UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

V.

JANSSEN ONCOLOGY, INC.
Patent Owner

Case IPR2016-01582 U.S. Patent No. 8,822,438

SUPPLEMENTAL DECLARATION OF PAUL A. GODLEY, M.D., Ph.D., MPP



- I, Paul A. Godley, hereby declare as follows.
- 1. I am over the age of eighteen and otherwise competent to make this declaration.
- 2. I am the same Paul A. Godley who submitted a declaration on August 10, 2016 in the *inter partes* review proceeding IPR2016-01582. My initial declaration was marked as Wockhardt Exhibit 1002.
- 3. I understand from counsel that Patent Owner Janssen Oncology, Inc. filed a paper on February 2, 2017, which, in part, objected to Exhibit 1034 cited in my initial declaration. I understand that Janssen asserted that the Petition and my Declaration did not establish the origin of Exhibit 1034 or that Exhibit 1034 is a true and correct copy of what it purports to be. I disagree with Janssen's assertions and submit this supplemental declaration in response.
- 4. Exhibit 1034 is a copy of a document comprising the approved prescribing information for Taxotere®. Experts in medical oncology routinely rely on materials such as Exhibit 1034 when analyzing a drug product's method of action, such as in the opinion set forth in my initial declaration. Exhibit 1034 is a true and correct copy of the Taxotere® prescribing information as published on the FDA's website, www.accessdata.fda.gov, accessed on August 8, 2016.
- 5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are



believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,

Paul A. Godley, M.D., Pl.D. MPP

Date: February 14, 2017

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