

Agent Who Signs ANDA Application On Behalf Of Foreign ANDA Applicant May Be Held Liable Under 35 U.S.C. § 271(e)(2)(A) (Farnan, J.)

In re: Rosuvastatin Calcium Patent Lit, 2010 U.S. Dist. LEXIS 64475 (D. Del. June 29, 2010), the Court addressed “submitter liability” in ANDA litigation. In this case, Apotex Corp., the U.S. agent of Apotex Inc., contended that its act of signing the application on behalf of its foreign parent was not sufficient to create liability. Nonetheless, the Court held that Apotex Corp. could be held liable under 35 U.S.C. § 271(e)(2)(A) for infringement because it submitted the ANDA as an agent of the foreign ANDA applicant (Apotex Inc.) and intends to benefit directly if the ANDA is approved. In so ruling, the Court followed its prior precedents as well as decisions in several other jurisdictions.