

Investor News

Court rules in favor of Bayer over Avelox[®] patents

Leverkusen, October 26, 2007 – Bayer today announced that the U.S. District Court for the District of Delaware has issued a ruling in its lawsuit against Dr. Reddy's Laboratories in which Dr. Reddy's challenged the validity and enforceability of two U.S. patents covering Avelox[®] (moxifloxacin HCl), the company's fluoroquinolone antibiotic for the treatment of respiratory tract and other infections. The court ruled in Bayer's favor, rejecting all of Dr. Reddy's challenges to the validity and enforceability of both Bayer patents.

This patent infringement suit was brought in response to the filing of an Abbreviated New Drug Application (ANDA) by Dr. Reddy's, a manufacturer of generic drugs. In submitting its ANDA with the U.S. Food and Drug Administration, Dr. Reddy's sought approval of a generic version of Avelox[®] prior to the expiration of Bayer's patents. The patents in suit for Avelox[®] cover active ingredient, composition and methods of treatment. It is not unusual for generic drug companies to file ANDAs on successful pharmaceutical products prior to the expiration of the relevant patents. Under U.S. law, the filing of the ANDA is an act of patent infringement.

Another generic company, Teva Pharmaceuticals USA, Inc. has also challenged the validity of the same Bayer patents at issue in the Dr. Reddy's case in a case pending in the U.S. District Court for the District of Delaware. Trial of Teva's case is currently scheduled to commence on February 25, 2008 in Wilmington, Delaware. Bayer intends to defend its patents vigorously.

In the U.S., Avelox[®] is approved to Acute Exacerbations of Chronic Bronchitis (AECB), Acute Bacterial Sinusitis (ABS), Community Acquired Pneumonia (CAP), Uncomplicated Skin and Skin Structure Infections (uSSSI), Complicated Skin and Skin Structure Infections (cSSSI) and Complicated Intra-Abdominal Infections (cIAI).

In Europe, Avelox[®] Oral is approved to treat Community Acquired Pneumonia (CAP) – except severe cases, Acute Bacterial Sinusitis (ABS) where adequately diagnosed, and Acute Exacerbations of Chronic Bronchitis (AECB). Avelox[®] IV (+ oral sequential therapy) is approved to treat Community Acquired Pneumonia (CAP), and Complicated Skin and Skin Structure Infections (cSSSI). In Germany, Avelox[®] is known as Avalox[®].

Avelox[®] was launched in the U.S. in 1999 and is currently marketed in more than 80 countries worldwide. In the U.S., Avelox[®] is marketed by Bayer's partner, Schering-Plough Corporation.

References:

1) Avelox IV is licensed in the following 17 European Member States: Austria, Belgium, Denmark, Finland, Germany, Greece, Republic of Ireland, Luxembourg, Malta, The Netherlands, Sweden, Hungary, Estonia, Latvia, Lithuania, Slovakia and Slovenia.

About Bayer Healthcare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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