UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC

Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD

Patent Owner

Patent No. 9,815,827

Inter Partes Review No. IPR2020-01053

SUPPLEMENTAL DECLARATION OF DR. THOMAS R. KOSTEN, M.D.

1. In this proceeding, I, Thomas R. Kosten, M.D., submitted my Declaration (EX-1002) dated March 26, 2020.

2. My deposition was taken in this proceeding on February 17, 2021.

3. I have reviewed the part of my deposition transcript (EX-2134) from page 88, line 8 to page 90, line 14 (using the page numbers at the bottom right of the page). I understand from counsel that Patent Owner cites from this part of my deposition transcript to assert I recanted (i.e. "took back") part of my opinion. I did not recant.

4. Rather, when I testified in that part of my deposition that I did not have an "objection" to the "schizophrenia claims" of U.S. Patent No. 9,815,827 (EX-1001 "the '827 Patent") I meant that the clinical data in the '827 Patent (EX-1001 5:1-10:25) demonstrated the safety and efficacy of using lurasidone to treat schizophrenia.

5. I also understand from counsel that Patent Owner cites to Wong (EX-2032) to argue that Wong taught it was necessary to co-administer a second active agent with a number of antipsychotic drugs in a single formulation to minimize weight gain. I reviewed Wong and I disagree. Although Wong does state that the two active components "can be given as a single combined dose," Wong goes on to state that the two active ingredients can be "given separately" and at "different times" as long as both drugs are given "over a 24-hour period." EX-2032 9:25-28.

Teaching that a second drug can be given separately and within 24 hours of a first drug is the exact opposite of teaching that it was necessary to co-administer a second drug with the antipsychotic in a single formulation.

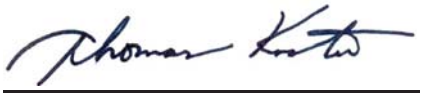
6. Moreover, Wong emphasizes that the second drug is preferably a selective norepinephrine reuptake inhibitor such as reboxetine. *Id*. 1:16-19. However, putting a second drug such as reboxetine in a fixed combination with an atypical antipsychotic (e.g. olanzapine) would remove important flexibility from the prescribing psychiatrist. This is because olanzapine is typically dosed before bedtime and reboxetine is typically dosed in the morning due to the fact that dosing reboxetine at bedtime can make it difficult for the patient to sleep. This is another reason that Wong does not teach that it was necessary to co-administer a second drug with the antipsychotic in a single formulation.

7. I also understand from counsel that Patent Owner does not argue that the second drug would have to be a second antipsychotic. This makes perfect sense because, although second drugs are often prescribed to help ameliorate the weight gain associated with certain atypical antipsychotic drugs, the paradigm second drug is metformin. Metformin, a drug often used in the treatment of diabetes, is not an anti-psychotic. The successful use of metformin as a treatment for weight gain in children taking olanzapine, risperidone, quetiapine or valproate was reported in the American Journal of Psychiatry in April 2002. EX-1056 ("Morrison"). Although

metformin is the paradigm second drug, I am not aware of a fixed combination drug marketed in the United States where metformin in combined with an antipsychotic drug in a single formulation.

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

Dated: June 09, 2021

By: 
Thomas R. Kosten, M.D.