

Lupin issues notice to Depomed Inc relating to Glumetza patent

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Our Bureau, Mumbai

Lupin Ltd, a Rs 3,775 crore fifth largest Indian pharma major, has issued a Paragraph IV certification notice to Depomed, Inc regarding filing of an ANDA with the US FDA for a generic version of Glumetza (metformin hydrochloride extended release tablets), 500 mg and 1000 mg strengths.

Lupin's certification notice alleges that Depomed's US Patents (Nos. 6,340,475; 6,488,962; 6,635,280; and 6,723,340) listed in the FDA Orange Book for Glumetza are invalid and/or will not be infringed by Lupin's commercial manufacture, use or sale of the products described in Lupin's ANDA.

US Patent No. 6,340,475 will expire in 2016, US Patent No. 6,488,962 will expire in 2020, US Patent No. 6,635,280 will expire in 2016 and US Patent No. 6,723,340 will expire in 2021.

Depomed is evaluating the Paragraph IV certification and continues to have full confidence in the intellectual property protecting Glumetza. Depomed has 45 days from the receipt of the Paragraph IV certification to commence a patent infringement lawsuit against Lupin that would automatically stay, or bar, the FDA from approving Lupin's ANDA for 30 months or until a district court decision that is adverse to the company, whichever is earlier.

Depomed is a specialty pharmaceutical company with one product candidate through phase-3 clinical development, another in phase-3 clinical development, two approved products on the market and other product candidates in its early stage pipeline.