ENDO PHARMACEUTICALS HOLDINGS INC
Form 8-K
September 05, 2001

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 5, 2001
(September 4, 2001)

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

DELAWARE	39040	13-4022871
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

100 Painters Drive Chadds Ford, Pennsylvania	19317
(Address of principal executive offices)	(Zip Code)

(610) 558-9800

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Item 5. Other Events.

On September 4, 2001, the Registrant issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 7. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

Not applicable

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on September 4, 2001

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

By: /S/ CAROL A. AMMON

Name: Carol A. Ammon
Title: President & Chief Executive Officer

Dated: September 5, 2001

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Endo Pharmaceuticals Holdings Inc. on September 4, 2001

Exhibit 99.1

Contact: Robert Siegfried/Jeremy Fielding
Kekst and Company
212-521-4800

ENDO PHARMACEUTICALS CHALLENGES THE PURDUE FREDERICK COMPANY'S OXYCONTIN(R)(OXYCODONE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 80 mg) PATENTS

Chadds Ford, PA, September 4, 2001 - Endo Pharmaceuticals Holdings Inc. (NASDAQ: ENDP and ENDPW), a fully integrated, specialty pharmaceutical company with market leadership in pain management, announced today that, on August 30, 2001, The Purdue Frederick Company (and related companies, "Purdue") filed suit against Endo Pharmaceuticals Holdings Inc. and its subsidiary, Endo Pharmaceuticals Inc., in the U.S. District Court for the Southern District of New York alleging that Endo Pharmaceuticals Inc.'s bioequivalent version of Purdue's OxyContin(R), 80 mg strength, infringes three of its patents. This is the third suit filed by Purdue against Endo relating to Endo Pharmaceuticals Inc.'s bioequivalent versions of Purdue's OxyContin(R).

The first suit was filed on October 20, 2000 after Purdue was informed that the United States Food and Drug Administration (FDA) accepted Endo Pharmaceuticals Inc.'s Abbreviated New Drug Application (ANDA) submission, including the required Paragraph IV certification, for a bioequivalent version of Purdue Frederick's OxyContin(R), 40 mg strength. The second suit was filed on March 13, 2001 after Purdue was informed that on February 9, 2001, Endo Pharmaceuticals Inc. amended this ANDA to add bioequivalent versions of the 10 mg and 20 mg strengths of OxyContin(R). On July 30, 2001, Endo Pharmaceuticals Inc. amended this ANDA again to add the bioequivalent version of the 80 mg strength of OxyContin(R), which is the subject of the third suit.

OxyContin(R) is indicated for the treatment of moderate-to-severe pain. Although Endo believes the patents asserted by Purdue are invalid and/or not infringed, no assurance can be given as to the outcome of the patent challenge process.

Carol A. Ammon, Endo's President and Chief Executive Officer, said, "Endo is very pleased to have amended its ANDA to add the 80 mg strength of oxycodone hydrochloride extended-release tablets. Endo now has an ANDA on file with the FDA for every strength of OxyContin(R) presently available. This litigation with Purdue Frederick highlights Endo's continued commitment to expanding its portfolio of pain management products. As with the 10 mg, 20 mg and 40 mg lawsuits, we are prepared to vigorously defend our position in this litigation."

Endo, through its wholly owned subsidiaries Endo Pharmaceuticals Inc. and Endo Inc., is a fully integrated specialty pharmaceutical company with market leadership in pain management. The company is engaged in the research, development, sales and marketing of both branded and generic pharmaceutical products primarily for the treatment of pain. Endo has a portfolio of thirteen branded products that includes established brands such as Percocet(R) and Percodan(R), opioid analgesics that treat moderate-to-severe pain.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking and are subject to risks and uncertainties. As a result of such risks and uncertainties, which include, but are not limited to, the difficulty of predicting FDA approvals, risks with respect to technology and product development, the effect of competing products and prices, uncertainties regarding intellectual property protection, uncertainties as to the outcome of litigation, changes in operating results and other risks discussed from time to time in Endo's filings with the Securities and Exchange Commission, actual results may differ materially from those expressed or implied by such forward-looking statements.

# # #