

## **Sanofi files patent infringement lawsuit against Mylan following NDA for biosimilar insulin glargine - October 25, 2017**

Earlier this week, Sanofi [filed](#) a lawsuit against Mylan for infringement on 18 patents related to Lantus (insulin glargine) and Lantus SoloStar pens in Mylan's New Drug Application (NDA) for Biocon-partnered biosimilar insulin glargine. Mylan submitted the NDA in mid-September. FDA filing for the product has been a source of confusion for some time, with Mylan reporting several unexplained delays from the [original estimate](#) of submission at the end of 2016. Sanofi shared no further details on the lawsuit. That said, the company issued, and subsequently settled a similar [patent lawsuit](#) with Lilly/BI for their biosimilar insulin glargine Basaglar, and has an ongoing lawsuit [against Merck](#) for its tentatively-approved biosimilar insulin glargine [Lusduna Nexvue](#). We imagine the lawsuit against Mylan will follow a similar process, meaning it could be settled in one of three ways: (i) Mylan and Sanofi reach an agreement, (ii) a court decides in favor of Mylan, or (iii) 30 months elapse since the lawsuit was filed (pushing the timeline for US launch to April 2020). Legal issues aside, another (likely third) biosimilar basal insulin should reach the US market (Mylan/Biocon's glargine product has already launched in Japan). [Past experience](#) tells us that at least two generics are needed on the marketplace to meaningfully drive down cost for patients. On the other hand, unlike Lilly, Mylan does not have longstanding experience as an insulin manufacturer, leaving looming questions on safety and quality assurance. Indeed, real-world HCPs have shown some reluctance to prescribing biosimilar insulins to-date, not yet fully convinced of their safety and comparable efficacy. While the FDA Oncologic Drugs Advisory recently [recommended](#) the approval of Mylan/Biocon's biosimilar trastuzumab (breast cancer), reflecting positively on the company's capability in manufacturing biosimilars, we are not sure how manufacturing in diabetes will evolve.

-- by Abigail Dove, Payal Marathe, and Kelly Close