

ASTRAZENECA PLC  
Form 6-K  
April 02, 2013

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For the month of April 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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  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 the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b):  
82-\_\_\_\_\_

US DISTRICT COURT RULES ONE PULMICORT RESPULES® (BUDESONIDE INHALATION SUSPENSION) PATENT INVALID AND ANOTHER PATENT NOT INFRINGED

AstraZeneca today announced that the United States District Court for the District of New Jersey ruled that AstraZeneca's US Patent No. 6,598,603 ("the '603 patent"), protecting PULMICORT RESPULES in the US, is invalid. The Court further ruled that the generic defendants involved in the litigation do not infringe AstraZeneca's second patent, US Patent No. 7,524,834 ("the '834 patent").

"AstraZeneca strongly disagrees with the Court's decision," said Paul Hudson, Executive Vice President, North America. "AstraZeneca has full confidence in the strength of its intellectual property rights protecting PULMICORT RESPULES. AstraZeneca is considering next steps, including an appeal of the Court's decision."

The decision is limited to the US and has no impact on the validity of patents related to PULMICORT RESPULES in other countries. This decision will not change AstraZeneca's revenue guidance for 2013, which is that the company anticipates a mid to high-single digit decline in revenue on a constant currency basis (Full Year 2012 PULMICORT RESPULES US sales were \$136 million). In the event that additional generics enter the market, this would materially impact royalties received on sales of Teva's generic version of PULMICORT RESPULES. These royalties represented an annualised value of approximately \$260 million in 2012 under the Core Other Income line in the company's annual report and accounts. Subject to additional generics entering the market, our guidance for Core Other Income in 2013 is now that it could be significantly below \$600 million. The company still expects Core EPS to decline significantly more than revenue in 2013.

The patents protecting PULMICORT RESPULES expire in 2018, with paediatric exclusivity extending into 2019.

#### About the trial

AstraZeneca filed patent infringement lawsuits against Apotex Inc.; Apotex Corp.; Watson Laboratories and Breath Limited; and Sandoz, Inc., for infringement of US patents directed to methods of use and formulation and form of active ingredient (budesonide) for PULMICORT RESPULES.

Two of the manufacturers, Apotex and Watson/Breath, had received FDA approval. Neither manufacturer launched its generic product. Apotex was previously enjoined from launching a generic product. Under agreement with AstraZeneca, Teva has a generic PULMICORT RESPULES product in the market.

At the trial, AstraZeneca contended that the defendants' generic budesonide inhalation suspension products and their use will infringe the claims of the two AstraZeneca patents, should those defendants market their generic products in the US. The defendants denied that they will infringe and asserted that each patent is invalid under the US patent laws.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

#### CONTACTS

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2nd April 2013

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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.

AstraZeneca PLC

Date: 02 April 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary