# Pfizer files Groundbreaking Lawsuit against J&J Alleging Anticompetitive Practices

Pfizer filed a lawsuit on Wednesday, September 20, alleging Johnson &amp|Johnson (J&J) made "exclusionary contracts" with insurers regarding their drug Remicade. Remicade (infliximab) is biologic medication that must be administered via IV infusion. In contrast to most drugs that are chemically synthesized, biologic medications are large biological molecules or complex mixtures that are not easily duplicated. Remicade (infliximab) is a monoclonal antibody. As biologic medications cannot be exactly duplicated, the FDA process for approving biosimilars is similar but not identical to the Abbreviated New Drug Application (ANDA) process for small molecule generic drugs. In April 2016, the FDA approved Pfizer's drug Inflectra, a biosimilar version of Remicade. Inflectra was only the second biosimilar ever approved by the FDA. Despite its 30% lower price, Inflectra has gained less than 1% of the market for infliximab since it was released in November 2016. In the lawsuit, Pfizer claims that J&J required insurers to not cover Inflectra or "to do so only in the rarest of circumstances." Pfizer alleges that J&J required insurers to designate Remicade as a "fail first" drug. Specifically, these contracts require patients to try Remicade first and switch to Inflectra only if the drug is not effective. Pfizer alleges that J&J would refuse to pay rebates to any insurer who did not accept these exclusivity requirements. "In short, insurers that decline J&J's offer face a substantial financial penalty, and those that accept receive a payoff (multimillion dollar rebate payments) in return for their commitment to exclude biosimilars." In its filing, Pfizer notes that this practice essentially eliminates the market for Inflectra. "If Remicade, which is an infliximab

product, does not work for a patient, a physician would turn to a non-infliximab drug, not to Inflectra, which also is an infliximab product and has no clinically meaningful differences from Remicade."

The Affordable Care Act (ACA) created the approval process for biosimilars at the FDA in 2010. In the 7 years since it was passed, however, the FDA has approved only 7 biosimilars. Of the approved biosimilars, only 3 are on the market|the rest are tied up in patent challenges brought by the manufacturer of the branded biologic. The case filed by Pfizer against J&J is particularly important because manufacturers, lawmakers, physicians, pharmacists, and patients are working to determine how to handle biosimilars and if they should be treated as generic equivalents to biologics. According to Bloomberg Law, "much of the antitrust litigation in the pharmaceuticals industry has focused to date on "product-hopping" cases, in which companies make minor changes to a drug, such as dosage levels, to extend a patent. But the Pfizer suit could open the door to more challenges to contracts that bar providers from covering a particular drug's costs." This case is likely to have an impact on what terms are considered exclusionary in contracts between drug manufacturers and pharmacy benefit managers (PBM).

The impact of this trial may not be felt immediately. Most state substitution laws for biologics require the FDA to determine that the biosimilar is "interchangeable," something the FDA has not yet done. Until biosimilars have the same ability to decrease the price for biologics in the way generics can for brand name pharmaceuticals, the biologic market will continue to be plagued by exceptionally high prices and stymied market competition. The Source will continue to follow this case closely!