EXHIBIT 16
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY
Plaintiffs,
v.
CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.
Defendants.

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DECLARATION OF KENNETH J. DOW, ESQ.

I, Kenneth J. Dow, Esq., declare and state as follows:

1. I am an Assistant General Counsel for Patents in the Johnson & Johnson
   ("J&J") Law Department and a Vice President, Patent Law, at Janssen Biotech, Inc.

2. I have been with the Johnson & Johnson Law Department for over 20
   years. Since J&J’s acquisition of Centocor in 1999, the focus of my work has been with
   Centocor, Inc., or its successors in interest, first Centocor Ortho Biotech Inc. and then Janssen
   Biotech, Inc. (all three referred to collectively herein as “Janssen”).

3. My role as Assistant General Counsel and Vice President relates to,
   among other things, reviewing invention disclosures, procuring patents, and licensing patents
   (both to and from third parties and to and from other J&J companies) on behalf of Janssen.

4. I submit this declaration to explain the customs and practices of Janssen
   with respect to ownership of patents. I also address Janssen’s records...
5. Throughout my tenure at Janssen, employees of Janssen have been required to sign agreements obligating them to disclose promptly inventions that are invented in the course of their employment, assigning rights in such inventions and agreeing to execute further assignments and related documents as requested. The further assignments typically occur after a patent application has been filed and/or a patent has issued; for purposes of documenting and publicly recording ownership of a particular patent, it is preferable to have an assignment document that specifically mentions the application or patent.

6. All six inventors of the '083 patent signed such agreements. Attached as Exhibit A are the employment agreements of the four inventors who began working at Janssen since the acquisition of Centocor, Inc. by J&J: David Epstein, Roger Monsen, Christopher Marsh, and Sadettin Ozturk. In all four of these agreements, paragraph 1 contains the obligation to disclose inventions and the assignment of title to inventions. Paragraph 3 requires the employees to execute additional assignments and other instruments as requested.
For example, Janssen employees disclose inventions by means of an invention disclosure form addressed to me. This invention disclosure form is on Janssen letterhead and indicates that its contents are Janssen confidential information. The inventors of the '083 patent submitted such an invention disclosure to me in May 2004. Since Janssen was then Centocor, Inc., the disclosure is on Centocor letterhead and states that its contents are Centocor confidential information. A copy of this invention disclosure form (redacted to remove information protected by the attorney-client privilege) is attached hereto as Exhibit B. The disclosure lists five of the six inventors of the '083 patent. Inventor Marsh was added at a later time, as is not uncommon in patent prosecution.

In addition, Janssen employees regularly execute additional assignment of ownership documents on request (paragraph 3 of the agreements in Exhibit A). With respect to the invention claimed in the '083 patent, the inventors have executed a number of such additional ownership assignment documents:

- On August 17, 2005, Susan Lenk executed an assignment referencing provisional application No. 60/623,718 (to which the '083 patent claims priority) naming "Centocor, Inc." as assignee. That assignment document is attached hereto as Exhibit C.

- In June and July 2007, each of the inventors executed an assignment document in connection with a Canadian patent application for the invention disclosed in the '083 patent. These assignments documents name "Centocor, Inc." as assignee. They are attached hereto as Exhibit D.

- On June 3, 2009, Roger Monsell executed an assignment document referencing non-provisional application No. 11/260,788 (which matured into the '083 patent) naming "Centocor, Inc." as assignee. That assignment document is attached hereto as Exhibit E.
• On June 8, 2009, Susan Lenk executed an assignment document referencing non-provisional application No. 11/260,788 naming “Centocor, Inc.” as assignee. That assignment document is attached hereto as Exhibit F.

• In April and July 2015, each of the inventors executed assignment documents referencing the “application for Letters Patent of the United States” entitled “CHEMICALLY DEFINED MEDIA COMPOSITIONS,” which named “Janssen Biotech, Inc. (formerly Centocor, Inc.)” as assignee. These assignments were recorded in the USPTO and are attached hereto as Exhibit G.

• In August 2015, each of the inventors executed assignment documents referencing the ’083 patent and stating that each inventor had “by virtue of, inter alia, his [or her] employment agreement, assigned his [or her] entire right, title, and interest in the invention described in U.S. Patent No. 7,598,083 ... to JANSSEN BIOTECH, INC. (formerly CENTOCOR, INC.).” The August 2015 assignment documents also attach and refer to the April/July 2015 assignment documents, and state that “Assignor has previously executed an assignment ..., confirming said assignment.” These assignment documents are attached hereto as Exhibit H.

