TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 17, 2005

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a 16 or 15d 16

under the Securities Exchange Act of 1934

For the month of May 2005

Commission File Number 0-16174

- 1 -

Teva Pharmaceutical Industries Limited

(Translation of registrant's name into English)

5 Basel Street, P.O. Box 3190

Petach Tikva 49131 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F X Form 40-F _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes _____ No X

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b): 82-_____

Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

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TEVA'S FENOFIBRATE PRODUCT RECEIVES FINAL APPROVAL; SEEKS THREE TIMES ITS LOST PROFITS IN ANTITRUST LAWSUIT AGAINST ABBOTT

Jerusalem, Israel, May 16, 2005 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration has granted final approval for the Company's ANDA for Fenofibrate Tablets, 54 mg and 160 mg.

Fenofibrate Tablets are the AB-rated generic equivalent of Abbott's Tricor&reg Tablets. This product is indicated for the treatment of hypercholesterolemia and hypertriglyceridemia.

Today's approval follows a ruling at the U.S. District Court for the District of Delaware, which granted summary judgment of non-infringement in favor of Teva on certain patent claims at issue. The Court ruled that Teva's ANDA for Fenofibrate Tablets, which was made under Paragraph IV of the Hatch-Waxman Act, does not infringe U.S. Patent Nos. 6,589,552 and 6,074,670, and one claim of U.S. Patent No. 6,277,405.

The FDA had initially granted tentative approval of Teva's ANDA in March 2004. At that time, Teva was subject to a second 30-month stay with respect to U.S. Patent No. 6,589,552, which Teva has now been found to not infringe. The court has yet to rule on certain claims relating to U.S. Patent Nos. 6,277,405 and 6,652,881. A trial on these two patents is scheduled for June 6, 2005.

Abbott is no longer marketing the 54 mg and 160 mg strength tablets, having converted its Tricor&reg product to 48 mg and 154 mg strength tablets during the pendency of the patent litigation and second 30-month stay. This is the second such market conversion undertaken by Abbott on Fenofibrate. Prior to this conversion, annual brand sales of the product were approximately $800 million.

In late 2001, Abbott began to convert the previous market for Fenofibrate Capsules to the 54 mg and 160 mg Fenofibrate Tablet products. At that time, Teva had an ANDA pending for Fenofibrate Capsules. Teva received FDA approval to market a generic capsule product following summary judgment on all Orange Book patents, but only after Abbott had ceased sales of its capsule products and had taken steps to frustrate Teva's ability to fully commercialize that product as a generic.

Shortly following Abbott's announcement last year that it was planning to switch the market to a different tablet formulation, Teva filed a motion to amend its answer to assert antitrust counterclaims against Abbott, contending that Abbott's actions have frustrated generic competition in Fenofibrate products through a combination of two market conversions and the gaming of the Hatch-Waxman Act, denying consumers access to a generic alternative to Abbott's products. Teva is seeking triple damages, including lost profits and attorneys' fees, as provided for under the antitrust laws.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva`s sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management`s current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva`s future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include Teva`s ability to successfully develop and commercialize

additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone&reg sales, Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind
Title: Chief Financial Officer

Date: May 16, 2005