PHARMABIZ.com
india's most comprehensive pharma portal

Gilead, Bayer & Genzyme sue Lupin for alleged Para IV patent infringements in US

Tuesday, July 27, 2010 08:00 IST
Our Bureau, Mumbai

The Mumbai-based Lupin Ltd and its US subsidiary, Lupin Pharmaceuticals Inc, have been sued by at least three firms in United States at various courts in the nation, within a week starting from July 14, for Para IV patent infringement allegedly by the former attempting to manufacture and sell generic version of products before expiry of patent protection, according to reports.

The patent infringement suits were filed by Gilead Sciences, Inc and Roche Palo Alto LLC for their angina drug Ranexa (ranolazine extended-release tablets), Bayer Schering Pharma AG and its US subsidiary Bayer Healthcare Pharmaceuticals Inc for its oral contraceptive Yaz and Yasmine, (drospirenone and ethinyl estradiol) and Genzyme Corporation for its Renvela (sevelamer carbonate) used for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

Gilead and Roche, which filed the petition to the District Court of New Jersey first and later to the District Court of Maryland, US, allege that by submitting Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA) for the generic version of extended release tablets ranolazine, Lupin has infringed nine patents on Ranexa, all licensed to Gilead.

The company announced that Ranexa is currently protected by 10 patents, which are listed in the FDA's Approved Drug Products List, and all 10 patents would need to be invalidated, expire or not be infringed before a generic version of Ranexa could be marketed. Gilead's Ranexa patents are expected to expire in May 2019, according to reports. Ranexa's global sales were reported at US$ 46 million for the fourth quarter of 2009, and US$ 131.1 million in the period 2008/09.

Bayer has complained to District Court of Maryland, US, alleging Lupin infringed patent rights of its oral contraceptive drug Yaz and Yasmin. The company also filed Para IV infringement suit with the District Court of Nevada for patent protection of Yaz and in the Southern District of New York for Yasmin. The company claims patent protection for the products under re examined patents, RE37,564, RE37,838 and RE38,253 for Composition for Contraception and 5,569,652 (`652) for dihydrospirorenone as an antiandrogen.

The first patents of Yaz, for dosage regimen, is expected to expire by June, 2014, subject to the decision of the patent regulator. Yasmin's US patent for formulation is valid till 2020 while patent for production process is dated to expire in 2025, informs Bayer Healthcare.

The company also reveals that the formulation patent for Yasmin was invalidated in March 2008 and the US Court of Appeals for the Federal Circuit affirmed this decision, in August 2009, following a patent infringement litigation between Bayer and Barr Laboratories, Inc. However, both the companies signed a supply and licensing agreement for Yasmin, covering the US market through which Bayer agreed to supply Bar with generic version of the product for exclusive marketing and Barr paying Bayer a fixed percentage of the revenues from the generic product sold. Bayer is pursuing its appeal of the court decision that invalidated Bayer's US patent '531 for Yasmin.

Meanwhile, the Genzyme Corporation's petition with the District Court of Maryland, US, against Lupin alleges that the latter's ANDA with the US FDA to manufacture generic version of evelamer carbonate, used for the control of serum phosphorus in patients with chronic kidney disease on dialysis, infringes its patent rights for the brand Renvela, which is patented under US Patent No 5,667,775, issued for Phosphate-Binding Polymers for Oral Administration. Renvela has a total US sales of around US$ 200 million till the twelve months ending March, 2010, according to IMS Health report. As reported earlier, the company has filed a similar petition against Lupin with the same Court alleging infringement of its six patents including the patent in the present suit.

Renvela, a non-calcium, non-metal, non-absorbed phosphate binder available in 800 mg, has been developed by Genzyme as a next generation phosphate binder to replace its sevelamer hydrochloride product Renagel, claimed to be the most-prescribed phosphate binder in the United States.