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Takeda files Para IV infringement suit against Aurobindo on oral diabetes combo

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Gireesh Babu, Mumbai

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<http://www.pharmabiz.com/article/detnews.asp?articleid=54353§ionid=>

The Japanese drug major, Takeda Pharmaceuticals and its US arm sued the Hyderabad-based Aurobindo Pharma and its US subsidiary for alleged Para IV patent rights infringement by attempting to manufacture and market generic version of the former's Actosplus Met, a combination of pioglitazone hydrochloride and metformin, used to treat type II diabetes.

In a complaint filed with the US District Court for the Southern District of New York, Takeda alleged that Aurobindo allegedly tried to manufacture and market a generic equivalent to the combination oral drug by filing an Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA). The company argues that the move will infringe patent rights under US Patent No 5,965,584 (`584), 6,166,043 (`043) and 6,172,090 (`090) for 'Pharmaceutical Composition,' issued on October, 1999, December, 2000 and January, 2001, respectively.

The `584 patent claims a pharmaceutical composition comprising pioglitazone or salts thereof in combination with a biguanide such as metformin and methods for treating diabetes, which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin. The `043 patent claims methods for reducing the amount of active components in the combination administered to a diabetic patient the `090 patent is for methods for reducing the side effects of active components administered to a diabetic patient. Takeda informed the Court that all the patents are valid till June 19, 2016.

The company details that the Aurobindo has filed ANDA with the US FDA seeking approval to market tablets comprising a combination of 15mg/500 mg and 15mg/850 mg tablets of pioglitazone hydrochloride/metformin hydrochloride. Takeda also indicates that Aurobindo, through the Notice Letter for Notification of Certification, opined that it has neither infringed any patent claims of the listed patents "and/or that those claims are invalid or unenforceable".

Actosplus Met is a major oral combination drug used to treat type II diabetes in US, where diabetes drug market is growing in double digits. According to a recent study published, oral drugs market is expected to grow in doubled-digit in the next six years. Other than Takeda, companies including Amylin, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co, Novo Nordisk, Pfizer also has their presence in the oral diabetes drug market.