10. Consistent with these customs and practices, Janssen is the sole assignee on the face of the vast majority of issued Janssen U.S. patents, with the exception of a small number of patents that were co-invented with another company. And, with respect to the ’083 patent in particular, “Centocor, Inc.” is the assignee named on the face of the patent.


11. Specifically, the J&J Law department maintains a database of all J&J patents. Attached as Exhibit I is a readout from the database of all 218 patents owned in whole or in part
12. The '083 patent appears at line 69 of Exhibit H. As the exhibit shows, J&J’s internal records indicate that the ‘083 patent is owned by Janssen Biotech, Inc. (“Originating Company” column). The only applicants or assignees of the ‘083 patent are Janssen Biotech, Inc. and its predecessor Centocor, Inc. (“List of Applicants or Assignees at filing” column).

13. when Janssen patents have been enforced, the patent infringement lawsuits have been brought in the name of Janssen (together, where applicable, with a third party co-owner).

14. I understand that an issue has arisen in this litigation as to whether, as a result of the employment agreements attached as Exhibit A, the ‘083 patent was assigned jointly to Janssen, J&J, and all other J&J subsidiaries and affiliates. I have never heard anyone at Janssen or J&J assert such a proposition and this was never Janssen’s intention. Assigning patent rights jointly to a large number of J&J companies would create a number of administrative burdens and practical difficulties that are entirely unnecessary.

15. Joint patent co-ownership by all of the more than 230 J&J operating companies would make certain practices at the U.S. Patent & Trademark Office (“USPTO”)
cumbersome or unnecessarily burdensome. For example, the filing of a reissue application requires the consent of all assignees, and that consent must include a showing of ownership by the assignees. Similarly, a petition to correct the inventorship on a patent requires the consent of all assignees, which requires a showing of ownership.

16. To make such a showing the USPTO requires (pursuant to 37 C.F.R. § 3.73), for each assignee, a statement signed by a person authorized to act on behalf of the assignee (or the practitioner of record) attaching either documentary evidence of a chain of title from the original owner to the assignee or a statement specifying where such documentary evidence was recorded in the assignment records of the USPTO. If a patent were co-owned by all of J&J's operating companies, J&J would need to make such a showing and obtain consent on behalf of all J&J companies in order to file a reissue application or correct inventorship.

17. Co-ownership by hundreds of distinct companies would also make licensing technology to third parties similarly cumbersome or unnecessarily burdensome. To grant an exclusive patent license, all owners of the patent must consent. Obtaining consent on behalf of more than 230 distinct companies would unduly impede any licensing efforts.

18. Furthermore, assigning patent ownership jointly to all of J&J's subsidiaries would hinder efforts to enforce patents. Under U.S. law, all the owners of a patent must be joined as plaintiffs in patent infringement litigation. Routinely joining hundreds of J&J companies as plaintiffs in federal lawsuits, with the attendant need for appropriate internal approvals and potential for burdensome discovery, would be highly inefficient and undesirable. Although this problem could be avoided in individual cases by assigning ownership to a single company prior to filing suit, obtaining these assignments before every patent infringement
lawsuit would itself be unduly burdensome. This is particularly true because patent litigation is often brought under time pressure to avoid immediate irreparable harm to the business.

19. I understand it has been suggested that co-ownership of Janssen patents by all of J&J’s operating companies would be advantageous because it would permit all J&J companies to use Janssen inventions without a formal license. This is not correct. Co-ownership by hundreds of distinct companies would provide no practical benefits from a freedom to operate or administrative perspective. In patent law, no writing is required to grant a patent license. As a result, a J&J company that owns patented technology may informally consent to the use of that technology by other J&J companies without entering into a written agreement. In practice, however, we typically do execute written agreements for tax accounting and documentation purposes when a licensing transaction has significant economic consequences. These same considerations would call for documentation even if a patent were co-owned by all of J&J’s operating companies. In fact, the documentation would be far more complex and burdensome if the patents were co-owned by multiple J&J entities. There would be no advantages, and many unnecessary disadvantages, to such an arrangement.

20. I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 7, 2017

Kenneth J. Dow, Esq.