TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
February 02, 2004

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 February 2004

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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FOR IMMEDIATE RELEASE

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TEVA COMMENTS ON THE COURT OF APPEALS DECISION REGARDING

MOEXIPRIL

Jerusalem, Israel, January 30, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the United States Court of Appeals for the Federal Circuit has vacated a March 24, 2003 summary judgment decision by the U.S. District Court for the District of New Jersey, which had found that Teva`s product, Moexipril HCl Tablets would not infringe U.S. Patent No. 4,743,450, asserted by Schwarz Pharma as licensee of Warner Lambert. The Court of Appeals has remanded the case to the District Court for further proceedings, which will involve Teva`s allegations of inequitable conduct, invalidity, and non-infringement.

Moexipril HCl Tablets are the AB-rated generic equivalents of Schwarz Pharma`s antihypertensive agent Univasc &reg Tablets. Annual sales of the brand and generic product through September 2003 were a combined $58.6 million. The U.S. Food and Drug Administration approved Teva`s ANDA for Moexipril HCl Tablets, 7.5 mg and 15 mg on May 8, 2003. As the first company to file an ANDA with a Paragraph IV patent certification. for Moexipril HCl

Tablets, Teva received 180 days marketing exclusivity for this product from the date of the summary judgment decision. Teva began commercially shipping the product in May 2003.

Yesterday`s ruling construes the scope of the `450 patent more broadly and, in Teva`s opinion, may enhance its invalidity and inequitable conduct arguments. The Company plans to continue selling its Moexipril product.

Warner Lambert has asserted this same patent against Teva in the same court in connection with Teva`s ANDA for Quinapril HCl Tablets. In that case, the Court issued a summary judgment decision dated October 2, 2003, in which it found that an important piece of prior art was highly material and was not disclosed to the Patent Office. The Court reserved decision as to whether the patent is unenforceable due to inequitable conduct pending a trial, which is expected sometime this year. As in the Moexipril case, the Company believes that yesterday`s ruling will provide additional support to its inequitable conduct and invalidity arguments.

Quinapril HCl Tablets are the AB-rated generic equivalents of Parke Davis` antihypertensive agent Accupril&reg Tablets. Annual sales of the brand product through September 2003 were $595 million. The FDA granted final approval for Teva`s ANDA for Quinapril HCl Tablets, 5 mg, 10 mg, 20 mg and 40 mg on June 2, 2003 and awarded the Company 180 days marketing exclusivity for being first company to file an ANDA with a Paragraph IV patent certification.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 30 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 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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Director, Investor Relations
Teva Pharmaceutical Industries Ltd
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FOR IMMEDIATE RELEASE

TEVA TO REPORT FOURTH QUARTER 2003 FINANCIAL RESULTS ON

February 17, 2004

CONFERENCE CALL SCHEDULED FOR 09:00 AM EST

Jerusalem, Israel, February 1, 2004 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that it will release its fourth quarter and full year 2003 financial results on Tuesday, February 17, 2004, early in the morning (EST). The earnings release will be available on Teva`s web site at www.tevapharm.com.

Teva will host a conference call and live webcast on that same day, at 09:00AM EST to discuss its fourth quarter results and overall business environment. A Question & Answer session will follow this discussion.

As announced on January 22, 2004, Teva has completed its acquisition of Sicor and Sicor's financial results will be consolidated into Teva's for the first time in Q1/04. Teva plans to provide guidance for the company's 2004 financial results, including Sicor, at that time.

Investors and other interested parties may access a live webcast through Teva`s web site at www.tevapharm.com. Please log in at least 10 minutes prior to the conference call in order to download the applicable audio software. Following the conclusion of the call, a replay of the webcast will be available within 24 hours at the Company`s web site. Alternatively, a replay of the call can be accessed until February 24, 2004 at midnight (EST), by calling (800) 642-1687 in the U.S. or (706) 645-9291 outside the U.S. The Pass Code to access the replay is: 5316033.

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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: February 2, 2004