

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. 8,835,460**

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. 8,835,460 (the “460 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 on 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 includes¹ the '460 Patent (Exhibit 1001), the file history of '460 Patent, the Petition for Inter Partes Review of the '460 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.,

¹ Exhibit numbers refer to the Exhibit numbers listed in the Petition.

entitled “Pharmaceutical hydrophilic spray containing nitroglycerin for treating angina,” issued December 6, 1994 (“the ‘862 patent,” Exhibit 1004), iii) United States Patent Publication 2002/0055496 by Randall McCoy et al. entitled “Formulation and System For Intra-oral Delivery Of Pharmaceutical Agents,” published May 9, 2002 (“the ‘496 publication,” Exhibit 1005), iv) United States Patent 6,946,150 by Brian Whittle entitled “Pharmaceutical formulation” issued September 20, 2005 (“the ‘150 patent,” Exhibit 1007), v) P. W. H. Peng et al., *A Review of the Use of Fentanyl Analgesia in the Management of Acute Pain in Adults*, *Anesthesiology*. 1999 Feb; 90(2):576-99 at p. 587, (Exhibit 1009), vi) Sebastiano Mercadante and Fabio Fulfarò, *Alternatives to Oral Opioids for Cancer Pain*, *Oncology*, February 01, 1999 (Exhibit 1010), vii) J. Lance Lichtor et al., *The Relative Potency of Oral Transmucosal Fentanyl Citrate Compared with Intravenous Morphine in the Treatment of Moderate to Severe Postoperative Pain*, *Anesth Analg* 1999; 89:732–8 at p. 736 (Exhibit 1011), viii) US Patent Application No. 20030178031 at paragraph [0360] (Exhibit 1016), and ix) U.S. Patent No. 8,889,176 (“the ‘176 Patent”) (Exhibit 1006).

C. Legal Standards

9. In my opinion, given the disclosure of the ’460 Patent, I consider a person of ordinary skill in the art at the time of filing of the patent 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 '460 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.

I have been told a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Further, I have been told if the prior art discloses its own range,

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