Exhibit 1004

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, 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. 6,315,720, its file history as well as the prior art cited in the Petition: (i) the THALOMID™ (thalidomide) Capsules

Revised Package Insert (15 July 1998), as appended to the "Thalomid Capsules (Celgene) 07/16/1998 Approval [Erythema Nodosum Leprosum: Approval Letter; Final Labeling; Supervisory Review" dated July 17, 1998, ("Thalomid PI" or "PI"), *Exhibit 1002*; and (ii) Keravich et al. (Am. J. Health-Syst. Pharm. 56: 1721 (1999), ("Keravich"), *Exhibit 1003*.

6. The Thalomid PI was approved as of the date of the Approval Letter, July 16, 1998, and was published on that date on the FDA's website at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory. It is common practice to look for pertinent drug approval information and labeling on this FDA website, drugs@fda.gov.

7. The Thalomid PI clearly sets forth "a method for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug" as claimed in the '720 patent. First, the PI includes "Indications and Usage" of the drug, and "Dosage and Administration". *Exhibit 1002,* at 8, 18. It describes risks of severe and life-threatening side effects and birth defects throughout. *Id.* at 1-2. It defines certain patient risk groups, female patients of childbearing age, and male patients capable of impregnating women, requires written informed consent and pregnancy testing,

counseling, and registration of patients, physicians, and pharmacists in the "S.T.E.P.S." program prior to prescribing the drug. *Id.* at 2-4, 20-21. The PI describes the risks associated with the drug, specifically, the Contraindications, Warnings and Precautions, which include precautions for "Drug Interactions" (the potential for thalidomide to interact with or affect the activity or sensitivity of other drugs the patient is taking or may be prescribed). *Id.* at 9-14. The S.T.E.P.S. program makes it clear that certain diagnostic testing is required prior to registration in the program, importantly, pregnancy testing (a form of genetic testing). *Id.* at 3. It is also clear from the nature of the potential side effects of thalidomide (as set forth in the Contraindications, Warnings, and Precautions sections of the PI), that other diagnostic testing would likely be required of patients prior to prescribing the drug. *Id.* at 9-14.

8. Keravich, which explains the S.T.E.P.S. program that is part of the Thalomid PI, describes the computerized database maintained by Celgene that requires prescriber, pharmacy and patient registration as part of the program. *Exhibit 1003* at 1721. At the time the S.T.E.P.S. program was put in place, the use of more advanced computerized systems for storing patient medical histories and records were in place, and methods of transmitting patient information to and from doctor's offices to pharmacies were also available. These included the use of

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