

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owners

Case IPR2021-00816
Patent 9,220,631

**PATENT OWNERS' OBJECTIONS TO ADMISSIBILITY OF EVIDENCE
SUBMITTED BY PETITIONERS**

Pursuant to 37 C.F.R. § 42.64(b), Patent Owners Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation hereby object as follows to the admissibility of evidence filed by Petitioner Regeneron Pharmaceuticals, Inc., in conjunction with the Petition, filed on April 16, 2021, and the Petitioner's Reply to Patent Owners' Preliminary Response, filed on August 20, 2021.

Evidence	Objections
Exhibit 1003	<p>FRE 105: To the extent that any portion of this exhibit may be deemed admissible, such admissibility should be for a limited purpose.</p> <p>FRE 402/403: The exhibit includes assertions and testimony that are not relevant to any ground upon which trial was instituted and/or for which the probative value to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly cumulative evidence.</p> <p>FRE 602: The exhibit includes assertions for which evidence has not been introduced sufficient to show that the witness has personal knowledge of the matter asserted.</p>

Evidence	Objections
	<p>FRE 701-703: The exhibit declarant is not qualified to opine on what a person of ordinary skill in the art would understand, to opine on patent claim limitations, to perform claim construction, and/or to perform legal analysis of invalidity. The opinion testimony offered in this exhibit is not based on scientific, technical, or other specialized knowledge, and is also not based on personal knowledge. The opinion testimony includes unsubstantiated leaps and advances inaccurate, unqualified and unsupported generalizations. The opinion testimony fails to properly disclose the underlying facts or data on which the opinion is based. The opinion testimony includes testimony on United States patent law and/or patent examination practice. The opinion testimony includes conclusions based on documents that are subject to objections indicated herein, that have not been sufficiently authenticated as what the declarant asserts or believes them to be, and/or that an expert in the field would not reasonably rely on in forming an opinion on the particular subject.</p>

Evidence	Objections
	<p>FRE 705: The exhibit includes expert testimony that does not disclose the underlying facts or data.</p> <p>FRE 802: The entirety of the exhibit contains inadmissible hearsay if offered to prove the truth of any matter allegedly asserted therein.</p>
Exhibit 1004	<p>FRE 105: To the extent that any portion of this exhibit may be deemed admissible, such admissibility should be for a limited purpose.</p> <p>FRE 402/403: The exhibit includes assertions and testimony that are not relevant to any ground upon which trial was instituted and/or for which the probative value to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly cumulative evidence.</p> <p>FRE 602: The exhibit includes assertions for which evidence has not been introduced sufficient to show that the witness has personal knowledge of the matter asserted.</p>

Evidence	Objections
	<p>FRE 802: The entirety of the exhibit contains inadmissible hearsay if offered to prove the truth of any matter allegedly asserted therein.</p> <p>FRE 901: Petitioner has not produced evidence sufficient to support a finding that the exhibit is what Petitioner claims it is.</p>
Exhibit 1005	<p>37 CFR § 42.6(a)(3): Petitioner's reliance on this exhibit entails improper incorporation by reference of arguments from one document into another document.</p> <p>FRE 105: To the extent the exhibit may be deemed admissible, such admissibility should be for a limited purpose.</p> <p>FRE 402/403: The exhibit is not relevant to any ground upon which trial was instituted and/or the exhibit's probative value to any ground upon which trial was instituted is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly cumulative evidence.</p> <p>FRE 602: The exhibit includes assertions for which evidence has not been introduced sufficient to show that the witness has personal knowledge of the matter asserted.</p>

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