

DECLARATORY JUDGMENT JURISDICTION
(PRECEDENTIAL)

DEY PHARMA, LP v. SUNOVION PHARMACEUTICALS INC., Appeal No. 11-1507 (Fed. Cir. April 16, 2012). Before Bryson, Dyk and Moore. Appealed from D. Del. (Judge Stark)

Background:

Under the Hatch-Waxman Act, the filer of an NDA must identify any patents reasonable to assert with regard to a drug for which FDA approval is sought. The first filer of a "paragraph IV" ANDA receives a 180-day exclusivity period from the date of its marketing launch before later ANDA filers will be approved by the FDA. The Act was amended in 2003 in view of an FTC report that the 180-day exclusivity period had at times been delayed through collusion between NDA and first ANDA filers. A trigger was created for a later ANDA filer to prompt a first ANDA holder's 180-day exclusivity period. The exclusivity period is forfeited for failure to launch marketing within 75 days of final judgment of invalidity or non-infringement obtained by a later ANDA filer with regard to all patents listed in an NDA.

Sunovion holds an NDA approved in 1999 for an asthma medication. The NDA identifies three patents, which Sunovion asserted in litigation settled by agreement with a first ANDA filer. Dey filed a later "paragraph IV" ANDA. Sunovion sued Dey over two of the patents, but did not assert the latest expiring patent in an attempt to prevent the triggering of the 180-day exclusivity period. Dey brought a declaratory judgment action for invalidity or non-infringement of the third patent. Sunovion provided Dey with a covenant not to sue on the third patent and moved to dismiss the declaratory judgment action for lack of subject-matter jurisdiction. The district court denied Sunovion's motion to dismiss, holding that the covenant not to sue did not defeat declaratory judgment jurisdiction. Pursuant to a stipulation of the parties, the district court entered a final judgment of noninfringement. Sunovion appealed on the jurisdictional grounds.

Issue/Holding:

Did the district court err in finding it had declaratory judgment jurisdiction? No, affirmed.

Discussion:

Sunovion argued that even if jurisdiction existed when Dey filed the declaratory judgment action, it did not still exist under the totality of the circumstances because, by agreement, the first ANDA holder is entitled to enter the market by August 20, 2012, thereby triggering the 180-day exclusivity period. The Federal Circuit did not find this argument compelling because the first ANDA holder had not indicated any intended date of launch, and could continue to delay by agreement with Sunovion. Thus, the Federal Circuit did not find that the covenant not to sue eliminated jurisdiction with regard to the third patent because, under the Hatch-Waxman Act, Dey needed a final judgment of invalidity or non-infringement on all three patents tied to Sunovion's NDA. Under Sunovion's logic, if two patents tied to an NDA were divided between two declaratory judgment actions, each would preclude a finding of jurisdiction in the other. This would circumvent the trigger to the 180-day exclusivity period provided by the 2003 amendments to the Act. Accordingly, the Federal Circuit found that subject matter jurisdiction was proper and affirmed the district court's findings.