

MEDICIS PHARMACEUTICAL CORP
Form 8-K
November 25, 2009

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 8-K
CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

November 24, 2009

Date of Report (Date of earliest event reported)

Medicis Pharmaceutical Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

001-14471
(Commission File Number)

52-1574808
(IRS Employer
Identification Number)

7720 North Dobson Road
Scottsdale, Arizona 85256
(Address of principal executive offices) (Zip Code)

(602) 808-8800
(Registrant's telephone number, including area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

The Company Receives a Paragraph IV Patent Certification

On November 24, 2009, Medicis Pharmaceutical Corporation (the Company) received a Paragraph IV Patent Certification from Lupin Ltd. (Lupin), advising that Lupin has filed a supplement to its earlier filed Abbreviated New Drug Application (ANDA) assigned ANDA number 91-424 (ANDA Supplement) with the U.S. Food and Drug Administration (FDA) for generic SOLODYN in its form of 65mg strength. Lupin has not advised the Company as to the timing or status of the FDA's review of its filing, or whether Lupin has complied with FDA requirements for proving bioequivalence. Lupin's Paragraph IV Certification alleges that the Company's U.S. Patent No. 5,908,838 (the 838 Patent) is invalid and/or will not be infringed by Lupin's manufacture, use, sale and/or importation of the products for which the ANDA Supplement was submitted. The expiration date for the 838 Patent is in 2018. The Company is evaluating the details of Lupin's certification letter and considering its options. Lupin's submission amends an ANDA already subject to a 30-month stay. As such, the Company believes that the amendment cannot be approved by the FDA until after the expiration of the 30-month period or a court decision that the patent is invalid or not infringed.

The Company Files a Request for Continued Examination with the USPTO

On November 25, 2009, the Company filed a Request for Continued Examination (RCE) with the U.S. Patent and Trademark Office (USPTO) in U.S. Patent Application No. 11/166,817 (the 817 Application) so that the USPTO could consider references recently filed in the Reexamination of U.S. Patent No. 5,908,838, and in accordance with the Company's ongoing obligation to advise the USPTO of any references that could be deemed by the examiner to be material.

The Company Files a Terminal Disclaimer in Response to the Non-Final Office Action from the USPTO

On November 17, 2009, the Company received a non-final office action from the U.S. Patent and Trademark Office (USPTO) in U.S. Patent Application No. 12/253,845 (the 845 Application) in which the sole basis for rejection could be overcome by the filing of the Terminal Disclaimer. In response, the Company filed a Terminal Disclaimer with the USPTO on November 25, 2009. The Terminal Disclaimer has the effect of making the expiration dates of the 845 Application and the related 817 Application the same. A Terminal Disclaimer is routinely accepted by the USPTO.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 25, 2009

By: /s/ Jason D. Hanson
Jason D. Hanson
Executive Vice President, General Counsel and
Corporate
Secretary