

ASTRAZENECA PLC
Form 6-K
May 28, 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 May 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 APPEALS COURT ISSUES A TEMPORARY INJUNCTION PENDING APPEAL AGAINST DISTRIBUTION
OF GENERIC PULMICORT RESPULES
(Budesonide Inhalation Suspension)

AstraZeneca today announced that the US Court of Appeals for the Federal Circuit issued a temporary injunction blocking generic manufacturers from distributing generic versions of PULMICORT RESPULES in the US until the Court rules on AstraZeneca's appeal of a District Court decision that found one patent protecting the product to be invalid and another patent not infringed. As a condition of the injunction, the Court has also ordered that AstraZeneca post a bond in the amount of \$72 million.

"We intend to vigorously defend the intellectual property rights protecting PULMICORT RESPULES." said Paul Hudson, Executive Vice President, North America.

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

About the trial

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. 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

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)
Tony Jewell	+1 (302) 885 2677 (US)
Jacob Lund	+46 8 553 260 20 (Sweden)

Investor Enquiries

James Ward-Lilley	+44 20 7604 8122	mob: +44 7785 432613
Karl Hård	+44 20 7604 8123	mob: +44 7789 654364
Colleen Proctor	+ 1 302 886 1842	mob: +1 302 357 4882
Ed Seage	+ 1 302 886 4065	mob: +1 302 373 1361

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28 May 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: 28 May 2013

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary