

Mylan's ANDA allegedly constituted an act of infringement causing Janssen to bring suit against Mylan alleging infringement of the '798 patent in the Northern District of West Virginia (the "West Virginia Action"). 35 U.S.C. § 271(e). Janssen did not bring suit on the '179 patent. After Mylan expressed its interest in amending its counterclaims to add claims of invalidity or non-infringement as to the '179 patent, the parties executed a covenant-not-to-sue on the '179 patent. Thereafter, Mylan discovered it did not hold "first-filer" status on the '179 patent and moved to amend its counterclaims in the West Virginia Action to include invalidity and non-infringement claims on the '179 patent. Mylan then filed here under the Hatch-Waxman Act, 21 U.S.C. § (j)(5)(C). The West Virginia District Court denied Mylan's motion to amend (ECF Doc. No. 46).

Janssen moves to dismiss Mylan's claims arguing: 1) Mylan's claims are compulsory counterclaims in the West Virginia Action and thus, barred in this action; and 2) Mylan fails to allege a case or controversy with regard to the '179 patent.

Article III case or controversy

Mylan's instant declaratory action presents a sufficient Article III case or controversy. In *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, the Federal Circuit found a justiciable case or controversy to be present on facts similar to those here. 527 F.3d 1278, 1290-97 (Fed. Cir. 2008). The Federal Circuit found plaintiff had standing in a ripe matter and the presence of a covenant-not-to-sue did not moot the controversy between the parties. *Id.*

Just as the Federal Circuit did in *Caraco*, we find Mylan has standing to maintain this action. The '179 patent is blocking Mylan from obtaining FDA approval for its generic drug and this "is exactly the type of injury-in-fact that is sufficient to establish Article III standing" *Id.* at 1292. Further, Mylan's injury is traceable to Janssen's conduct as it listed the '179 patent

in the Orange Book. *Id.* at 1292-93 (listing of a patent in the Orange Book “creates an independent barrier” sufficient to satisfy Article III’s causation requirement). Finally, a favorable judgment of invalidity or non-infringement would clear at least one potential hurdle to FDA approval of Mylan’s generic version and satisfy the redressability prong. *Id.* at 1293 (finding redressability satisfied even where a separate patent must still be adjudged invalid or not infringed). Accordingly, Mylan has sufficient Article III standing.

Caraco and its progeny also militate the Court finding this action is not rendered moot by the covenant-not-to-sue. *See id.* at 1296-97; *Dey Pharma, LP v. Sunovion Pharms Inc.*, 677 F.3d 1158, 1164 (Fed. Cir. 2012); *Purdue Pharm. Prods., L.P. v. Actavis Elizabeth, LLC*, No. 12-5311, 2014 WL 1394178, *4-6 (D.N.J. Apr. 9, 2014). Janssen attempts to distinguish *Caraco* and similar cases by arguing the parties negotiated the covenant not to sue rather than being unilaterally tendered by Janssen. (Def.’s Mot., 11; ECF Doc. No. 45, Def.’s Reply, 7-9.) However, Janssen provides no persuasive reasoning why a negotiated covenant changes the mootness analysis.

We find this argument misses the mark on why a covenant not to sue—negotiated or not—does not moot the controversy. The Federal Circuit held a covenant not to sue does not moot the controversy because despite being insulated from suit on a particular patent, the generic drug company still faces the obstacle of getting its drug to market, which can only be achieved through the first-filer triggering its 180-day exclusivity period or through a judgment of invalidity or non-infringement. *Caraco*, 527 F.3d at 1296 (finding if threat of suit were only action excluding plaintiff from marketplace, covenant not to sue would moot controversy). Since Mylan can begin the process of bringing its generic version to market upon a finding of invalidity or noninfringement, the covenant not to sue does not moot the controversy. Negotiating

the covenant does not alter this conclusion. Accordingly, the covenant not to sue does not moot this Article III case or controversy. After considering “all the circumstances”, this Court finds a justiciable Article III case or controversy exists between the parties. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007) (citation omitted).

