MEDICINES CO /DE
Form 8-K
January 23, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

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FORM 8 K
CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of report (Date of earliest event reported): January 22, 2012

The Medicines Company
(Exact Name of Registrant as Specified in Charter)

Delaware	000-31191	04-3324394
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8 Sylvan Way Parsippany, New Jersey (Address of Principal Executive Offices)	07054 (Zip Code)

Registrant's telephone number, including area code: (973) 290-6000

(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 (see General Instruction A.2. below):
o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry Into a Material Definitive Agreement

On January 22, 2012, The Medicines Company (the "Company") and APP Pharmaceuticals, LLC and an affiliate ("APP") entered into a Settlement Agreement (the "Settlement Agreement") and a License Agreement (the "License Agreement", and together with the Settlement Agreement, the "Settlement Documents"). The Settlement Documents relate to The Medicines Company v. APP Pharmaceuticals, LLC., et al., an action for patent infringement in the U.S. District Court for the District of Delaware (the “ANDA Litigation”), and The Medicines Company v. Kappos, et al., an appeal before the U.S. Court of Appeals for the Federal Circuit relating to the August 2010 federal district court decision holding that the Company's application for Hatch Waxman patent term extension of the Angiomax composition of matter patent, U.S. Patent No. 5,196,404 (the “'404 patent”), was timely filed (the “Pending Appeal”, and together with the ANDA Litigation, the "Pending Litigations").

In the ANDA Litigation, the Company alleges that the Abbreviated New Drug Application (“ANDA”) for generic bivalirudin for injection filed by APP with the U.S. Food and Drug Administration (“FDA”) infringes U.S. Patent Nos. 7,582,727 and 7,598,343 (the "Litigated Patents"), two patents of the Company that cover bivalirudin for injection. The Litigated Patents are currently due to expire on July 27, 2028. The Company markets and sells a branded bivalirudin for injection product in the United States under the name Angiomax® (bivalirudin).

Regarding the Pending Appeal, in the first quarter of 2010, the Company filed suit against the U.S. Patent and Trademark Office (“PTO”), the FDA and the U.S. Department of Health and Human Services (“HHS”) seeking to set aside the PTO's denial of the Company's application to extend the patent term of the '404 patent. On August 3, 2010, the U.S. Federal District Court for the Eastern District of Virginia ordered the PTO to consider the Company's patent term extension application timely filed. The period for the government to appeal the court's August 3, 2010 decision expired without government appeal. However, on August 19, 2010, APP filed a motion to intervene for the purpose of appeal in the Company's case against the PTO, the FDA and HHS. On September 13, 2010, the federal district court denied APP's motion. APP appealed the denial of its motion, as well as the federal district court's August 3, 2010 order (and all related and underlying orders), to the U.S. Court of Appeals for the Federal Circuit.

Contemporaneously with entering into the Settlement Documents, the Company and APP entered into the following agreements:

- a Contract Manufacturing Agreement (the “Fill-Finish Manufacturing Agreement”) under which APP has agreed to manufacture and supply Angiomax finished product to the Company,
- a License and Supply Agreement (the “APP Generic Product License and Supply Agreement”) under which APP has agreed to license and supply to the Company a portfolio of ten generic products, and
- an AG Supply Agreement (the "AG Supply Agreement", and collectively with the Fill-Finish Manufacturing Agreement, APP Generic Product License and Supply Agreement and the Settlement Documents, the "Agreements") under which the Company has agreed to supply APP with an authorized generic bivalirudin product (the “AG Product”) upon specified circumstances set forth in the License Agreement.

The following is a summary of the material terms of the Agreements.

