

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**SANOFI-AVENTIS U.S. LLC AND
REGENERON PHARMACEUTICALS, INC.,
Petitioners**

v.

**GENENTECH, INC. AND CITY OF HOPE,
Patent Owners**

Case IPR2015-01624

U.S. Patent No. 6,331,415

**PETITIONERS' OBJECTIONS TO EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64**

Pursuant to 37 C.F.R. § 42.64, Petitioners sanofi-aventis U.S. LLC and

Regeneron Pharmaceuticals, Inc. object to the admissibility of the following exhibits served by Patent Owners Genentech, Inc. and City of Hope during the deposition of Jefferson Foote on April 21, 2016.¹

I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS

Evidence	Objections
<p>Foote Deposition Exhibit 1 (Expert Report of Jefferson Foote, Ph.D., in <i>Glaxo Group vs. Genentech</i>)</p>	<p>Hearsay: The exhibit sets forth inadmissible hearsay offered for the truth of the matters asserted therein and is not subject to any exceptions. Fed. R. Evid. 801, 802, 803. Furthermore, the exhibit does not contain any non-hearsay statements under Fed. R. Evid. 801(d).</p> <p>Improper Impeachment with Extrinsic Evidence: A proper foundation was not laid with the exhibit for introduction as extrinsic evidence of any prior inconsistent statements on non-collateral matters. Fed. R. Evid. 613, 611.</p> <p>Relevance: The exhibit is irrelevant to the extent that it contains Dr. Foote's statements in a prior litigation concerning the validity of U.S. Patent No. 6,331,415 ("the '415 patent")—the patent at issue in the instant IPR proceeding—on invalidity grounds that are not the same or substantially the same as the § 103 invalidity grounds currently instituted in the instant proceeding. Fed. R. Evid. 402. Secondly, any of the exhibit's probative value to the § 103 invalidity grounds instituted in the instant proceeding is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the Board as trier of fact, undue delay, wasting time, and</p>

¹ Petitioners also objected to the introduction of these exhibits during the deposition. Patent owners did not "provide evidence to cure the objection during the deposition," as required by 37 C.F.R. § 42.64(a).

	<p>needlessly presenting cumulative evidence. Fed. R. Evid. 403. Dr. Foote has submitted a Declaration in the instant proceeding (Exh. 1006), rendering this exhibit cumulative and wasteful of the Board's resources.²</p> <p>Scope: The contents of this exhibit are outside the scope of the direct testimony and thus are impermissible under the Rules. Fed. R. Evid. 611(b); 37 C.F.R. 42.53(d)(5)(ii).</p>
<p> Foote Deposition Exhibit 2 (Rebuttal Expert Report of Jefferson Foote, Ph.D., in <i>Glaxo Group vs. Genentech</i>)</p>	<p>Hearsay: The exhibit sets forth inadmissible hearsay offered for the truth of the matters asserted therein and is not subject to any exceptions. Fed. R. Evid. 801, 802, 803. Furthermore, the exhibit does not contain any non-hearsay statements under Fed. R. Evid. 801(d).</p> <p>Improper Impeachment with Extrinsic Evidence: A proper foundation was not laid with the exhibit for introduction as extrinsic evidence of any prior inconsistent statements on non-collateral matters. Fed. R. Evid. 613, 611.</p> <p>Relevance: The exhibit is irrelevant to the extent that the exhibit contains Dr. Foote's statements in a prior litigation concerning the validity of the '415 patent—the patent at issue in the instant IPR proceeding—on invalidity grounds that are not the same or substantially the same as the § 103 invalidity grounds currently instituted in the instant proceeding. Fed. R. Evid. 402. Secondly, any of</p>

² Relatedly, the B.P.A.I. has explained that "absent a compelling reason," a party may not "attempt to inquire on cross-examination into how direct testimony declarations came to be prepared," even for the proceeding at issue. *Pevarello v. Lan*, Patent Interference No. 105,394, Paper 85 at 23 (B.P.A.I. January 12, 2007) (citing efficient use of judicial resource among reasons to limit scope of cross-examination). Thus, Patent Owner's line of questioning regarding deposition exhibits 1-6 inquires into: (1) how Dr. Foote prepared and/or modified *vel non* his expert testimonies in different proceedings; and (2) whether he read his statements in preparation for a deposition, is irrelevant. As the B.P.A.I. noted, "it does not matter how a declaration for direct testimony is prepared, who suggested what, *what changes were made*, how drafts and the final declaration were transmitted to a witness for signature, etc. If a witness signed a declaration, a good starting point is to presume that the witness agrees with the content of the declaration apart from who wrote it and how many changes were made or why they were made." *Id.* at 21.

