

Sanofi's SoloStar hits US market despite patent suit

By Anna Lewcock

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Sanofi-Aventis' disposable insulin pen SoloStar has been launched across the US for use with the company's 24-hour basal insulin Lantus (insulin glargine), despite patent infringement claims emanating from fellow insulin pen manufacturer, Novo Nordisk.

The disposable pen was rolled out in France and Germany earlier this year, but a cloud formed over the company's US plans for the product when reports emerged that Danish firm Novo had filed a patent infringement suit against the company to prevent the pen's availability on the US market. On July 10 Novo filed a suit with the US District Court of New Jersey against Sanofi with regard to the Lantus SoloStar product, but Sanofi has yet to be officially served with the complaint, and says its understanding of the allegations is still preliminary. Novo's allegations pertain to the mechanisms for injection and dose-setting, features which Sanofi emphasises as advantages of its product but which Novo claims infringe on its NovoPen 4 insulin delivery system. Sanofi states that the dose-setting mechanism on the Lantus SoloStar is somewhat unique, in that it is the only pre-filled disposable insulin pen that allows patients to administer from one up to 80 units in single-unit increments with a single injection. The pen offers a 25 per cent higher capacity than other insulin pens, according to the company, capable of holding 300 units of insulin. The average Lantus dose is 35 units a day. Sanofi also highlights the reduced injection force used with its SoloStar product, with the pressure required to administer the insulin 31 per cent less than Novo's FlexPen device and 54 per cent less than Eli Lilly's Humulin/Humalog pen. A further advantage of the Lantus version of the pen product is that Lantus is currently the only 24-hour insulin approved exclusively for once-daily treatment of hyperglycaemia in patients with Type I or Type II diabetes. It also eliminates the problem of the 'peak-of-action' effect common with other insulins, where the insulin reaches a point of maximum effect in the body. Lantus, on the other hand, has no such pronounced peak and is released into the bloodstream at a relatively constant rate throughout the day. The cost of the pen on the US market is similar to other pen format analog insulins, according to Julissa Viana of Sanofi, coming in at around 10 cents a unit or \$30 (€22) per injection device. With insulin pens still somewhat under-utilised in the US compared to other regions such as Europe and Japan, Sanofi will be hoping to wean the American diabetic population onto the SoloStar pen, emphasising its ease of use and convenience over traditional needle-based injection systems. Although reluctant to disclose information regarding the potential share of the market that the company could garner with the Lantus SoloStar product, Viana said that Sanofi does *"feel confident that [it] will increase the percentage of patients initiating on Lantus in pen format above the national average of 12-14 per cent over the next two years."* The company is also awaiting approval for the use of the SoloStar pen with Anidra (insulin glulisine), the company's fast acting prandial insulin. Until approval is

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