Settlement Agreement

Under the Settlement Agreement, APP admits that the Litigated Patents are valid and enforceable and would be infringed by any generic bivalirudin for injection product that is the subject of APP's ANDA. APP has agreed that it will not make, use, sell, offer for sale or import generic bivalirudin for injection products under its ANDA except as provided in the License Agreement. The Company and APP have agreed that they will not pursue litigation activities related to the Pending Litigations and will file within three business days after the date of the Settlement Agreement a Judgment, Dismissal and Order of Permanent Injunction concluding the ANDA Litigation and a Joint Dismissal of the Pending Appeal concluding the Pending Appeal. Under the Settlement Agreement, the Company has agreed to make a one-time payment to APP within five business days following the later of the court's entry of the Judgment, Dismissal and

Order of Permanent Injunction with respect to the ANDA Litigation and the entry of the Joint Dismissal of the Pending Appeal with respect to the Pending Appeal, in recognition of the savings inuring to the Company in terms of the avoidance of costs, expenditure of time, disruption and burden associated with prosecuting the ANDA Litigation. The Settlement Agreement terminates upon the earlier of the expiration of the Litigated Patents, including any statutory or regulatory extensions thereof, and the termination of the License Agreement The Settlement Agreement provides that the Company and APP will submit the Agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice within ten business days following the date of the Settlement Agreement.

License Agreement

Under the License Agreement, the Company grants APP a non-exclusive license under the Licensed Patents to sell in the United States a generic bivalirudin for injection product under an APP ANDA (an "APP Product") beginning on May 1, 2019 or earlier under specified conditions, and, in certain limited circumstances, to sell a generic bivalirudin for injection product under the Company's NDA for Angiomax (an “Authorized Generic Product”) in the United States beginning on May 1, 2019 or, in certain limited circumstances, on June 30, 2019 or on a date prior to May 1, 2019. APP's right under the License Agreement to sell an Authorized Generic Product is subject to the payment to the Company of a royalty on sales of the Authorized Generic Product. If APP has the right to sell an Authorized Generic Product, such right could extend for a period of as long as 180 days. The Licensed Patents include the Litigated Patents and any other present or future patents owned, licensed or controlled by the Company that cover or would cover an APP Product or an Authorized Generic Product other than the '404 patent.

Under the License Agreement, the Company and APP have also agreed to negotiate an agreement under which the Company would supply APP with bivalirudin bulk drug substance for use by APP in the manufacture of APP Product to be sold under the License Agreement.

The License Agreement will remain in effect until the later of the expiration of all of the Licensed Patents, and the date six months after the expiration of the '404 patent. Each of the Company and APP may terminate the License Agreement in the event of a material breach by the other party, unless the material breach is cured within 60 days of written notice. Either party may also terminate the License Agreement if the other party undergoes bankruptcy events. The Company may terminate the License Agreement, effectively immediately, upon specified breaches by APP of the License Agreement, including if APP challenges the validity or enforceability of the Licensed Patents or markets a generic bivalirudin for injection product outside the License Agreement.

Fill-Finish Manufacturing Agreement

Under the Fill-Finish Manufacturing Agreement, the Company has agreed to purchase from APP a specified minimum percentage of the Company's requirements for Angiomax finished product for the sale of the Angiomax product in the United States. The Company has agreed to pay APP a fixed price per vial supplied and to reimburse APP for specified development costs and capital expenditures made by APP. The term of the Fill-Finish Manufacturing Agreement ends on May 1, 2019, but may be extended, at the Company's sole option, for an additional term of two years. If a generic form of bivalirudin for injection is marketed by APP or another third party during the term of the Fill-Finish Manufacturing Agreement, the Company has the right to renegotiate the price and minimum quantity terms of the Fill-Finish Manufacturing Agreement and, if such terms cannot be agreed to by the parties, the Company will have the right to terminate the Fill-Finish Manufacturing Agreement upon 90 days written notice. Each of the Company and APP may terminate the Fill-Finish Manufacturing Agreement in the event of a material breach by the other party, effective immediately in the case of a non-curable breach and effective upon 60 days written notice in the case of a curable breach if such breach is not cured within such 60-day period. Either party may also terminate the Fill-Finish Manufacturing Agreement if the other party undergoes bankruptcy events. The Company may terminate the Fill-Finish Manufacturing Agreement upon at least 12 months written notice if the Company decides to discontinue marketing the Angiomax product in the United States or upon 30 days written notice in the event that any government or regulatory authority prevents the Company from purchasing or selling the Angiomax product in the United States.

