ASTRAZENECA PLC
Form 6-K
December 17, 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 December 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-_____

ASTRAZENECA STATEMENT IN RESPONSE TO REPORTS OF A LAUNCH OF ESOMEPRAZOLE STRONTIUM PRODUCT IN THE US

AstraZeneca is aware of reports that an 505(b)(2) NDA esomeprazole strontium product has been launched in the US by Hanmi Pharmaceutical and affiliates ("Hanmi") and its US marketing partner Amneal Pharmaceuticals ("Amneal").

On 30 September 2013, the US Court of Appeals for the Federal Circuit ("CAFC") lifted a temporary injunction against Hanmi's US launch of its 505(b)(2) NDA esomeprazole strontium product (previously granted on 13 September 2013). AstraZeneca's appeal of the lower court's December 2012 claim construction remains pending. After oral argument on 18 November 2013, a decision is expected from the CAFC in early 2014.

Depending on the outcome of the appeal, Hanmi's sales are at risk of owing AstraZeneca patent infringement damages. AstraZeneca's appeal concerns both patents-at-issue in the patent-infringement litigation against Hanmi (US Patent Nos. 5,714,504 and 5,877,192). AstraZeneca understands that Hanmi's 505(b)(2) NDA esomeprazole strontium product is not AB-rated and is not automatically substitutable for Nexium.

There is no impact on AstraZeneca's full year 2013 financial guidance as a result of these developments.

NOTES TO EDITORS

About the underlying litigation

In June 2013, AstraZeneca entered into an agreement with Hanmi and Amneal to streamline litigation issues regarding Hanmi's proposed 505(b)(2) NDA esomeprazole strontium product.

Under terms of the agreement, Amneal and Hanmi have conceded the validity and enforceability of AstraZeneca's US Patent Nos. 5,714,504 and 5,877,192 that protect Nexium. The US District Court for the District of New Jersey ("District Court") entered a Consent Judgment.

In July 2013, AstraZeneca filed a Notice of Appeal in the US CAFC regarding critical aspects of the District Court's December 2012 claim construction. Among issues, AstraZeneca is seeking a reversal of claim construction.

On 6 August, Hanmi received US FDA approval for its 505(b)(2) NDA esomeprazole strontium product.

On 13 September, the US CAFC issued a temporary injunction against the US launch of Hanmi's 505(b)(2) NDA esomeprazole strontium product.

On 30 September 2013, the US Court of Appeals for the US CAFC lifted a temporary injunction against Hanmi's US launch of its 505(b)(2) NDA esomeprazole strontium product (previously granted on 13 September 2013).

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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-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: 17 December 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary