

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,

Petitioner

v.

ELI LILLY AND COMPANY,

Patent Owner

U.S. Patent 7,772,209

Issue Date: Aug. 10, 2010

Title: Antifolate Combination Therapies

Inter Partes Review No. Unassigned

Declaration of Ron D. Schiff, M.D., Ph.D.

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I. BACKGROUND

1. My name is Ron D. Schiff. I hold M.D. and Ph.D. degrees from Saint Louis University, and am currently the principal of Schiff BioMedical Consulting.

2. I have been retained by counsel for Petitioner, Sandoz Inc. (“Sandoz”), to investigate and opine as to the validity of claims 1-22 of U.S. Patent No. 7,772,209 (“the ’209 patent”).

3. I am being compensated at my usual hourly rate for the time I spend working on this matter. My compensation is not contingent upon the substance of my testimony or the outcome of this matter.

II. QUALIFICATIONS AND EXPERIENCE

4. My qualifications and experience are set forth in my curriculum vitae, which is attached as Appendix A.

5. I worked as practicing physician in the field of oncology for 29 years with a specialty in internal medicine and sub-specialties in medical oncology and hematology.

6. I frequently treated patients with antifolates, particularly methotrexate which is used in the treatment of multiple hematologic and solid-organ malignancies, including acute lymphoblastic leukemia, non-Hodgkin’s lymphoma, head and neck cancer, breast cancer, bladder cancer, and meningeal leukemia or lymphoma.

7. I have treated hundreds of patients with methotrexate throughout my 29 years of practice and since I began my post-graduate training in 1980. I have also administered pemetrexed and am familiar with its vitamin pre-treatment regimen.

III. MATERIALS CONSIDERED

8. In forming my opinions, I have reviewed, *inter alia*, the '209 patent and its prosecution history, as well as the exhibits referenced in Sandoz's Petition for *Inter Partes* Review. I understand that the exhibit numbers referenced in this declaration correspond to the same exhibit numbers used in Sandoz's petition. A copy of the exhibit list from Sandoz's petition is attached as Appendix B.

9. A list of the documents I have considered in preparing this declaration is attached as Appendix C.

10. This declaration is based upon information currently available to me. To the extent additional information becomes available, I reserve the right to continue my investigation and study.

IV. SUMMARY OF OPINIONS

11. For the reasons explained herein, claims 1-22 would have been obvious to the person of ordinary skill in the art as of June 1999.

V. LEGAL PRINCIPLES

12. I am a medical, not a legal, expert. Counsel for Sandoz has advised

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