APP Generic Product License and Supply Agreement

Under the APP Generic Product License and Supply Agreement, APP grants the Company a non-exclusive license

under APP's marketing authorizations and intellectual property to sell ten specified generic products to hospitals and integrated delivery networks in the United States. The Company has agreed to purchase its entire requirements for these products from APP for a price equal to APP's cost of goods. Under the terms of this agreement, the Company will make a one-time, upfront payment of $30 million to APP.

The term of the APP Generic Product License and Supply Agreement ends January 22, 2022. Each of the Company and APP may terminate this agreement in the event of a material breach by the other party, unless the material breach is cured within 90 days of written notice or within 120 days of written notice if the breach is incapable of being cured within the 90-day period. Either party may also terminate this agreement if the other party undergoes bankruptcy events. APP may terminate this agreement upon 60 days written notice if the Company fails to pay in full any invoice that is past due unless such payment is the subject of a dispute set forth in writing by the Company. The Company may terminate this agreement if, with respect to two purchase orders in a calendar year, APP has failed to supply at least the aggregate quantity of conforming product specified in the purchase order or failed to deliver the product prior to the applicable delivery date specified in the purchase order and APP has failed to cure these breaches in the manner specified in the APP Generic Product License and Supply Agreement.

In addition, either party may terminate the APP Generic Product License and Supply Agreement on a product-by-product basis, effective immediately, upon written notice to the other party in the event the FDA takes any action the result of which is to permanently prohibit the manufacture of the product in the United States. APP may also terminate the APP Generic Product License and Supply Agreement on a product-by-product basis upon 180 days written notice if APP has determined that it will discontinue the marketing authorization for the product in the United States. The Company may terminate the APP Generic Product License and Supply Agreement on a product-by-product basis upon 180 days written notice if the total market value of a product falls below a specified percentage of the total market value of the product as of the effective date of the agreement. In the event that this agreement is terminated with respect to a product, the parties shall agree upon a substitute product.

AG Supply Agreement

Under the AG Supply Agreement, the Company has agreed to supply APP with the AG Product in the event APP has the right to market the AG Product under the License Agreement. The Company agrees to use commercially reasonable efforts to supply the AG Product during the period during which APP can market the AG Product (the "Supply Period"). APP shall purchase the AG Product from the Company at a price based on the costs paid by the Company to third parties in connection with the manufacture of the AG Product. The AG Supply Agreement terminates upon the earlier of the end of the Supply Period or December 27, 2019. In addition, each of the Company and APP may terminate the AG Supply Agreement upon the termination of the License Agreement or the Fill-Finish Manufacturing Agreement or in the event of a material breach by the other party, unless the material breach is cured within 60 days of written notice. Either party may terminate the AG Supply Agreement if the other party undergoes bankruptcy events.

The Agreements also contain provisions including indemnification, confidentiality, dispute resolution and other customary provisions for agreements of these kinds.

The foregoing descriptions of the Agreements do not purport to be complete and are qualified in their entirety by reference to the complete texts of the Agreements, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as exhibits to the Company's Quarterly Report on Form 10-Q for the period ending on March 31, 2012.

Item 8.01. Other Events

On January 23, 2012, the Company issued a press release to announce that it has settled the Pending Litigations with APP. The Company remains in infringement litigation involving the Litigated Patents with Hospira, Mylan Pharmaceuticals, Dr. Reddy's Laboratories and Sun Pharmaceuticals.

Upon dismissal of the Pending Appeal, all pending litigation regarding the '404 patent will have been resolved.

The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits
(d) Exhibits

99.1 Press release dated January 23, 2012 entitled “The Medicines Company Settles Angiomax® (bivalirudin) Patent Litigations with APP Pharmaceuticals”

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 hereunto duly authorized.

THE MEDICINES COMPANY
Date: January 23, 2012
By: /s/ Paul M. Antinori
Paul M. Antinori
Senior Vice President and General Counsel

Exhibit Index

Exhibit No.	Description
99.1	Press release dated January 23, 2012 entitled “The Medicines Company Settles Angiomax® (bivalirudin) Patent Litigations with APP Pharmaceuticals”