Exhibit 1007

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. 6,045,501 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, 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 pharmacist, R.Ph, as well as a licensed physician.

3. Since 1998, I have directed clinical development, medical affairs and pharmacovigilance 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. 6,045,501, its file history as well as the prior art cited in the Petition: (i) Dishman et al. (Am. J. Hosp. Pharm 51: 899

(1994), ("Dishman"), *Exhibit 1004*); (ii) Bastani et al. (Psychopharmacology 99:S122 (1989), (Bastani"), *Exhibit 1005*); (iii) Powell et al. (Postgrad. Med. J. 70:901 (1994), ("Powell"), *Exhibit 1006*); (iv) Mitchell et al. (New England J. Med. 333(2):101 (1995), ("Mitchell"), *Exhibit 1008*); (v) Honigfeld (Psychiatric Services 47:52 (1996), ("Honigfeld") (*Exhibit 1009*); (vi) the 47th Meeting of the Dermatologic and Ophthalmic Advisory Board (September 4-5, 1997, (the "FDA Meeting"), *Exhibit 1010 (a) and (b)*; and (vii) CDC Meeting (Centers for Disease Control, Preventing Birth Defects, March 26, 1997, (*Exhibit 1011*) (the "CDC Meeting")).

6. Dishman discloses a program instituted by the Department of Veterans Affairs (VA) for controlling the dispensing of an antipsychotic drug, clozapine. *Exhibit 1004*, Abstract. Because clozapine treatment is associated with a number of serious and potentially fatal serious side effects, its use needs to be tightly controlled. *Exhibit 1005 at* S122. In 1994, the VA developed a clozapine monitoring program. *Exhibit 1004 at* 900. A National Clozapine Coordinating Center (NCCC) was established. *Id.* The NCCC required that each hospital have a computerized clozapine prescription lockout system, which ties the hospital's laboratory database to the outpatient pharmacy dispensing software. *Id.* The program only allows clozapine prescriptions to be processed when the white blood

cell counts are within defined limits, i.e., when certain pre-defined clinical criteria are met. *Id.* The NCCC guidelines require extensive patient evaluation and documentation. In order to receive clozapine, the patients have to undergo a complete physical examination, including laboratory tests. *Id.* Patients are screened by the pharmacist to determine eligibility for treatment with clozapine. *Id.* The pharmacist then sends the information to the NCCC and after approval, the patient is then enrolled in the hospital's clozapine tracking system and therapy is begun. *Id.* In other words, the clozapine monitoring system in the VA, provides for (i) "registration into one or more computer readable storage media of the prescriber, pharmacy and patient"; (ii) "a means to monitor and authorize distribution of contraindicated drugs, including teratogenic drugs"; and (iii) denial of "dispension or prescriptions of contraindicated drugs, including teratogenic drugs, to patients, pharmacies or prescribers who fail to abide by the methods of the present invention". *Exhibit 1001 at* 10:13-20. A similar clozapine monitoring system has been instituted at numerous other hospitals throughout the U.S., for example, see the Clozaril Patient Management System (CPMS), *Exhibit 1005*. The CPMS program provides for extensive counseling of patients, including meetings with physicians, psychiatric research technicians and supportive group therapy. *Id. at* S123.

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