Mylan’s claim is not a compulsory counterclaim in West Virginia

We now determine whether this case or controversy is a compulsory counterclaim in the West Virginia Action and thus barred from being litigated here. In doing so, we apply the “logical relationship” test adopted by both the Third Circuit and the Federal Circuit. *See Nasalok Coating Corp. v. Nylok Corp.*, 522 F.3d 1320, 1325 (Fed. Cir. 2008); *Transamerica Occidental Life Ins. Co. v. Aviation Office of Am., Inc.*, 292 F.3d 384, 389 (3d Cir. 2002). We consider the nature of the Hatch-Waxman Act, the gamesmanship it apparently engenders and the declaratory judgment relief afforded generic brand companies under the Hatch-Waxman Act. Weighing these various considerations, we find Mylan’s claims are not compulsory in the West Virginia Action and thus deny Janssen’s motion.

Janssen argues this declaratory judgment is a compulsory counterclaim because the claims arise out of the same “transaction or occurrence”, i.e., Mylan’s ANDA. (Def.’s Mot., 6-7.) Mylan counters by arguing each patent is a “separate right[.]” and as such, a declaratory judgment action on a previously unasserted patent cannot be a compulsory counterclaim. Mylan argues imposing Fed.R.Civ.P. 13(a) in the Hatch-Waxman context makes “even less sense” given the brand name drug company’s ability to withhold certain patents from suit in attempt to leverage the system. (Pl.’s Resp., 6.) We agree with Mylan in some regard. While we do not adopt a blanket rule finding each patent is separate in every case, we do agree the Hatch-Waxman protocol is unique and requires additional considerations.

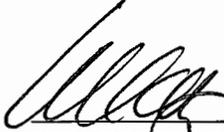
The parties cite no compulsory counterclaim cases in the Hatch-Waxman context and this Court's research reveals none. Courts find compulsory counterclaims to be barred in declaratory judgment cases where the defendant failed to bring a counterclaim of infringement on the same patent asserted by plaintiff. *Avante Intern. Tech., Inc. v. Hart Intercivic, Inc.*, No. 08-832, 2009 WL 2431993, *5 (S.D. Ill. July 31, 2009); *Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc.*, 347 F.3d 935 (Fed. Cir. 2003) (“[I]t is generally recognized that when the same patent is at issue in an action for declaration of noninfringement, a counterclaim for patent infringement is compulsory and if not made is deemed waived.”)

The distinct issue presented here is whether a claim of invalidity or noninfringement of one patent (the ‘179) is compulsory to a claim of infringement on a different patent (the ‘798). We observe the procedural posture in which this case arrives here is, in some ways, typical of a Hatch-Waxman case where the brand name company, for apparent tactical reasons, declines to initiate suit over all patents involved. *See Caraco*, 527 F.3d at 1288 (noting generic brand company brought separate declaratory judgment action on previously unasserted patent); *Dey*, 677 F.3d at 1163 (same); *Teva Pharms. USA, Inc. v. Eisai Co.*, 620 F.3d 1341, 1345 (Fed Cir. 2010) (same). Here, Janssen decided to sue Mylan only on the ‘798 patent in West Virginia. *Dey*, 677 F.3d at 1164. Having only been sued on the ‘798 patent, Mylan, pursuant to the plain language of the Hatch-Waxman Act, acted within its rights in filing this declaratory judgment action. *See* 21 U.S.C. § 355(j)(5)(C) (stating absent an infringement action on patent subject to a Paragraph IV certification, generic brand company may institute declaratory judgment action to determine validity or noninfringement of that same patent).

While Janssen is correct Mylan's ANDA is a transaction or occurrence from which both this action and the West Virginia Action arise, we find the more direct transaction or occurrence

is the filing of the Paragraph IV certifications with respect to each patent listed in the Orange Book. This declaratory judgment action is not a compulsory claim in West Virginia as the triggering event is the Paragraph IV certification relating to the '179 patent. The logical relationship between the two cases is more strained than Janssen would admit.

Fed. R. Civ. P. 13(a) does not prevent Mylan or Janssen from obtaining “a resolution of disputes involving all patents listed in the Orange Book” relating to CONCERTA. Congress expressly provides generic manufacturers a right to relief so as to facilitate “the prompt resolution of patent issues.” 149 Cong. Rec. S15882-03 (Nov. 25, 2003).



KEARNEY, J.