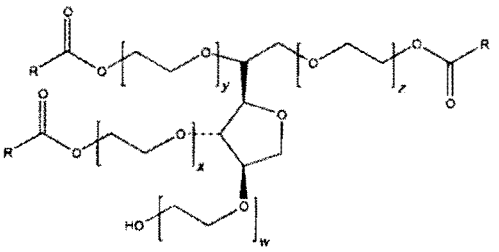
1. "polysorbate" ('652 patent: claims 7, 24)

a. *Plaintiffs' proposed construction*: Plain and ordinary meaning. If the Court finds construction is necessary: Partial fatty acid esters of sorbitol and its anhydrides copolymerized with approximately 20, 5, or 4 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

b. *Defendant's proposed construction*: Compounds with the following structure:



or



where w+x+y+z is approximately 4, 5, or 20, and where R is a fatty acid.

c. *Court's construction*: Partial fatty acid esters of sorbitol and its anhydrides copolymerized with approximately 20, 5, or 4 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

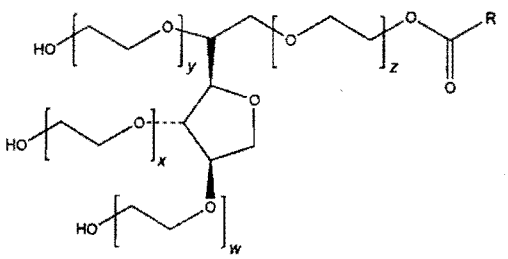
The '652 patent has an effective filing date of June 18, 2002, which is the relevant time period for purposes of claim construction. (D.I. 1-3 at 2). Lilly's expert, Dr. Jerry L. Atwood, makes clear that "[p]resented with terms that are ingredients added to a 'pharmaceutical

formulation,' a POSA would consult standard pharmaceutical references to ascertain the meaning of those terms." (D.I. 191 at 9). For this reason, Lilly bases its proposed construction on the "Structural Formula" of "polysorbates" provided in the *Handbook of Pharmaceutical Excipients* (the "*Handbook*"). (D.I. 138-2 at 39). Lilly, however, relies upon the fourth edition of the *Handbook*, which was published in 2003, after the '652 patent's priority date. (*Id.* at 37). Sanofi's expert, Dr. Ralph Tarantino, bases Sanofi's proposed construction on the definition of "polysorbates" provided in the "Applications in Pharmaceutical Formulation or Technology" section in the third edition of the *Handbook*, which was published in 2000. (D.I. 189 at 10). The 2000 *Handbook* defines "polysorbates" as "a series of partial fatty acid esters of sorbitol and its anhydrides copolymerized with approximately 20, 5, or 4 moles of ethylene oxide for each mole of sorbitol and its anhydrides." *Handbook of Pharmaceutical Excipients* 417 (Arthur H. Kibbe ed., 3d ed. 2000). The parties' experts agree that a person of ordinary skill in the art would rely upon the *Handbook*'s definition of "polysorbate," and thus, I adopt the definition provided in the 2000 edition of the *Handbook*.

2. "polysorbate 20" ('652 patent: claims 1, 2, 8, 23)

a. *Plaintiffs' proposed construction*: Plain and ordinary meaning. If the Court finds construction is necessary: A polysorbate that is a mixture of fatty acid (characteristically lauric acid) esters of sorbitol and its anhydrides copolymerized with 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

b. *Defendant's proposed construction*: Compounds with the following structure:



where w+x+y+z is approximately 20, and R is fatty acids present in the following amounts:

Carbon-Chain Length	**Number of Double Bonds**	**Percentage**
6	0	≤ 1.0
8	0	≤ 10.0
10	0	≤ 10.0
12	0	40.0–60.0
14	0	14.0–25.00
16	0	7.0–15.0
18	0	≤ 7.0
18	1	≤ 11.0
18	2	≤ 3.0

c. *Court's construction*: A laurate ester of sorbitol and its anhydrides copolymerized with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

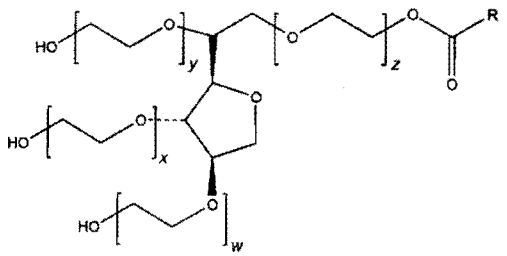
Dr. Atwood recognizes that *The United States Pharmacopeia and The National Formulary* (*USP-NF*) is a "standard pharmaceutical reference[]" and is "widely cited and used in the pharmaceutical industry." (D.I. 191 at 9). Lilly relies upon the 2014 *USP-NF* for its proposed construction of "polysorbate 20," which provides the assay table depicted above. (*Id.* at 9–10 ¶ 34; D.I. 138-2 at 44). Sanofi, on the other hand, cites the 2002 *USP-NF*, which became official on January 1, 2002, as the basis for its proposed construction. (D.I. 189 at 12 ¶ 38 n.11; D.I. 189-5). The 2002 *USP-NF* defines "polysorbate 20" as "a laurate ester of sorbitol and its anhydrides copolymerized with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides." (D.I. 189-5 at 6). A person of ordinary skill in the art as of

June 18, 2002 would have used the definition provided in the 2002 *USP-NF* to understand the term "polysorbate 20." Therefore, I adopt the definition provided in the 2002 *USP-NF*.

3. "polysorbate 80" ('652 patent: claims 1, 2, 8, 23)

a. *Plaintiffs' proposed construction*: Plain and ordinary meaning. If the Court finds construction is necessary: A polysorbate that is a mixture of fatty acid (characteristically oleic acid) esters of sorbitol and its anhydrides copolymerized with 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

b. *Defendant's proposed construction*: Compounds with the following structure:



where w+x+y+z is approximately 20, and R is fatty acids present in the following amounts:

Fatty Acid	**Percentage**
Myristic acid	≤ 5.0
Palmitic acid	≤ 16.0
Palmitoleic acid	≤ 8.0
Stearic acid	≤ 6.0
Oleic acid	≥ 58.0
Linoleic acid	≤ 18.0
Linolenic acid	≤ 4.0

c. *Court's construction*: An oleate ester of sorbitol and its anhydrides copolymerized with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

Lilly's proposed construction is based on the definition of "polysorbate 80" from the 2014 *USP-NF*. (D.I. 191 at 11–12 ¶ 38; D.I. 138-2 at 46). The 2002 *USP-NF* defines

"polysorbate 80" as "an oleate ester of sorbitol and its anhydrides copolymerized with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides." (D.I. 189-5 at 6). A person of ordinary skill in the art as of June 18, 2002 would have used the definition provided in the 2002 *USP-NF* to understand the term "polysorbate 80." Therefore, I adopt the 2002 *USP-NF* definition.