

Paper No. \_\_\_\_  
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN LABORATORIES LIMITED  
Petitioner,

v.

AVENTIS PHARMA S.A.  
Patent Owner.

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Case IPR2016-00712  
Patent No. 8,927,592

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**PETITIONER'S REPLY IN SUPPORT OF  
MOTION TO EXCLUDE (PAPER 64)**

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Case IPR2016-00712

Patent 8,927,592

**I. Aventis's Market Share Evidence Should Be Excluded**

Sections II.A-B of Paper 64 (“Mot”) justify the exclusion of Exhibits 2170, 2171 & 2179 and Mr. Tate’s opinions based thereon. Aventis assumes that Petitioner must depose Mr. Lathers to point out the deficiencies in the Lathers declaration. Paper 72 (“Opp.”) at 2. However, the deficiencies are clear from the face of the declaration, which does not provide foundation for admission of the hearsay statements in the exhibits. Mot. at 3; EX2231, ¶¶1-7. These include, at least, the [REDACTED] [REDACTED] the raw data AlphaImpactRx collected and compiled based thereon, and the selected summary of data Sanofi elected to use. Mot. at 2, 4-6. Simply adding a document to one’s business record does not transform all hearsay statements within it into admissible evidence. *See, e.g., Wilson v. Zapata Off-Shore Co.*, 939 F.2d 260, 271 (10th Cir.1991); F.R.E. 805.

Aventis argues there is “no reason to think Sanofi would act against its own interest to regularly commission unreliable, biased, or skewed data.” Opp. at 9. But the record establishes that Sanofi departed from its regular practice of relying on IMS Health data and instead commissioned a subset of AlphaImpactRx data after litigation commenced. Mot. at 3, 6-7, 10; EX1042, 43:5-24; *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00043, Paper 97 at 4-7 (excluding exhibits created “to address issues in the case.”). Moreover, Aventis has failed to establish that the

reports it commissioned are regularly relied upon by experts in Mr. Tate's field.

Mot. at 6 (citing EX1042, 99:9-18 (Tate could not recall hearing of AlphaImpactRx)). Furthermore, Aventis fails to provide the "equivalent circumstantial guarantee of trustworthiness" required to support admission under the residual hearsay exception because neither Mr. Lathers nor Mr. Tate could explain how the [REDACTED] [REDACTED] were used to create the values Mr. Tate relied upon). Mot. at 2-5, 12; Opp. at 6; EX2231, ¶¶1-7; EX1042, 98:7-14, 103:12-17, 107:20-25, 135:9-17, 147:9-150:7; *Conoco Inc. v. Dept. of Energy*, 99 F.3d 387, 392 (Fed. Cir. 1996) (residual exception only "for exceptional cases").

Aventis mistakenly asserts that "Exhibit 2179 is the underlying data" and that these exhibits "are relied on directly for expert opinions, not to prove the contents of another writing." Opp. at 3-4. But Mr. Tate relies on these exhibits to prove the content of the [REDACTED] to approximate the percentage of post-docetaxel patients receiving cabazitaxel treatment. Mot. at 9-10; EX2149, ¶¶29-30, 35, Schedules 4-4.7. Mr. Tate also confirmed that Exhibit 2179 is merely a summary of underlying data and that he had not seen or requested the "granular data" [REDACTED] Mot. at 5; EX1042, 134:5-15. Thus, *JPMorgan* is inapposite because the spreadsheet at issue there provided the raw data and was not created "in anticipation of litigation." 2013 WL 2473013 at \*1-2, \*5-7.

The *Guzman* case on which also Aventis relies (Opp. at 4) is also inapposite because the expert testimony at issue was not attempting to prove the contents of the hospital policies (the parties had stipulated to the authenticity of the original documents, but merely addressed the impact of those policies). 637 F. Supp. 2d at 520. In contrast, Aventis's exhibits are offered to summarize [REDACTED] [REDACTED] and therefore must comply with F.R.E 1006. Rule 42.65 independently requires Aventis to disclose the underlying data.

Mr. Tate confirmed that it is impossible to establish that the summarized results in Sanofi's exhibits are representative of the population without the raw data. Mot. at 7-8; EX1042, 83:15-18, 104:8-105:2, 106:3-10, 107:9-19, 119:9-120:4. The Well Fargo reports indicate that Aventis's exhibits include only some of the AlphaImpactRx data. Mot. at 7-11, 13; Opp. at 7-9; EX1042, 106:3-10, 107:9-19; 118:5-120:4, 157:11-25. Mr. Tate's failure to ensure the [REDACTED] [REDACTED] renders his opinions and the [REDACTED] exhibits unreliable and inadmissible. Mot. at 8-9, 12; EX1042, 133:20-134:4, 147:9-148:5, 149:9-150:7, 157:11-25 (Tate never saw [REDACTED] [REDACTED]; *Spraying Systems Co. v. Delavan, Inc.*, 975 F.2d 387, 394 (7th Cir. 1992) (survey with problematic questionnaire and low 38% response rate excluded); EX2171 at 36 [REDACTED] [REDACTED], 53 [REDACTED]; *J&J Snack Foods*

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