

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
July 31, 2003

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 July 2003

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):

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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-_____

____(2)____

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

Contact: Dan Suesskind

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Teva Pharmaceutical Industries Ltd
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Bill Fletcher
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FOR IMMEDIATE RELEASE

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**TEVA SIGNS AGREEMENT WITH ANDRX AND IMPAX FOR GENERIC FORMULATIONS OF
WELLBUTRIN[®] SR AND ZYBAN[®]**

Jerusalem, Israel, July 31, 2003 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that one of its subsidiaries has entered into an exclusivity transfer agreement with Andrx Corporation (NASDAQ:ADRX) and IMPAX Laboratories, Inc. (NASDAQ NM:IPXL) pertaining to pending Abbreviated New Drug Applications (ANDAs) for bioequivalent versions of Wellbutrin[®] SR and Zyban[®] (Bupropion Hydrochloride) 100 mg and 150 mg Extended Release Tablets filed by Andrx, as well as by IMPAX. Pursuant to Teva's existing strategic alliance agreement with IMPAX, Teva has U.S. marketing rights to IMPAX's versions of these products. Wellbutrin[®] SR and Zyban[®] (GlaxoSmithKline products) had U.S. sales of over \$1.6 billion for the twelve-month period ended March 31, 2003 according to IMS.

FOR IMMEDIATE RELEASE

The parties believe that the Andrx ANDAs for the products are entitled, under the Hatch-Waxman Act, to an 180-day period of marketing exclusivity. Under the exclusivity transfer agreement, Andrx will continue to seek approval of its ANDAs. The agreement provides, among other things, that if Andrx is unable to launch its own products within a defined period of time, and IMPAX is able to market its products, Andrx will enable IMPAX to launch its own products. IMPAX would then launch its products through Teva, with the parties sharing certain payments with Andrx relating to the sale of the products for a 180-day period. Should Andrx launch its own products prior to IMPAX launching its products, Andrx will share with Teva and IMPAX certain payments for a 180-day period.

Mr. Israel Makov, President and CEO of Teva, said: "We are pleased to enter into this agreement with Andrx and IMPAX. We believe that this agreement will facilitate the introduction of these important treatments at lower prices at the earliest possible time."

Andrx and IMPAX have both obtained favorable summary judgment decisions that their formulations of the products do not infringe GlaxoSmithKline's patents. GlaxoSmithKline, however, has appealed both decisions.

The transactions contemplated by the exclusivity transfer agreement are subject to obtaining all necessary government approvals.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 30 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Close to 90% of Teva's sales are in North America and Europe. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients.

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 current 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 their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, the availability of product liability coverage in the current insurance market, 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 ("FDA") and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, 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 ("SEC"). 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

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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: July 31, 2003

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