Paper No. 35
Filed: October 7, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
APOTEX INC., APOTEX CORP.,
TEVA PHARMACEUTICALS USA, INC.,
and FRESENIUS KABI USA, LLC,

PETITIONERS,

V.

ELI LILLY & COMPANY,

PATENT OWNER.

Case IPR2016-00240[1]
Patent 7,772,209

PETITIONER'S OBJECTIONS TO PATENT OWNER'S RESPONSE EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(b)(1)

[1] Cases IPR2016-01191 and IPR2016-01343 have been joined with the instant proceeding.

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Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner submits the following objections to the evidence that Patent Owner first served on September 30, 2016:

Evidence	**Petitioner's Objections**
Exs. 2020, 2023-2024, 2026, 2043-2049, 2052, 2053, 2056-2057, 2061, 2065-2067, 2069-2071, 2073-2083,2085, 2088-2099, 2101-2102, 2111-2114, 2116-2121, 2123	Relevance

The above-listed documents should be excluded because they are not relevant. *See* Fed. R. Evid. 401–403. For example, none of Exhibits 2023-2024, 2026, 2043-2049, 2052, 2053, 2056-2057, 2061, 2065-2067, 2069-2071, 2073-2083, 2085, 2088-2090, 2092-2099, 2101-2102, 2114, 2117, 2119, 2121, or 2123 are cited by Patent Owner in its Response (Paper 32). Petitioner reserves its right to submit additional objections to these exhibits if and when Patent Owner cites or relies upon them.

Patent Owner also cites testimony from other IPR proceedings not joined with the present proceeding, as well as other litigation with different prior art at issue from the present proceeding. *See*, *e.g.*, Exs. 2026, 2061, 2092, 2116.

Patent Owner further cites documents including a date of 1999, without making clear when in 1999 the documents were published, despite admitting that the "relevant date for analyzing Neptune's obviousness arguments is June 29, 1999 …" (Paper 32 at 14.) *See, e.g.*, Exs. 2020, 2076. Because it is not possible to determine whether these exhibits qualify as prior art, it is not clear that these

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exhibits have any relevance as to what a person of ordinary skill would have understood as of the relevant date for the obviousness inquiry. Additionally, Patent Owner cites Exhibit 2091, which has a 2004 publication date, and Exhibit 2044, which has no publication date, and so are similarly irrelevant to the obviousness of the patent at issue.

Patent Owner additionally cites what appear to be non-public documents related to antifolate development, and so are irrelevant as to whether the claimed invention would have been obvious based on publicly available information. *See* Exs. 2111-2113.

Evidence	**Petitioner's Objections**
2020-2022, 2025, 2026, 2030-2035, 2037-2038, 2040-2063, 2065-2067, 2069-2071, 2073-2083, 2085-2114, 2116, 2122	Hearsay

The above-listed documents should be excluded because they are hearsay and Patent Owner cannot establish a hearsay exception for admissibility. *See* Fed. R. Evid. 801(c)(2).

Evidence	**Petitioner's Objections**
Exs. 2116, 2118, 2120	Fed. R. Evid. 602, 702-703

The above-listed documents should be excluded because they contain content over which the testifier has no personal knowledge, as well as putative expert testimony that is unqualified, unreliable, and based on facts or data that

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experts in the field would not reasonably rely upon. *See* Fed. R. Evid. 602, 702-703; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). For example, Exhibit 2116 contains testimony from Clet Niyikiza regarding topics about which he had no personal knowledge, and for which he is not qualified to testify as an expert. Exhibit 2118 contains testimony from Dr. Zeisel regarding topics about which he had no personal knowledge, and for which he is not qualified to provide the opinions of a POSA because he is not a medical oncologist as required by both Petitioner and Patent Owner's POSA definitions. Exhibit 2120 contains testimony from Dr. Chabner which repeatedly relies on Dr. Ron Schiff's expert declaration and deposition transcript, even though those documents are not evidence in this proceeding.

Evidence	**Petitioner's Objections**
Exs. 2032, 2099, 2101, 2111-2113	Authentication

The above-listed documents should be excluded because they have not been properly authenticated and are not self-authenticating. *See* Fed. R. Evid. 901, 902. For example, Exhibit 2032's certificate of translation indicates a publication date of 1988 for the 74th edition, but the scanned cover page indicates a copyright date of 1998, so it is not clear whether the translation certification relates to Exhibit 2032.

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Evidence	Petitioner's Objections
Exs. 2099, 2101, 2116	Completeness

The above-listed documents should be excluded because they are not complete, true and correct copies of the documents. *See* Fed. R. Evid. 106. For example, Exhibit 2099 contains unexplained redactions at ELA00007715, Exhibit 2101 contains unexplained redactions at ELAP00008711, and Exhibit 2116 contains direct testimony from Clet Niyikiza from a different proceeding, but omits the cross-examination testimony.

Evidence	Petitioner's Objections
Ex. 2116	37 C.F.R. § 42.53

The above-listed document should be excluded because it is not submitted in the form of an affidavit and, despite requests to Patent Owner, an opportunity for cross-examination has thus far been denied. *See* 37 C.F.R. §§ 42.51(b)(1)(ii), 42.53.

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