

DNJ Judge Denies Generic Defendants' Bid to Dismiss Case Based on Non-Listing of Patents in Orange Book and Absence of Paragraph IV Certifications

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U.S. District Judge Susan D. Wigenton recently denied a generic pharmaceutical defendants' motion to dismiss for lack of subject matter jurisdiction in a case involving non-Orange Book listed patents for the branded cancer drug Revlimid®. In particular, Judge Wigenton found that a Paragraph IV certification is not required for subject matter jurisdiction, nor is it required that the asserted patents be listed in the Orange Book.

On July 13, 2018, Celgene Corporation sued various Sun Defendants, claiming that Sun's proposed generic product will infringe three Celgene patents listed in the Orange Book for Revlimid®. *See Celgene Corp. v. Sun Pharma Global FZE, et al.*, Civ. No. 18-11630 (D.N.J.). Subsequently, on April 16, 2019, Celgene filed a second suit against the Sun Defendants, Civ. No. 19-10099 (D.N.J.), for infringement of three additional patents that are *not* listed in the Orange Book for Revlimid®: U.S. Patent Nos. 7,977,357; 8,193,219; and 8,431,598. Sun thereafter filed a motion to dismiss the second case for lack of subject matter jurisdiction and failure to state a claim, arguing that the three patents asserted in the second case are *not* listed in the Orange Book and as a result, are not subject to any Paragraph IV certifications by Sun.

Rejecting Sun's motion to dismiss, Judge Wigenton held that "the plain text of the Hatch-Waxman Act does not require the submission of a Paragraph IV certification to the FDA to commit the technical 'act of infringement' set forth in the statute, nor does it require that the asserted patent be listed in the Orange Book." Op., ECF No. 71, Civ. No. 19-10099, at 3 (Apr. 6, 2020). While Sun argued that it was "black letter law" that an infringement action under the Hatch Watchman Act requires the listing of the asserted patents in the Orange Book and Paragraph IV certifications, Judge Wigenton noted that Sun relied primarily on an older, unpublished, and non-binding district court decision. Op. at 3.

Citing more recent cases from the Federal Circuit, *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) and *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012), Judge Wigenton concluded that "a Paragraph IV certification is not necessary to confer subject matter jurisdiction under § 271(e)(2)." Op. at 3. Likewise, Judge Wigenton observed that subsequent decisions in the District of New Jersey have followed the Federal Circuit holding in *AstraZeneca*, that a Paragraph IV certification is not required to confer subject matter jurisdiction. Op. at 4. Therefore, subject matter jurisdiction exists over the second case, involving the three asserted patents that were *not* listed in the Orange Book, and Sun's motion to dismiss was denied. *Id.*

A full copy of Judge Wigenton's opinion is attached.