	<p>the exhibit's probative value to the § 103 invalidity grounds instituted in the instant proceeding is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, misleading the Board as trier of fact, and needlessly presenting cumulative evidence. Fed. R. Evid. 403. Dr. Foote has submitted a Declaration in the instant proceeding (Exh. 1006), rendering this exhibit cumulative and wasteful of the Board's resources.</p> <p>Scope: The contents of this exhibit are outside the scope of the direct testimony and thus are impermissible under the Rules. Fed. R. Evid. 611(b); 37 C.F.R. 42.53(d)(5)(ii).</p>
<p>Foote Deposition Exhibit 3 (Deposition Transcript of Jefferson Foote, Ph.D., in <i>Glaxo Group vs. Genentech</i>, 12/9/11)</p>	<p>Hearsay: The exhibit sets forth inadmissible hearsay offered for the truth of the matters asserted therein and is not subject to any exceptions. Fed. R. Evid. 801, 802, 803. Furthermore, the exhibit does not contain any non-hearsay statements under Fed. R. Evid. 801(d).</p> <p>Improper Impeachment with Extrinsic Evidence: A proper foundation was not laid with the exhibit for introduction as extrinsic evidence of any prior inconsistent statements on non-collateral matters. Fed. R. Evid. 613, 611.</p> <p>Relevance: The exhibit is irrelevant to the extent that the exhibit contains Dr. Foote's statements in a prior litigation concerning the validity of the '415 patent—the patent at issue in the instant IPR proceeding—on invalidity grounds that are not the same or substantially the same as the § 103 invalidity grounds currently instituted in the instant proceeding. Fed. R. Evid. 402. Secondly, any of the exhibit's probative value to the § 103 invalidity grounds instituted in the instant proceeding is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the Board as trier of fact, undue delay, wasting time, and needlessly presenting cumulative evidence. Fed. R. Evid. 403. Dr. Foote has submitted a Declaration in the instant</p>

	<p>proceeding (Exh. 1006), rendering this exhibit cumulative and wasteful of the Board's resources.</p> <p>Scope: The contents of this exhibit are outside the scope of the direct testimony and thus are impermissible under the Rules. Fed. R. Evid. 611(b); 37 C.F.R. 42.53(d)(5)(ii).</p>
<p>Foote Deposition Exhibit 4 (Expert Report of Jefferson Foote, Ph.D. in <i>Bristol-Myers Squibb vs. Genentech</i>)</p>	<p>Hearsay: The exhibit sets forth inadmissible hearsay offered for the truth of the matters asserted therein and is not subject to any exceptions. Fed. R. Evid. 801, 802, 803. Furthermore, the exhibit does not contain any non-hearsay statements under Fed. R. Evid. 801(d).</p> <p>Improper Impeachment with Extrinsic Evidence: A proper foundation was not laid with the exhibit for introduction as extrinsic evidence of any prior inconsistent statements on non-collateral matters. Fed. R. Evid. 613, 611.</p> <p>Relevance: The exhibit is irrelevant to the extent that the exhibit contains Dr. Foote's statements in a prior litigation concerning the validity of the '415 patent—the patent at issue in the instant IPR proceeding—on invalidity grounds that are not the same or substantially the same as the § 103 invalidity grounds currently instituted in the instant proceeding. Fed. R. Evid. 402. Secondly, any of the exhibit's probative value to the § 103 invalidity grounds instituted in the instant proceeding is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the Board as trier of fact, undue delay, wasting time, and needlessly presenting cumulative evidence. Fed. R. Evid. 403. Dr. Foote has submitted a Declaration in the instant proceeding (Exh. 1006), rendering this exhibit cumulative and wasteful of the Board's resources.</p> <p>Scope: The contents of this exhibit are outside the scope of the direct testimony and thus are impermissible under the Rules. Fed. R. Evid. 611(b); 37 C.F.R. 42.53(d)(5)(ii).</p>

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