

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
November 10, 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 November 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): \_\_\_\_\_

[www.tevapharm.com](http://www.tevapharm.com)

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**TEVA FILES AMENDED COMPLAINT AGAINST MOMENTA/SANDOZ TO INCLUDE  
INFRINGEMENT OF THREE COPAXONE<sup>®</sup>-RELATED PATENTS**

Jerusalem, Israel, November 10, 2009 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today it is seeking to amend its existing complaint against Momenta Pharmaceuticals, Inc./Sandoz Inc. to include patent infringement of three additional patents related to the characterization of COPAXONE<sup>®</sup> (glatiramer acetate injection). The proposed updated complaint has been filed under seal with the U.S. District Court for the Southern District of New York along with a motion requesting that the Court grant Teva leave to amend.

Teva originally filed suit against Momenta/Sandoz in August 2008 for infringement of multiple patents (seven in the Orange Book which extend through May 24, 2014), covering the chemical composition of COPAXONE<sup>®</sup>, pharmaceutical compositions containing it and methods of using it. Teva seeks leave to amend its complaint to include the additional patents related to the characterization of the active ingredient in COPAXONE<sup>®</sup>. These patents do not expire until several years after the patents currently in litigation.

COPAXONE<sup>®</sup> is a highly-complicated product to develop and manufacture, and given the inability to fully characterize the active ingredients of COPAXONE<sup>®</sup>, 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<sup>®</sup>. Internal research at Teva has indicated that even minor changes in the synthetic process and/or molecular weight distribution of a glatiramoid (glatiramir acetate-like substance) can have severe ramifications on the safety and mechanism of action of the product.

Teva contends that any company that files an application for any glatiramoid, via an ANDA or 505(b)(2) application, should conduct pre-clinical testing as well as full-scale, placebo-controlled clinical trials with measured clinical endpoints in MS patients to establish safety, efficacy and immunogenicity in this patient population.

Teva remains committed to vigorously defending its COPAXONE<sup>®</sup> intellectual property rights against infringement wherever they are challenged and intends to pursue all relevant regulatory avenues via the U.S. Food and Drug

Administration (FDA). In September 2009, Teva received a Paragraph IV certification notice from Mylan Pharmaceuticals Inc./Natco Pharma Ltd. relating to their ANDA containing a Paragraph IV certification for COPAXONE<sup>®</sup>. On October 16, 2009, Teva filed a lawsuit in the U.S. District Court for the Southern District Court of New York with respect to Mylan's filing. A trial date has not been set.

## About Teva

Teva Pharmaceutical Industries Ltd. 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.

## Teva's 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<sup>®</sup>, Lotrel<sup>®</sup>, Protonix<sup>®</sup> and Eloxatin<sup>®</sup>, 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<sup>®</sup> 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 through 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](http://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 November 10, 2009

