

Filed: March 5, 2019

Filed on behalf of: Eli Lilly and Company

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ELI LILLY AND COMPANY  
Petitioner

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH  
Patent Owner

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Case IPR2018-01422 (Patent No. 9,340,614)  
Case IPR2018-01423 (Patent No. 9,266,951)  
Case IPR2018-01424 (Patent No. 9,346,881)  
Case IPR2018-01425 (Patent No. 9,890,210)  
Case IPR2018-01426 (Patent No. 9,890,211)  
Case IPR2018-01427 (Patent No. 8,597,649)<sup>1</sup>

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**PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE**

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<sup>1</sup> The word-for-word identical paper is filed in each proceeding identified in the caption. For the Board's convenience, citations to the POPR refer to the paper filed in IPR2018-01422 involving Teva's Patent No. 9,340,614.

The Federal Rules of Evidence (“FRE”) generally apply to proceedings before the Board. 37 C.F.R. § 42.62(a). Pursuant to 37 C.F.R. § 42.64(b)(1) and the FRE, Patent Owner Eli Lilly and Company (“Lilly” or “Patent Owner”) submits the following objections to certain exhibits submitted by Petitioner Teva Pharmaceuticals International GMBH (“Teva” or “Petitioner”). These objections apply equally to Petitioner’s reliance on these exhibits in any subsequently filed documents. These objections are timely filed and served within ten business days of the Board’s decision to institute trial in these proceedings.

**Exhibit 2001**

To the extent Teva relies on the content of Exhibit 2001 for the truth of the matter asserted, Lilly objects to Exhibit 2001 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2002**

To the extent Teva relies on the content of Exhibit 2002 for the truth of the matter asserted, Lilly objects to Exhibit 2002 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2003**

To the extent Teva relies on the content of Exhibit 2003 for the truth of the

matter asserted, Lilly objects to Exhibit 2003 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

#### **Exhibit 2004**

Lilly objects to Exhibit 2004 under FRE 401-403 as lacking relevance to the instituted grounds. Teva relies on Exhibit 2004 and asserts that CGRP<sub>8-37</sub> was identified in 1989. POPR, 5. But Exhibit 2004 does not establish that CGRP<sub>8-37</sub> was first identified in 1989. Thus, this exhibit does not make any fact more or less probable than it would be without this exhibit. Moreover, Exhibit 2004 is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

#### **Exhibit 2007**

Lilly objects to Exhibit 2007 as being duplicative of its Exhibit 1052. “A document already in the record of the proceeding must not be filed again, not even as an exhibit or an appendix, without express Board authorization.” 37 C.F.R. § 42.6(d). Thus, this exhibit should be expunged.

#### **Exhibit 2008**

To the extent Teva relies on the content of Exhibit 2008 for the truth of the matter asserted, Lilly objects to Exhibit 2008 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2011**

To the extent Teva relies on the content of Exhibit 2011 for the truth of the matter asserted, Lilly objects to Exhibit 2011 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2012**

To the extent Teva relies on the content of Exhibit 2012 for the truth of the matter asserted, Lilly objects to Exhibit 2012 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2019**

To the extent Teva relies on the content of Exhibit 2019 for the truth of the matter asserted, Lilly objects to Exhibit 2019 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

**Exhibit 2021**

To the extent Teva relies on the content of Exhibit 2021 for the truth of the matter asserted, Lilly objects to Exhibit 2021 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Lilly further objects to Exhibit 2021 because it lacks proper foundation or

authenticity under FRE 901.

In addition, Lilly objects to Exhibit 2021 under FRE 401-403 as lacking relevance to the instituted grounds. Because Exhibit 2021 does not reflect any knowledge of one skilled in the art at the time of the alleged invention, this exhibit does not make any fact more or less probable than it would be without this exhibit. Moreover, Exhibit 2021 is unfairly prejudicial, confuses the issues, misleads the factfinder, and/or is a waste of time.

### **Exhibit 2022**

To the extent Teva relies on the content of Exhibit 2022 for the truth of the matter asserted, Lilly objects to Exhibit 2022 as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807. Lilly further objects to Exhibit 2022 because it lacks proper foundation or authenticity under FRE 901.

In addition, Lilly objects to Exhibit 2022 under FRE 401-403 as lacking relevance to the instituted grounds. Teva relies on Exhibit 2022 and asserts that “Merck ultimately discontinued MK-0974.” POPR, 6. Exhibit 2022, which allegedly contains clinical trial search results for MK-0974, does not establish discontinuation of clinical trials for MK-0974. Because Exhibit 2022 does not reflect any knowledge of one skilled in the art at the time of the alleged invention, this exhibit does not make any fact more or less probable than it would be without

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