Cantor Colburn LLP

Cantor Colburn Client Alert:
Fed. Cir. Tackles Venue Question for Hatch-Waxman Suits

Summary
On November 5, 2020, the U.S. Court of Appeals for the Federal Circuit ("CAFC") weighed in on a question of first impression about proper venue in Hatch-Waxman suits with respect to where infringement occurs. The CAFC concluded that in cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of generic products is contemplated.

Overview
The case in question is *Valeant Pharm. N. Am. LLC v. Mylan Pharm., Inc.*, No. 2019-2402, 2020 U.S. App. LEXIS 35040 (Fed. Cir. Nov. 5, 2020). *Valeant* further clarifies proper venue for Hatch-Waxman litigants after the Supreme Court "dramatically changed the venue landscape" in *TC Heartland*. Since *TC Heartland*, when analyzing venue, district courts have disagreed on exactly what constitutes an act of infringement in ANDA cases – until now.

In *Valeant*, the district court concluded venue in New Jersey was improper because Mylan's alleged act of infringement occurred in either West Virginia (where Mylan submitted its ANDA) or Maryland (where the FDA received Mylan's ANDA). Valeant then appealed to the CAFC.

Valeant made several arguments as to why New Jersey was the proper venue, including that Mylan's planned future conduct included the marketing and sales of its ANDA product in New Jersey. The CAFC disagreed, however, and affirmed the district court's decision as to venue regarding the Mylan domestic defendants. The CAFC explained, "in Hatch-Waxman cases, venue is not proper in all judicial districts where a generic product specified in an ANDA is likely to be distributed. It is proper only in those districts that are sufficiently related to the ANDA submission—in those districts where acts occurred that would suffice to categorize those taking them as a 'submitter' under § 271(e)."

Valeant has therefore limited where Hatch-Waxman suits can be litigated against domestic defendants. It is now clear that a generic's alleged future acts of infringement cannot form the basis of proper venue in a given district.

For Further Information and Assistance
Cantor Colburn's Pharmaceutical Litigation Practice, chaired by litigation partner Steven M. Coyle, has substantial experience representing clients in Hatch-Waxman and related pharmaceutical litigation matters. Please do not hesitate to contact Steven, at scoyle@cantorcolburn.com and +1 (860) 286-2929, or your Cantor Colburn attorney with any questions you may have regarding this matter and your IP in general.

Please note that each situation has its own unique circumstances and ramifications. This Client Alert is for informational purposes only and is not legal advice.