IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
In the *Inter Partes Review* (IPR) of
U.S. Patent No. 8,440,170

DECLARATION OF Dr. Kinam Park

I, Kinam Park, do hereby declare:

1. I am making this declaration at the request of the Petitioners in the matter of the *Inter Partes Review (IPR)* of U.S. Patent No. 8,440,170 (the "'170 Patent"), as set forth in the above caption.

2. I am being compensated for my work in this matter at the rate of $600.00 per hour. My compensation in no way depends on the outcome of this proceeding.

A. Education and Professional Background

3. I am currently the Showalter Distinguished Professor of Biomedical Engineering and Professor of Pharmaceutics at Purdue University.

4. I have a Ph.D. in Pharmaceutics from the University of Wisconsin at Madison, Wisconsin. I also completed post-doctoral training in Chemical Engineering at the University of Wisconsin at Madison, Wisconsin.

5. I began my independent research since 1986 when I became an

Assistant Professor at Purdue University. My research focus has been developing various delivery systems for controlled drug delivery applications. I have served on many scientific advisory boards and journal editorial boards. I have been the Editor-in-Chief of the Journal of Controlled Release since 2005. Details of these and other positions are listed on my curriculum vitae. I'm an inventor of 18 U.S. Patents and have published over 250 papers in multiple peer-reviewed scientific journals.

6. I have experience in drug delivery systems, including oral formulations (fast-dissolving tablets & gastric retention devices using smart polymers & hydrogels), polymer micelles (for delivery of poorly soluble drugs), drug-device combinations such as drug-eluting stents, and microparticles for long-term drug delivery.

7. A copy of my curriculum vitae is submitted herewith as Attachment A to this Declaration.

B. Materials Considered

8. The list of materials I considered in forming the opinions set forth in this declaration includes the ’170 patent, the file history of the ’170 patent, the Petition for Inter Partes Review of the ’170 patent, and the prior art including i) PREVACID® (lansoprazole) Delayed-Release Capsules; PREVACID® (lansoprazole) For Delayed-Release Oral Suspension; PREVACID® SoluTab™

(lansoprazole) Delayed-Release Orally Disintegrating Tablets (Ex. 1004 hereafter "the *Prevacid Label*") TAP Pharmaceuticals, Lake Forest Il, 60045 USA, 102-004-R26 June 2007; ii) US 2006/0193909 to Stawski *et al.* entitled "Breath Freshening Presses Tablets and Methods of Making and Using Same" Published August 31, 2006. (Ex. 1005 hereafter "*Stawski*"); and iii) US 4,744,991 to Serpelloni entitled "Speckled Sugarless Chewing-Gum and Process for its Manufacture" issued May 17, 1988. (Ex. 1006 hereafter "*Serpelloni*").

C. Legal Standards

9. In my opinion, given the disclosure of the '170 patent, I consider a person of ordinary skill in the art at the time of filing of this patent would have either a Pharm. D. or a Ph.D. in pharmaceutics, chemistry, chemical engineering, or a related discipline; or a Bachelor's or Master's degree in pharmacy/ pharmaceutics or a related field with about four years of experience relating to formulation of compounds. A person of ordinary skill in the art may have collaborated with others having expertise in, for example, methods of treating diseases and administering medicines.

10. I have been told that the obviousness inquiry is a question of law based on four factual predicates: (1) "the scope and content of the prior art," (2) the "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) "secondary considerations" such as "commercial

success, long felt but unsolved needs, failure of others, etc. I have also been told that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

I have also been told that the motivation to combine may be found in many different places and forms. Thus, for example, a challenger is not limited to the same motivation that the patentee had.

D. Background and the '170 Patent

11. The '170 Patent is directed "to orally disintegrating tablets with speckled appearance." (Ex. 1001 abstract; col 1:14-16). The '170 Patent states that "the orally disintegrating tablets with speckled appearance are readily and easily identifiable by physicians, nurses, and patients." (*Id.*). The '170 Patent indicates that colored granules and excipients give tablets the "speckled appearance." (Ex. 1001 col 3:44-46). The '170 makes no claim as to the active pharmaceutical ingredient (API) useful in the so-called invention, listing hundreds of active ingredients that could be used with the speckled tablet in a laundry list stretching almost four full columns of the patent. (Ex. 1001 col 3: 48 – col 7:27).

E. Claim Construction

12. I understand that the claims in an IPR proceeding are construed in accordance with the broadest reasonable construction consistent with the

specification.

13. I have been told that the claim term "speckled appearance" should mean, with regard to a pharmaceutical tablet, a tablet that "has the look of being covered with small spots or patches of color." I have been told that the claim term "colored granules" is properly construed as "small particles of a size from about 10 µM to about 1200 µM having or having been given color." I have been told that the claim term "pharmaceutically acceptable carrier" should be construed to mean "a substance that can be included in the compositions of the invention and that causes no significant adverse toxicological effects to a patient." I agree with these constructions because they are consistent with the broadest reasonable construction as understood by one of ordinary skill in the art and the Specification of the '170 Patent. For example, it is well known and accepted that a "pharmaceutically acceptable carrier" is generally known as an excipient that can be included in a pharmaceutical compositions and that causes no significant adverse toxicological effects to a patient.

F. Claim 1 of the '170 Patent is unpatentable as obvious over the Prevacid Label in view of Stawski under 35 U.S.C. § 103.

14. It is my opinion that claim 1 of the '170 patent would have been obvious to one of ordinary skill in the art in light of the teachings of the Prevacid Label and Stawski.

15. The Prevacid Label teaches the claimed "orally disintegrating tablets

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