

ASTRAZENECA PLC  
Form 6-K  
February 17, 2015

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 February 2015  
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 DECISION IN  
PULMICORT RESPULES® (BUDESONIDE INHALATION SUSPENSION) PATENT LITIGATION

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

AstraZeneca has announced that the US District Court for the District of New Jersey ruled US Patent No. 7,524,834 ("the '834 patent"), protecting PULMICORT RESPULES in the US, is invalid.

"AstraZeneca strongly disagrees with the Court's decision," said Paul Hudson, President, AstraZeneca US and Executive Vice President, North America. "AstraZeneca has full confidence in the strength of its intellectual property rights protecting PULMICORT RESPULES. We are reviewing the decision and considering our legal options, including an appeal."

The decision is limited to the United States and has no impact on the validity of patents related to PULMICORT RESPULES in other countries. The 834 patent was set to expire in 2018, with paediatric exclusivity extending into 2019.

This decision will not impact AstraZeneca's guidance for 2015, which is that sales revenue is expected to decline by mid single-digit percent at Constant Exchange Rates (CER) and Core EPS is expected to increase by low single-digit percent at CER.

### About the litigation

AstraZeneca had 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.

On 1 April 2013, the US District Court for the District of New Jersey ruled that AstraZeneca's US Patent No. 6,598,603 ("the '603 patent") 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").

On 30 October 2013, AstraZeneca announced that the United States Court of Appeals for the Federal Circuit had reversed and remanded for further proceedings the US District Court decision that generic defendants involved in the litigation do not infringe the '834 Patent. The Court of Appeals upheld, however, the trial court's decision as to the '603 Patent.

At the remand, AstraZeneca contended that the defendants' generic budesonide inhalation suspension products and their use will infringe the claims of the '834 Patent. The defendants denied that they will infringe and asserted that the '834 Patent is invalid.

Under agreement with AstraZeneca, Teva has a generic PULMICORT RESPULES product in the market.

### 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

#### Media Enquiries

Esra Erkal-Paler	+44 20 7604 8030 (UK/Global)
Vanessa Rhodes	+44 20 7604 8037 (UK/Global)
Ayesha Bharmal	+44 20 7604 8034 (UK/Global)
Jacob Lund	+46 8 553 260 20 (Sweden)
Michele Meixell	+1 302 885 2677 (US)

Investor Enquiries

Thomas Kudsk Larsen

Karl Hård

Eugenia Litz

Craig Marks

Christer Gruvris

+44 20 7604 8199 mob: +44 7818 524185

+44 20 7604 8123 mob: +44 7789 654364

+44 20 7604 8233 mob: +44 7884 735627

+44 20 7 604 8591 mob: +44 7881 615764

+44 20 7604 8126 mob: +44 7827 836825

16 February 2015

-ENDS-

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: 16 February 2015

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary