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Generic's Conversion from Paragraph IV to Section viii Upends Subject Matter Jurisdiction on Declaratory Judgment Counterclaims

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The District Court of Delaware dismissed a generic drug company's declaratory judgment counterclaims of non-infringement and invalidity, finding that the court no longer had subject matter jurisdiction after the generic company converted its Paragraph IV certification to a Section viii statement.

The generic company initially submitted its Abbreviated New Drug Application ("ANDA") seeking FDA approval for a generic version of Entresto® with certifications pursuant to 35 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications"), stating that its generic version would not infringe the listed patents or that those patents are not enforceable. The patent owner promptly asserted infringement claims for three method of use patents against the generic company, and the generic filed declaratory judgement counterclaims of non-infringement and invalidity of the asserted patents.

Nearly a year after the generic company notified the patent owner of its ANDA, the generic company converted its Paragraph IV certifications to a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii statement"). That statement confirmed the generic's ANDA no longer sought approval for indications covered by the asserted method patents. In response, the patent owner moved to dismiss its own infringement claims as well as the generic company's declaratory judgment counterclaims.

The patent owner argued that by converting its Paragraph IV certifications to a Section viii statement, the generic company was no longer seeking FDA approval for an infringing use, and therefore, there was no longer a case or controversy between the parties. The generic

company, however, argued that the court retained subject matter jurisdiction over its counterclaims under 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act. In addition, the generic company claimed that an actual controversy remained because the patent owner could re-file its infringement claims in the future.

As an initial matter, the court accepted the patent owner's voluntary dismissal of its infringement claims under Federal Rule of Civil Procedure 41(a)(2), finding that dismissal would not result in substantial prejudice to the generic company given that the ANDA litigation was at an early stage and minimal expenses had been incurred. Specifically, the court noted that the mere prospect of a subsequent lawsuit does not amount to prejudice for the generic company.

Without the patent owner's infringement claims to establish an actual controversy, the court then dismissed the generic company's declaratory judgment counterclaims for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). In doing so, the court explained that declaratory judgment actions require a case or actual controversy to maintain subject matter jurisdiction and an ANDA applicant's reliance on a Paragraph IV certification is dispositive for a justiciable declaratory judgment controversy. By converting its Paragraph IV certification to a Section viii statement, the generic company limited the scope of FDA approval sought to only non-patented indications. As such, the generic company was no longer under threat of an infringement suit, and the district court no longer had jurisdiction to adjudicate the declaratory judgment counterclaims of non-infringement and invalidity.

Practice Tip: Challenges to subject matter jurisdiction may be raised at any point during litigation, so parties should be mindful of how certain actions may affect subject matter jurisdiction. Particularly with respect to declaratory judgment counterclaims in ANDA litigation, there must be a case or actual controversy for the court to have subject matter jurisdiction. Because Section viii statements do not create a threat of an infringement suit, this alone will not create a case or actual controversy to establish subject matter jurisdiction over declaratory judgment counterclaims.

In re Entresto (Sacubitril/Valsartan) Patent Litigation, 1:20-md-02930 (D. Del. Nov. 14, 2022).

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