Shire Files Lawsuits Against Sandoz and Amneal for Infringement of VYVANSEÃ,® (lisdexamfetamine dimesylate) Patents

Bio-Medicine.Org

DUBLIN, July 1, 2011 /PRNewswire/ --

Shire plc (LSE: SHP, NASDAQ: SHPGY [1]), the global specialty biopharmaceutical company, announces that it has filed lawsuits in the U.S. District Court for the District of New Jersey against each of Amneal Pharmaceuticals, LLC ("Amneal") and Sandoz, Inc. ("Sandoz") for infringement of certain of Shire's VYVANSE patents.

The lawsuits were initiated in response to Abbreviated New Drug Applications ("ANDAs") filed by Amneal and Sandoz seeking FDA approval to market and sell generic versions of all currently approved doses of VYVANSE.

Under the Hatch-Waxman Act, the FDA must refrain from approving the Sandoz and Amneal ANDAs for 30 months (expiring August 23, 2014), or until a district court decision finding that the patents are invalid or not infringed, whichever occurs earlier.

Notes to editors

SHIRE PLC

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company's website: http://www.shire.com [2].

"SAFEHARBOR" STATEMENT UNDER THE PRIVATE SECURITIES
'/>"/>

SOURCE [3]

Source URL (retrieved on *04/28/2015 - 3:31pm*):
http://www.mdtmag.com/news/2011/07/shire-files-lawsuits-against-sandoz-and-amneal-infringement-vyvanse%C3%A3%E2%80%9A%C2%AE-lisdexamfetamine-dimesylate-patents

Links:
[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=SHPGY
[2] http://www.shire.com/
[3] http://www.bio-medicine.org/medicine-technology-1/Shire-Files-Lawsuits-Against-Sandoz-and-Amneal-for-Infringement-of-VYVANSE-AE--28lisdexamfetamine-dimesylate-29-Patents-18565-1/