IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mylan Laboratories Ltd. Petitioner,

V .

Janssen Pharmaceutica NV Patent Owner.

U.S. Patent No. 9,439,906 to Vermeulen *et al.*Issue Date: September 13, 2016
Title: Dosing Regimen Associated with Long
Acting Injectable Paliperidone Esters

Inter Partes Review No.: IPR2020-00440

Declaration of Alys Tryon



I, Alys Tryon, state and declare as follows:

- 1. I have prepared this Declaration in connection with the Petition of Mylan Laboratories Ltd. ("Petitioner") for *inter partes* review of U.S. Patent No. 9,439,906 ("the '906 patent"). I understand that December 5, 2008 is a date that is relevant for determining what is prior art to the '906 patent.
- 2. I am currently a Research Analyst contractor at Katten Muchin Rosenman LLP, 525 W. Monroe Street, Chicago, IL 60661-3693. My employer is the LAC Group.
- **3.** I am over 18 years of age and am competent to make this Declaration. I make this Declaration based on my own personal knowledge and based on my knowledge of library sciences practices.
- **4.** I earned a Master's of Library and Information Services ("MLIS") from San José State University in 2011.
- 5. I have used and become familiar with WorldCat, which is an online catalog that itemizes the collections of 17,900 libraries in 123 countries and territories. It is the most comprehensive index of library holdings worldwide and largest online public access catalog. I am familiar with the searching features of WorldCat, and I have used WorldCat to conduct research. WorldCat is a well-known research tool known to those in the field



of research since 2001. WorldCat operates by combining the library collections of numerous libraries into a single searchable database. This is accomplished by OCLC (a non-profit organization that was formed in 1967 to help catalog member library's collections) member libraries uploading information on their collections to the OCLC System. When a library uploads information related to the library's reference collection, OCLC stores information identifying a date when the information was uploaded.

- 6. I have been asked to search for the circulation information regarding the following scientific journals: (1) Clinical Pharmacology & Therapeutics; (2) International Journal of Clinical Practice; (3) European Neuropsychopharmacology; and (4) Hospital Pharmacy.
- 7. All of the titles I was asked to search had *at least* one record associated with a reputable publisher, and they are all in at least several hundred individual academic library catalogs worldwide.
- **8.** I conducted this search on January 13, 2020. My findings are attached as Exhibits A-D.
- 9. I accessed and searched WorldCat Clinical Pharmacology & Therapeutics, and WorldCat returned two catalog entries: (1) Clinical Pharmacology & Therapeutics; and (2) Clinical Pharmacology &



Therapeutics: Official Publication of the American Therapeutic Society. A copy of the report summary is attached as Exhibit A.

- 10. Clinical Pharmacology & Therapeutics is authored by the American Society of Pharmacology and Therapeutics. The WorldCat search returned a total of 695 library results between the two catalog entries.
- 11. I accessed and searched WorldCat for the International Journal of Clinical Practice, and WorldCat returned two catalog entries: (1) International Journal of Clinical Practice; and (2) The International Journal of Clinical Practice IJCP. A copy of the report summary is attached as Exhibit B.
- 12. The International Journal of Clinical Practice is published by Wiley-Blackwell. The WorldCat search returned a total of 575 library results between the two catalog entries.
- WorldCat returned three catalog entries: (1) Hospital Pharmacy; (2) Hospital Pharmacy Europe HPE; and (3) Hospital Pharmacy: A Peer-Reviewed Journal for Hospital and Organized Health Care Systems Pharmacists. A copy of the report summary is attached as Exhibit C.
- **14.** The WorldCat search returned a total of 609 library results between the three catalog entries.



- 15. I accessed and searched WorldCat for European Neuropsychopharmacology and WorldCat returned four catalog entries: (1) (2) European Neuropsychopharmacology; European Neuropsychopharmacology: ENP; The Journal of the European College of Neuropsychopharmacology; (3) European Neuropsychopharmacology: ENP: The Journal of the European College of Neuropsychopharmacology; and (4) European Neuropsychopharmacology. A copy of the report summary is attached as Exhibit D.
- **16.** The WorldCat search returned a total of 907 results between the four catalog entries.
- 17. To the best of my knowledge and based on my experience, all titles that I was asked to search are academic in nature and the results indicate that these references are widespread.
- 18. For example, European Neuropsychopharmacology was located in the Stanford University Lane Medical Library and the University of California, Riverside. Exhibit D at 6-9. Hospital Pharmacy was located in the University of Florida library and the National Library of Medicine. Exhibit C at 3. The International Journal of Medicine was located in several universities within California alone: University of California, Irvine; The Claremont Colleges; and the University of Southern California, Norris Medical Library.



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