Alert

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COZEN O'CONNOR

First Circuit Permits Antitrust Claims for Improperly Listing a Device Patent on the FDA's Orange Book to Move Forward

In a holding that could significantly broaden the antitrust inquiry in the context of the Hatch-Waxman regulatory scheme, on February 13, 2020, the U.S. Court of Appeals for the First Circuit issued an opinion that may have wide-ranging implications for both branded companies that own, and generic companies that challenge, patents listed on FDA's Orange Book that claim drug delivery devices. *In re: Lantus Direct Purchaser Antitrust Litigation*, Civil Action No. 18-2086 (1st Cir. 2020)

A group of drug purchasers sued Sanofi-Aventis in Massachusetts District Court alleging that Sanofi had violated Section 2 of the Sherman Act by extending its patent monopoly on Lantus (insulin glargine), which has annual sales in the United States of more than $7 billion. In reversing the district court's grant of Sanofi's motion to dismiss plaintiffs' antitrust complaint, the appellate panel found sufficient allegations that Sanofi had improperly listed U.S. Patent No. 8,556,864 on the Orange Book for its Lantus SoloSTAR (insulin glargine) injectable product. This, based on a finding that the '864 patent's claims were merely directed to "an integral part" of the injector pen, but failed to claim, let alone mention, insulin glargine or the Lantus SoloSTART device.

Under the Hatch-Waxman statute, NDA holders are required to list patents "which claim the drug [for which an NDA is submitted] ... or which claim a method of using such drug." 21 U.S.C. 355(b)(1). Examining the statute and FDA's history of regulations concerning the listing of patent information in the Orange Book, the appellate panel reasoned that:

> Even if we ... assume for the sake of argument that the Lantus SoloSTAR is a drug under the statute, there is still a vital link missing: the '864 patent does not claim or even mention the Lantus SoloSTAR. Indeed, though it claims a device intended for use in an injector pen, it does not claim any injector pen, nor even a method of using a pen.

The appellate panel also rejected Sanofi's argument that FDA's regulations require listing in the Orange Book any patents that contain "integral components" of an approved drug product, stating that:

> We see nothing in the statute or regulations that welcomes such a further expansion of the already stretched statutory terms, whereby an integral part of an injector pen becomes the pen itself, and in turn is a drug. One would not think, for example, that a patent claiming only a transmission system must be read as also claiming any car in which it is used.

In remanding plaintiffs' antitrust claims, the appellate panel held that further discovery is necessary in order to determine whether Sanofi should be liable under the Sherman Act for any antitrust injury caused by its improper listing of the '864 patent. While Section 2 cases typically are limited to examining the effects of a monopolist's alleged market power and improper conduct, the panel reasoned that the FDA regulatory scheme compels consideration of a monopolist's procompetitive rationale for its conduct in evaluating whether there has been an antitrust violation. This is because an NDA holder's failure to submit a patent to FDA could similarly result in antitrust allegations of anticompetitive effects arising from an NDA holder's alleged failure to submit patents to FDA (similar to standard-setting based claims). In agreeing with Sanofi's argument that antitrust liability could therefore flow from its either listing or not listing the '864 patent on FDA's Orange Book, the district acknowledged that antitrust inquiry must look beyond the effects of Sanofi's actions.

In delineating the scope of discovery on remand, the panel cited precedent from another heavily regulated sector, the telecommunications industry. There, conduct accused of having

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anticompetitive effect may be excused from antitrust liability where it occurs as part of a good faith, reasonable attempt to comply with a regulatory scheme (under the *Noerr Pennington* doctrine). Applying that standard to Sanofi's conduct within FDA's regulatory scheme, the court remanded the case for further discovery concerning whether Sanofi's decision to list the '864 patent was both reasonable and made in good faith. Such determination could include an examination of custom and practice in the pharmaceutical industry, and what, if any, legal opinions Sanofi sought and obtained before submitting the '864 patent to FDA.

NDA holders should reevaluate their procedures for patent-listing, as well as the types of patent claims that are sought in conjunction with the patenting of devices useful for drug delivery. Conversely, generic companies may be able to pursue antitrust claims against brand companies for improper listing of certain patents in the Orange Book.