

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ADELLO BIOLOGICS, LLC, APOTEX INC. and APOTEX CORP.,  
Petitioners

v.

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,  
Patent Owner

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Case PGR2019-00001  
Patent 9,856,287

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**PATENT OWNERS' OBJECTIONS TO EVIDENCE  
UNDER 37 C.F.R. § 42.64**

Patent Owners<sup>1</sup> Amgen Inc. and Amgen Manufacturing, Limited

(collectively, “Amgen”) object under the Federal Rules of Evidence (“FRE”) and 37 C.F.R. § 42.64(b)(1) to the admissibility of EX1002, 1006, 1009, 1013-1016, 1018-1033, 1037, 1038, and 1040-1051.

The Institution Decision issued on April 19, 2019. Amgen’s objections are timely under 37 C.F.R. § 42.64(b)(1). Amgen serves Petitioner with these objections to provide notice that Amgen may move to exclude EX1002, 1006, 1009, 1013-1016, 1018-1033, 1037, 1038, and 1040-1051 as improper evidence.

**1. EX1006, 1009, 1013-1016, 1018-1033, 1038, 1040-1051 And Any Reference To/Reliance Thereon**

Amgen objects to EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 for at least the following reasons:

Petitioner has failed to authenticate EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 under **FRE 901** (authentication) and **FRE 602** (personal knowledge). Specifically, Petitioner has failed to establish that each of EX1006,

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<sup>1</sup> Petitioners listed both Amgen Inc. and Amgen Manufacturing, Limited in the caption as “Patent Owner.” Amgen Manufacturing, Limited is an exclusive licensee. Nevertheless, consistent with the caption, these objections refer collectively to both parties as “Patent Owners.”

1009, 1013-1016, 1018-1033, 1038, and 1040-1051 is what Petitioner claims it to be.

To the extent that Petitioner relies on these documents for the truth of the matter asserted, or attempts to rely on any date that may appear in EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 for an argument to establish public accessibility as a printed publication, the material, including any date is hearsay under **FRE 801** (hearsay) and is inadmissible under **FRE 802** (hearsay), and further, any such date has not been authenticated and is inadmissible under **FRE 901**.

Because of these deficiencies, and Petitioner's failure to provide any other supporting evidence, Petitioner has failed to establish EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 are prior art printed publications. Therefore, EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 are also not relevant under **FRE 401** to the extent they are relied on as prior art and are inadmissible under **FRE 402** and **FRE 403**.

## **2. Robinson Declaration (EX1002) And Any Reference To/Reliance Thereon**

Amgen objects to the Robinson Declaration for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Robinson's (EX1002) opinions are inadmissible because they are conclusory, do not disclose underlying facts or data

in support, and are unreliable. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, and wasting time) their opinions are irrelevant, confusing, and of minimal probative value.

In addition, to the extent Dr. Robinson relies on EX1006, 1009, 1013-1016, 1018-1033, 1038, and 1040-1051 for her analysis, the Robinson Declaration is also inadmissible under **FRE 702** and for the reasons discussed above.

**3. “Table of Categorized Claims For ‘287 Patent” (EX1037) And Any Reference To/Reliance Thereon**

Amgen objects to Petitioner’s “Table of Categorized Claims” (EX1037) for at least the following reasons:

Exhibit 1037 is attorney argument and is therefore an improper exhibit and not evidence. For example, the material is hearsay under **FRE 801** (hearsay) and thus inadmissible under **FRE 802** (hearsay).

To the extent Amgen is required to raise this issue in evidentiary objections in order to preserve it, Amgen further states that this Exhibit amounts to improper and impermissible incorporation by reference.

Respectfully submitted by:

Dated: May 3, 2019

/Megan Raymond/  
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