

# Sanofi settles lawsuit enabling rival to Lantus insulin

September 28 2015, by Linda A. Johnson

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This product image provided by Sanofi shows Lantus SoloStar, the French drugmaker's once-daily insulin in a pen-like injector. Sanofi on Monday, Sept. 28, 2015 said it settled a lawsuit over patents for Lantus SoloStar that allows rivals Eli Lilly and Co. and German drugmaker Boehringer Ingelheim GmbH to sell their version, Basaglar in their Kwikpen device, in the U.S. starting Dec. 15, 2016. (Sanofi via AP)

A less-expensive version of the world's top-selling insulin, Sanofi's Lantus, could go on sale in the U.S. late next year.

The French drugmaker said Monday it settled a lawsuit over patents for Lantus SoloStar, its once-daily insulin in a pen-like injector. The settlement allows rivals Eli Lilly and Co. and German drugmaker Boehringer Ingelheim GmbH to sell their version, Basaglar in their

Kwikpen device, in the U.S. starting Dec. 15, 2016.

Partners Eli Lilly, based in Indianapolis, and Boehringer Ingelheim obtained tentative approval from the Food and Drug Administration in August 2014 for their version. The approval was tentative because of the ongoing lawsuit. The two companies still need full FDA approval to sell the product in the U.S.

Lantus is Sanofi's top product, though sales have been declining. It's the world's third best-selling medicine, with 2014 sales of \$12.4 billion, according to British research firm GlobalData.

Sanofi SA said 61 percent of Lantus sales come from the SoloStar pen and the rest from Lantus in vials. Pen-like insulin devices are gaining popularity because they're easier to inject than using syringes to extract a specific insulin dose from a vial and then inject it.

Eli Lilly and Boehringer Ingelheim have not sought approval to sell their version in vials. They already sell Basaglar in the Kwikpen in several European countries and are seeking approval in other foreign countries. The two companies have not set a U.S. price yet, but it likely will be significantly lower than the price for Lantus SoloStar.

The settlement ends all lawsuits worldwide between the companies over patents for Lantus SoloStar. Lilly will pay undisclosed royalties to Sanofi in exchange for a license to certain Sanofi patents that would have kept Basaglar off the U.S. market until April 2025.

The settlement doesn't involve other Sanofi insulin products, such as Toujeo, its Lantus successor launched in February that uses smaller insulin amounts.

The diabetes market is fiercely competitive, and top rivals recently have

been introducing new products across several classes of diabetes pills, as well as easier-to-use insulins.

Denmark's Novo Nordisk is the world's top maker of diabetes medicines. Top rivals include Sanofi, Merck & Company, Pfizer Inc. and Eli Lilly. Lilly also sells the new diabetes pill Jardiance, recently shown in a study to prevent fatal heart attacks and strokes.

People with diabetes either do not produce enough insulin, which helps convert sugar from food into energy, or their body does not properly use insulin.

About 95 percent of the estimated 29 million Americans and 387 million people worldwide with diabetes have Type 2 diabetes, which is often linked to obesity and a sedentary lifestyle. Type 1 diabetes, often called insulin-dependent diabetes, typically is diagnosed in childhood or adolescence, while Type 2 diabetes typically strikes in middle age.

Worldwide, the market for Type 2 diabetes treatments was \$23.5 billion last year and is forecast to rise to \$39 billion by 2021, according to GlobalData.

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