Exhibit 1009

DECLARATION OF MATTHEW W. DAVIS M.D. RPH.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes Review*	:	PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,315,720 UNDER 35 USC §§ 311-319 AND 37 CFR §42.100 ET SEQ.
Case No.	:	To be Assigned
Petitioner	:	To be Named
Filed	:	
Attorney Docket No.	:	
Customer No.	:	27571

Appeal Related Matters

Patent Trial and Appeal Board

US Patent and Trademark Office

PO Box 1450

Alexandria, Virginia 22313-1450

DECLARATION OF MATTHEW W. DAVIS M.D. R.Ph.

Sir:

I, the undersigned, hereby declare the following, based on my own knowledge, information, and belief:

1. I am presently Senior Vice President of Clinical Operations and Development at Sun Pharmaceuticals.

2. I received an M.D. degree from the Medical College of Pennsylvania in 1994 and a B.S. in Pharmacy from Temple University School of Pharmacy. I did an internship in surgery, followed by a residency in urology. I am a registered pharmacist, R.Ph, as well as a licensed physician.

3. Since 1998, I have directed clinical development and medical affairs at a number of different companies. These companies include, Endo Pharmaceuticals, Dermik Laboratories, Dr. Reddy's Laboratories, Eisai Global Research and most recently, URL Pharma, now Sun Pharmaceuticals.

4. I have co-authored 20 articles in peer reviewed scientific and medical journals. I am the sole inventor of 17 U.S. patents, named inventor on numerous other patents and patent applications. A copy of my resume is attached.

5. I have reviewed U.S. Patent No. 6,315,720, its file history as well as the prior art cited in the Petition: (i) Powell et al. (Postgrad. Med. J. 70:901 (1994),

("Powell"), *Exhibit 1002*); (ii) Dishman et al. (Am. J. Hosp. Pharm 51: 899 (1994), ("Dishman"), *Exhibit 1003*); (iii) Bastani et al. (Psychopharmacology 99:S122 (1989), (Bastani"), *Exhibit 1004*); (iv) Mitchell et al. (New England J. Med. 333(2):101 (1995), ("Mitchell"), *Exhibit 1007*); (v) Honigfeld (Psychiatric Services 47:52 (1996), ("Honigfeld"), *Exhibit 1008*); (vi) the 47th Meeting of the Dermatologic and Ophthalmic Advisory Board (September 4-5, 1997, (the "FDA Meeting"), *Exhibit 1005 (a) and (b))*; and (ix) CDC Meeting (Centers for Disease Control, Preventing Birth Defects, March 26, 1997, (the "CDC Meeting"), *Exhibit 1006*).

6. The medical community was acutely aware of the need to put in-place a program for tightly controlling the distribution of drugs causing adverse side effects. In fact, there were numerous drug dispensing and restriction programs in place in the mid to late 1990's, including: (i) restricted distribution (Fentanyl, Oralet); (ii) limited quantity (Clozaril); (iii) consent (Accutane, Felbatol); (iv) laboratory testing (Clozaril/ requiring a white blood count); (v) registry (AZT, Acyclovir); and, (vi) patient/provider education (Accutane). *Exhibit 1006 at* 8. I found the following statements from FDA and CDC meetings held in 1997 especially informative.

7. Dr. Bergfeld recommended the system (STEPS) "What I would like to recommend is that registry for the physician include that they have signed off on an informed consent that they have been informed about the information, they have read it, and they agree to participate in that manner. " Dr. Williams then responded, "[t]hat is reasonable." (*Exhibit 1005(a) at* 121).

8. Dr. Woodcock from the FDA stated "the need to impose a mandatory restriction, under regulation, depends on our judgment of whether that is necessary to ensure the safety of the product. So, it really depends on how safe we feel the safety would be under a voluntary system or whatever safety is available compared to the need for additional safety that would merit, that would require for approval a restricted distribution." (*Exhibit 1005(a) at* 220).

9. Finally, Dr. Williams stated that, "[t]he other thing is that the way the system is being developed, it would be designed to utilize some of the systems that are currently in place within pharmacy practice where there are central computer databases that pharmacists log in and out on when they are filling prescriptions. A portion of one of those databases will be carved out to actually have the pharmacist tracking and recording information on this patient so that we'd be in a position to

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