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Conversion of Paragraph IV Certification to Paragraph III Did Not Necessarily Deprive Court of Subject Matter Jurisdiction Over Hatch-Waxman Act Case

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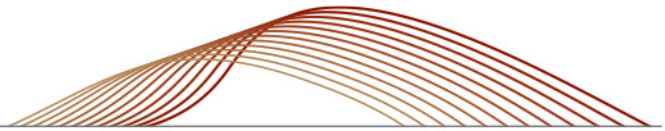
On January 26, 2017, the District of Delaware rejected Sandoz's attempt to have an infringement action against it dismissed for lack of subject matter jurisdiction based on its conversion from a paragraph IV ("PIV") certification to a paragraph III ("PIII") certification. *Sanofi v. Lupin Atlantis Holdings SA*, No. 15-415-RGA (D. Del. Jan. 26, 2017) ("Slip Op.").

A decade ago, the District of New Jersey rejected an attempt by Teva to do the same thing—have a pending action for infringement dismissed by converting its Paragraph IV certification to a Paragraph III certification. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 99-922 (DRD) (D.N.J. Dec. 14, 2006).

In this alert, we explore these decisions and offer practical guidance. In the recent Delaware case, Sanofi sued Sandoz for infringement of two Orange Book patents covering Multaq®. After a June 2016 trial, the Court ruled against Sandoz and enjoined it until 2029. Meanwhile, Sanofi had obtained another patent, the '900 patent, which also expired in 2029, listed that patent in the Orange Book, and sued Sandoz for infringement in a new case. After being enjoined until 2029, Sandoz sought a stay of the '900 patent case pending appeal from the earlier case. The Court denied Sandoz's stay request, so Sandoz converted its PIV certification on the '900 patent to a PIII certification and sought dismissal for lack of subject matter jurisdiction.

Judge Andrews considered the question of "whether a generic who has filed a Paragraph IV certification divests the district court of jurisdiction by the mere act of converting the Paragraph IV certification to a Paragraph III certification." The Court looked at two legal theories raised by the facts: jurisdiction under the Hatch-Hatch Waxman Act, and mootness. Slip Op. at 2.

As to the Hatch-Waxman Act issue, the Court held that, at a minimum, the initial PIV certification was sufficient under 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 1338 and that it "also appears that 28 U.S.C. § 2201 may confer jurisdiction." Slip Op. at 3. The Court further relied on Judge Robinson's prior opinion in *Cephalon, Inc. v. Sandoz, Inc.*, 2012 WL 682045 (D. Del. Mar. 1, 2012) (finding jurisdiction under both 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 1338(a) over infringement claims for two late-listed patents for which Sandoz had not filed PIV certifications). The District of New Jersey has held



similarly. *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 2013 WL 591976 (D.N.J. Feb. 14, 2013) (finding jurisdiction over infringement claim concerning patent for which there was no PIV certification because patent was not listed in the Orange Book at time of ANDA filing).

Judge Andrews also rejected Sandoz's mootness argument, finding that Sandoz's PIII conversion was a matter of convenience and expedience after "having exhausted legitimate means to seek a postponement of a trial scheduled for April 24, 2017." Slip Op. at 1, 3. The Court recognized that Sandoz's conversion was reversible again, and Sandoz indeed said it "could and very well might, convert its Paragraph III certification back to a Paragraph IV at some future date under certain circumstances." *Id*. at 3.

The Court recognized that a finding of mootness could incentivize gamesmanship:

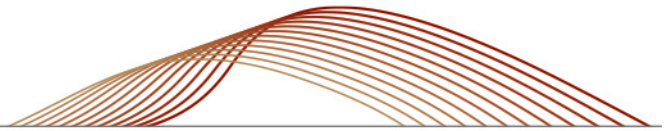
> If changing from Paragraph IV to Paragraph III were all that was required to divest the court of jurisdiction, presumably, assuming the generic were willing to pay some sanctions, it could moot the case after completion of the trial but before issuance of the decision if it did not like the way the trial had gone.

Id. at 5, n.2.

Although not discussed in the Delaware decision, Teva years earlier had tried the approach suggested by Judge Andrews. In litigation by Warner-Lambert against Teva, after years of litigation, including two summary judgment opinions, a week-long trial and decision, and a Federal Circuit affirmance of those trial rulings, Teva converted its PIV certification to a PIII certification and sought to have the case dismissed for lack of subject matter jurisdiction, seeking to avoid a trial on one remaining issue left in the case. *See,* e.g., D.I. 256 and 260-62 in *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 99-922 (DRD) (D.N.J.). Teva contended that it converted because "the parties ran out of time to obtain a final resolution of this case sufficiently in advance of the expiration of the patent-in-suit to permit generic launch before patent expiration." *Id.* at D.I. 262-1, p. 17. Teva even represented to the Court that "it will not change its Paragraph III certification" or launch the generic product described in the ANDA in suit before the patent expires or is declared invalid. *Id.* at D.I. 256-2, p. 3.

The wrinkle was that Teva was also litigating that patent in the context of another ANDA for a different product and was potentially facing a damages claim. It therefore appeared that Teva preferred not to resolve the sole remaining issue in the pending case on the record in that case. In a bench opinion rejecting the argument of mootness, the late Judge Debevoise found that "[t]he substitution of the Paragraph III certification for a Paragraph IV certification is an artificial rule lacking any substance in the context of the present bitterly fought case in which validity remains very much at issue." *Id.* at D.I. 274, p. 45:17-21.

The use of Paragraph III certifications for some patents in the Orange Book, or the conversion between certifications during litigation, has become more commonplace since the time of the *Teva* ruling. Generic drug companies use these approaches in order to, among other things, (1) avoid litigation altogether, (2) minimize the patents at issue in a litigation (at least initially), (3) try to control the timing of litigation, (4) position themselves differently from other generic companies, and/or (5) as a tool for trying to argue leverage against innovators. As this latest ruling shows, there are cases in which the courts decline to apply a *per se* rule for jurisdiction in the context of a PIII certification, and instead consider the facts. When there is a legitimate reason for patent enforcement despite a PIII certification, the facts providing that need for enforcement should be



carefully considered because they may justify subject matter jurisdiction and, ultimately, determine the best strategic course of action for the patent holder.

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