TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
October 19, 2009

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 October 2009

Commission File Number 0-16174

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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www.tevapharm.com

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TEVA COMMENTS ON MYLAN PARAGRAPH IV FILING FOR COPAXONE® FILES LAWSUIT AGAINST GENERIC FILER FOR PATENT INFRINGEMENT

Market-Leading Multiple Sclerosis Therapy Presents Significant Legal, Regulatory and Technical Challenges for Generic Filers

Jerusalem, Israel, October 16, 2009 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) commented today on the abbreviated new drug application (ANDA) containing a Paragraph IV certification for COPAXONE&reg (glatiramer acetate injection), filed by Mylan Pharmaceuticals Inc. Teva also announced that it has filed a lawsuit against Mylan Pharmaceuticals, Inc., Mylan Inc. and Natco Pharma Ltd. for patent infringement in the U.S. District Court for the Southern District of New York.

Mylan`s filing of a purported generic version of COPAXONE&reg was not unexpected, as the company announced its intention over a year ago. Teva received Mylan`s Paragraph IV certification notice referring to Teva's U.S. Patents, which cover the chemical composition of COPAXONE&reg, pharmaceutical compositions containing it, and methods of using it. These patents are listed in the U.S. Food and Drug Administration's (FDA) Orange Book and extend through May 24, 2014.

Teva remains committed to vigorously defending its COPAXONE&reg intellectual property rights against infringement wherever they are challenged and intends to pursue all relevant regulatory avenues via the FDA. Teva`s lawsuit has been filed within the 45-day period provided under the Hatch-Waxman legislation. The lawsuit triggers a stay of FDA approval for the Mylan ANDA until the earlier of the expiration of a period of 30 months and a district court decision in its favor, and is also subject to the expiration of any exclusivity rights that may attach to earlier filed ANDAs.

COPAXONE&reg is a highly-complicated product to develop and manufacture, and given the inability to fully characterize the active ingredients of COPAXONE&reg, Teva has serious doubts about any generic applicant`s ability to demonstrate conclusively that the composition of its product is identical to that of COPAXONE&reg.

Teva contends that any company that files an application for any glatiramoid substance, via an ANDA or 505(b)(2) application, should conduct full-scale, placebo-controlled clinical trials with measured clinical endpoints in MS patients to establish safety, efficacy and immunogenicity in this patient population. Internal research at Teva has indicated that even minor changes in the synthetic process and/or molecular weight distribution of a glatiramoid can have severe ramifications on the safety and mechanism of action of the product.

In July 2008, Teva received a Paragraph IV certification notice from first-to-file Momenta Pharmaceuticals, Inc./Sandoz Inc. relating to their ANDA containing a Paragraph IV certification for COPAXONE&reg. On August 28, 2008, Teva filed a lawsuit in the U.S. District Court for the Southern District of New York with respect to Momenta's filing. A trial date has not been set.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent 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 our 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 risks relating to: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin&reg, Lotrel&reg and Protonix&reg, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone&reg sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results though our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent

litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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

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/ Eyal Desheh

Name: Eyal Desheh
Title: Chief Financial Officer

Date October 19, 2009

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