

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,  
Petitioner,

v.

NOVARTIS PHARMA AG,  
NOVARTIS TECHNOLOGY LLC,  
NOVARTIS PHARMACEUTICALS CORPORATION,  
Patent Owner.

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Case No. IPR2021-00816

U.S. Patent No. 9,220,631

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**PETITIONER'S OBJECTIONS TO  
ADMISSIBILITY OF EVIDENCE SUBMITTED BY PATENT OWNER**

Pursuant to 37 C.F.R. § 42.64(b), Petitioner Regeneron Pharmaceuticals, Inc., hereby objects as follows to the admissibility of evidence filed by Patent Owners Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, in conjunction with the Patent Owner Preliminary Response, filed on July 29, 2021, and Patent Owner Sur-Reply, filed on August 27, 2021.

Evidence	Objections
<p><b>Exhibit 2001</b></p>	<p><b>FRE 105:</b> To the extent that any portion of this exhibit may be deemed admissible, such admissibility should be for a limited purpose.</p> <p><b>FRE 602:</b> As to at least paragraphs 37-41, 43-44, 46, 48-51, 56-58, 68, 71-75, 79-80, 86-89, 92, 94-95, 99, 101, 106-117, 120-121, 125-132, 134, 136, 138-140, 142-145, 148, 152, 154-164, 166-170, 173-174, 176-179, 184-185, 189-192, 195, 198, 202, 210, 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> <p><b>FRE 701/702 and/or 37 C.F.R. § 42.65:</b> As to at least paragraphs 10-11, 28-60, 63-211, 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,</p>

Evidence	Objections
	<p>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.</p> <p><b>FRE 705 and /or 37 C.F.R. § 42.65:</b> As to at least paragraphs 39-41, 43-44, 46, 48-51, 56-58, 68, 71-75, 79-80, 86-89, 92, 94-95, 99, 101, 106-117, 120-121, 125-132, 134, 136, 138-140, 142-145, 148, 152, 154-164, 166-170, 173-174, 176-179, 184-185, 189-192, 195, 198, 202, 210, the exhibit includes expert testimony that does not disclose the underlying facts or data.</p> <p><b>FRE 802:</b> The entirety of the exhibit is inadmissible hearsay</p>

<b>Evidence</b>	<b>Objections</b>
	if offered to prove the truth of any matter allegedly asserted therein.
<b>Exhibit 2002</b>	<b>FRE 602:</b> As to at least paragraphs 8-15, 18, the exhibit includes assertions for which evidence has not been introduced sufficient to show that the witness has personal knowledge of the matter asserted. <b>FRE 802:</b> The entirety of the exhibit is inadmissible hearsay if offered to prove the truth of any matter allegedly asserted therein.
<b>Exhibit 2003</b>	<b>FRE 402:</b> The exhibit is not relevant to any ground upon which trial was instituted. <b>FRE 403:</b> 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.
<b>Exhibit 2004</b>	<b>FRE 402:</b> The exhibit is not relevant to any ground upon which trial was instituted. <b>FRE 403:</b> The exhibit's probative value to any ground upon which trial was instituted is substantially outweighed by the

Evidence	Objections
	<p>danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly cumulative evidence.</p> <p><b>FRE 901:</b> Petitioner has not produced evidence sufficient to support a finding that the exhibit is what Petitioner claims it is.</p>
<b>Exhibit 2005</b>	<p><b>FRE 402:</b> The exhibit is not relevant to any ground upon which trial was instituted.</p> <p><b>FRE 403:</b> 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>
<b>Exhibit 2006</b>	<p><b>FRE 402:</b> The exhibit is not relevant to any ground upon which trial was instituted.</p> <p><b>FRE 403:</b> 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>
<b>Exhibit 2007</b>	<p><b>FRE 402:</b> The exhibit is not relevant to any ground upon which trial was instituted.</p>

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