ASTRAZENECA PLC Form 6-K October 31, 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 October 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 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):
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 X
If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82

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#### US APPEALS COURT ISSUES DECISION IN PULMICORT RESPULES PATENT LITIGATION

AstraZeneca today announced that the United States Court of Appeals for the Federal Circuit has reversed and remanded for further proceedings a trial court decision that generic defendants involved in the litigation do not infringe a patent (US Patent No. 7,524,834) protecting PULMICORT RESPULES in the US. The Court of Appeals upheld, however, the trial court's decision that another patent (US Patent No. 6,598,603) protecting AstraZeneca's PULMICORT RESPULES in the US is invalid.

On 24 May 2013, AstraZeneca announced that the US Court of Appeals for the Federal Circuit issued a temporary injunction blocking the generic manufacturers from distributing generic versions of PULMICORT RESPULES in the US during the pendency of AstraZeneca's appeal.

AstraZeneca has full confidence in the strength of its intellectual property rights protecting PULMICORT RESPULES.

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

#### **NOTES TO EDITORS**

#### About the litigation

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"), 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 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.

Two of the manufacturers, Apotex and Watson/Breath, had received FDA approval. A third manufacturer, Sandoz, received FDA approval while the appeal was pending. None of these manufacturers have launched their generic products. 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

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31 October 2013

## **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: 31 October 2013 By: /s/ Adrian Kemp

Name: Adrian Kemp Title: Company Secretary