IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENDO PHARMACEUTICALS INC., Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 1:12-cv-01936 (RBW)

DECLARATION OF JULIE H. MCHUGH IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

I, JULIE H. MCHUGH, hereby declare under penalty of perjury as follows:

1. I am a citizen and resident of the Commonwealth of Pennsylvania, I am over the age of 21 years, and I suffer from no mental or physical infirmities that would render me incompetent to testify in this matter. I have personal knowledge of matters set forth in this declaration, and I have reviewed records maintained by Endo Pharmaceuticals Inc. ("Endo") in the ordinary course of business and data referenced herein are drawn from reliable and authoritative sources.

2. I was appointed Chief Operating Officer of Endo in March 2010. Prior to joining Endo, I was the CEO of Nora Therapeutics, Inc., and before that I was Company Group Chairman for Johnson & Johnson's Worldwide Virology Business Unit.

3. I received a Bachelor of Science degree from Pennsylvania State University and my masters of business administration degree from St. Joseph's University. I currently serve on the Board of Directors of Viro Pharma Inc., the Board of Directors of the Biotechnology Organization (BIO), the Board of Directors of the New England Healthcare Institute (NEHI), the

Board of Visitors for the Smeal College of Business of the Pennsylvania State University, and the Board of Directors for the Nathaniel Adamczyk Foundation.

4. Endo earns its revenues primarily from the sale of four drugs: Lidoderm, Opana® extended release ("ER") crush resistant formulation ("CRF"), Voltaren gel, and Percocet. Of these four drugs, sales of Opana® ER CRF are second only to Lidoderm in the revenues the drugs generate.

5. I estimate that Endo has invested more than $125 million to develop and market Opana® ER CRF. A summary of this estimate is attached as Exhibit A to this Declaration. (For a number of categories of costs included in this estimate, I have included only expenses incurred in 2012 because Endo did not always differentiate between costs relating to Original Formulation Opana® ER and those relating to Opana® ER CRF). In addition to this $125 million investment estimate, over the 5 year period from 2007 through 2011, Endo had, on average, 16 full time employees devoting approximately one quarter of their time to development of Opana® ER CRF.

6. If FDA waits until May 10, 2013 to make its withdrawn-for-safety determination (even assuming it agrees that original formulation Opana® ER was withdrawn for safety reasons), and Impax enters the market with generic non-crush resistant oxymorphone extended release tablets on January 1, 2013, Endo projects that Opana® ER CRF annualized net sales will decrease by an amount up to $135 million. This estimate of lost sales is based on standard generic erosion rates and marketplace dynamics.

7. Were Endo to suffer a net sales decrease by an amount up to $135 million Endo would be forced to reduce its marketing, sales, and research and development staff. These changes could result in the termination of up to 150 employees and contractors employed by Endo. A decrease in net sales of this magnitude would also result in the significant scaling back

or abandonment of ongoing research and development of new drugs, including development of (a) compounds for palliative and curative treatment of serious medical conditions such as prostate cancer and (b) tamper resistant formulations of other currently available long and short acting opioids.

8. A net sales decrease by an amount up to $135 million as well as the resulting effect on employees and reduction in loss of research and development and loss of resources devoted to CRF over more than 5 years would cause significant hardship to Endo.

9. If Impax enters the market with generic non-crush resistant oxymorphone extended release tablets on January 1, 2013, it is projected—based on standard generic erosion models—that Impax will garner a significant share of Endo's Opana® ER CRF market share. Based on current prescription volumes, this market entry on or soon after January 1, 2013, will result in a roughly tenfold increase in the number of easily crushable generic Opana® ER pills in the marketplace raising that number from the approximately 4.5 million pills (Actavis' generic low dose 7.5mg and 15mg pills 2012 projected distribution) to 50 million or more pills with dosages as high as 40mg (projected 2013 oxymorphone er generic distribution).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief. Due to illness I am unable to sign this declaration by hand; my electronic signature is provided.

Executed on this fourteenth day of December, 2012.

Julie H. McHugh
Chief Operating Officer

EXHIBIT A

Opana ER CRF Investment

Marketing (1)	19,362,442
Less Rare Tablet Items(1)	(3,134,900)
Market Research/BI(1)	868,096
Managed Markets(1)	1,851,824
Selling(2)	30,828,672
Allocated Marketing Costs(1)	10,985,067
R&D 2007-2012	19,914,716
NDA Milestones 2007-2012	43,012,740
Health Care Reform Fee (2)	1,947,827
Total	125,636,483

(1) All incurred or planned for in 2012
(2) Q2 thru Q4 2012