

EXHIBIT 1002

**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. 8,835,459**

DECLARATION OF Dr. Kinam Park

I, Kinam Park, do hereby declare:

1. I am making this declaration at the request of Petitioner Coalition For Affordable Drugs XI LLC, in the matters of the *Inter Partes Review* (IPR) of U.S. Patent No. 8,835,459 (the “459 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 polymer micelles (for delivery of poorly soluble drugs) and oral formulations (fast-dissolving tablets & gastric retention devices using smart polymers & hydrogels), 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 '459 patent, the file history of the '459 patent, the Petition for Inter Partes Review of the '459 patent, and the prior art including i) Great Britain patent publication GB2399286A by Calvin John Ross et al, entitled "Sub-

lingual fentanyl formulation.” published September 15, 2004 (“Ross_GB,” Exhibit 1003), ii) United States Patent 5,370,862 by Karin Klokkers-Bethke et al., entitled “Pharmaceutical hydrophilic spray containing nitroglycerin for treating angina,” issued December 6, 1994 (“the ‘862 patent,” Exhibit 1004), iii) United States Patent Application Publication 2006/0062812 by Calvin John Ross et al. entitled “Novel compositions,” published March 23, 2006 (“Ross_US2006,” Exhibit 1005), iv) “New Concepts For Administration of Drugs In Tablet Form: Formulation and Evaluation Of A Sublingual Tablet For Rapid Absorption and Presentation Of An Individualised Dose Administration System,” by Susanne Bredenberg, Uppsala University, Tryck & Medier, Uppsala 2003 (“Bredenberg_2003,” Exhibit 1006), v) The ACTIQ Label (Exhibit 1008).

C. Legal Standards

9. In my opinion, given the disclosure of the ’459 patent, I consider a person of ordinary skill in the art at the time of filing of these patents to be someone who holds a B.S. degree in pharmacy, chemistry, engineering, or related fields with several years of experience, or a Ph.D. degree in the same fields, and is a highly trained formulation chemist, well-versed in developing formulations from experience with drug formulations in an industrial or academic environment. I met or exceeded the requirements for one of ordinary skill in the art at the time of the

invention of the '459 Patent and continue to meet and/or exceed those requirements.

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 '459 Patent

11. The '459 patent "is directed to sublingual formulations containing fentanyl, a pharmaceutically acceptable salt thereof, or derivative thereof, suitable for administration to humans, and methods for treatment with the sublingual formulations."¹ The sublingual formulations "are useful in the treatment of

¹ Exhibit 1001, '459 patent, col. 1, ll. 12-15.

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