UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.

Petitioner,

V.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR **Unassigned**

Patent No. 8,497,393

DECLARATION OF JEFFREY D. WINKLER IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1 – 22 OF U.S. PATENT NO. 8,497,393

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- 1. I have been retained by counsel for the Petitioner, SteadyMed Ltd., to offer technical opinions with respect to U.S. Patent No. 8,497,393 ("the '393 Patent") and prior art references cited in *inter partes review* proceedings for the '393 Patent.
- 2. I have reviewed the '393 Patent and, in assessing it, I have considered the teachings of the scientific literature before December 17, 2007, in light of general knowledge in the art before that date.
- 3. This declaration presents my opinion that Claims 1-22 of the '393 Patent would have been anticipated and/or obvious to a person of ordinary skill in the art before December 17, 2007. The technology of the '393 Patent involves nothing more than basic organic chemistry techniques in my view, "organic chemistry 101" all of which were well-known in the art prior to December 17, 2007.

I. QUALIFICATIONS

4. I am the Merriam Professor of Chemistry at the University of Pennsylvania, a position I have held since 2001. Prior to that time, I was a Professor of Chemistry from 1996 to 2001, and an Associate Professor of Chemistry from 1990 to 1996 at the University of Pennsylvania. I was an Assistant Professor of Chemistry at the University of Chicago from 1983 to 1990.



- 5. I have over 30 years of experience in the fields of organic and medicinal chemistry. My area of expertise includes design and synthesis of various biologically active natural and unnatural products, as well as mechanisms and stereochemistry in organic synthesis.
- 6. I earned my A.B. in Chemistry from Harvard College in 1977 and my Ph.D. in Chemistry from Columbia University in 1981.
- 7. I have an excellent reputation in the field of organic chemistry as evidenced by several awards, including the American Chemical Society Cope Scholar Award and an Alfred P. Sloan Fellowship.
- 8. I have co-authored numerous publications reporting results of my research in the field of organic chemistry in peer-reviewed journals. I have also presented numerous lectures on organic chemistry at national and international scientific meetings around the world.
- 9. Accordingly, I am an expert in the field of organic chemistry, and I have been an expert in this field since prior to December 17, 2007. Further information regarding my qualifications and credentials are fully set forth in my *curriculum vitae*, attached as Ex. 1010.

II. MATERIALS CONSIDERED

10. In forming my opinions, I have had available the materials cited in the Petition, the materials cited in this report, as well as those listed in the publications



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