Filed on behalf of: Par Pharmaceutical, Inc.

Entered: February 28, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.
Petitioner

v.

NOVARTIS AG
Patent Owner

Case IPR2016-01479
U.S. Patent No. 9,006,224

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EVIDENCE

Under 37 C.F.R. § 42.64(b)(1), Petitioner Par Pharmaceutical, Inc. ("Petitioner") submits the following objections to evidence submitted by Patent Owner Novartis AG ("Patent Owner"). Petitioner's objections apply equally to Patent Owner's reliance on this evidence in any subsequently-filed documents or further proceedings in this matter. These objections are timely, having been filed and served within ten business days of the institution of the trial.

Notwithstanding these objections, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Objections

Exhibit 2001 (Kulke Decl.)

Petitioner objects to this document as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807, and as improper expert testimony under FRE 702, 703, and 37 C.F.R. § 42.65, to the extent it impermissibly acts as a conduit for hearsay, including the hearsay objected to herein, and does not rely on the kinds of facts or data that experts in the relevant field would reasonably rely on in forming an opinion on the subject without providing the underlying facts, data, and other required disclosures.

Petitioner objects to this document for lack of foundation and lack of personal knowledge, as improper expert testimony under FRE 702, 703, and 37

C.F.R. § 42.65, and as improper lay testimony under FRE 701, to the extent it offers testimony in areas outside of Dr. Kulke's area of expertise or fails to properly provide the underlying facts, data, and other required disclosures, including but not limited to the portions at paragraphs 5 and 89-96 purporting to address whether the FDA approval and the underlying clinical trial data from the RADIANT-3 clinical trial would have been unexpected to a person of ordinary skill as of November 2005.

Exhibits 2003 (Seeley) and 2021 (Remington's)

Petitioner objects to these documents under FRE 106 (completeness), as the documents are incomplete and only include select portions of larger documents that in fairness ought to be considered in connection with these exhibits.

To the extent Patent Owner relies on these exhibits for the truth of the matter asserted, Petitioner objects to them as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Exhibit 2016 (Novartis Press Release)

Petitioner objects to this document as not properly authenticated under FRE 901 because Patent Owner has not presented any evidence that the document is authentic nor that the document is self-authenticating under FRE 902.

Petitioner objects to this as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Exhibits 2017 (Ritchel) and 2018 (WHO)

Petitioner objects to these documents as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Petitioner objects to these documents under FRE 106 (completeness), as the documents are incomplete and only includes select portions of larger documents that in fairness ought to be considered in connection with these exhibits.

Exhibits 2024 (Ratain Trial Tr. I), 2025 (Ratain Trial Tr. II), and 2026 (Ratain Dep. Tr.)

Petitioner objects to these documents as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Petitioner objects to these documents under FRE 106 (completeness), as the documents are incomplete and only include select portions of larger documents that in fairness ought to be considered in connection with these exhibits.

Exhibits 2010 (Pazdur), 2011 (Kouvaraki), 2015 (Margolin), 2019 (Gemzar® Prescribing Information 2005), 2022 (Yao), 2027 (Dancey 2005), and 2028 (Duran 2006)

Petitioner objects to these documents under FRE 401 and 402, as the documents do not have a tendency to make the facts for which they are offered any more or less probable than those facts would otherwise be.

Petitioner objects to these documents under FRE 403, as any probative value

is substantially outweighed by a danger of unfair prejudice, confusing the issues, wasting time, and needlessly presenting cumulative evidence.

To the extent Patent Owner relies on the contents of these exhibits for the truth asserted, Petitioner objects to these documents as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including FRE 803, 804, 805, or 807.

Exhibits 2005 (Laughlin Cancer Glossary), 2008 (Motzer), 2012 (Delaunoit), 2013 (Kulke 2003), 2014 (Kulke 2004), 2020 (Kulke 1999), and 2023 (Kola & Landis)

To the extent Patent Owner relies on the contents of these exhibits for the truth asserted, Petitioner objects to them as hearsay not falling under any exception. These exhibits contain out of court statements by non-parties, but Patent Owner does not provide any basis for the PTAB to conclude that they fall within any hearsay objection.

Respectfully submitted,

Dated: February 28, 2017

By: /Daniel G. Brown/

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