



# PHARMACEUTICAL LAW & INDUSTRY



## REPORT

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### Hatch-Waxman Act

## The Evolving Standard for Declaratory Judgment Jurisdiction In Hatch-Waxman Act Litigation

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Over the past year, Hatch-Waxman litigants have witnessed a transformation in the standards for bringing a declaratory judgment action. For several years, it was virtually impossible for an ANDA applicant to satisfy the Federal Circuit's rigid "reasonable apprehension of suit" test, which required actions on the part of both parties just short of an actual infringement suit. That changed with the Supreme Court's decision in *MedImmune Inc. v. Genentech Inc.*, where the Supreme Court criticized the Federal Circuit's approach in favor of a more flexible "all the circumstances" test. Although *MedImmune* was hailed initially as a rejection of the reasonable-apprehension-of-suit test, the Federal Circuit has continued to examine many of the same factors that were necessary to satisfy the old standard.

### A. The Federal Circuit Historically Applied a Strict Standard that Limited Declaratory Judgment Actions

An ANDA filer may pursue a declaratory judgment action under two different statutes: the Declaratory

Judgment Act, 28 U.S.C. § 2201(a), and the Civil Action to Obtain Patent Certainty provision in the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5) (ANDA filer may seek declaratory judgment on paragraph IV patent if patentee has not brought suit within 45 days of notice letter). To proceed under either statute, an ANDA filer must first establish that there is a constitutional "case or controversy" (see *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005)).

Prior to *MedImmune*, the Federal Circuit applied a strict two-part test to determine whether there was a case or controversy in patent cases. The party filing for a declaratory judgment was required to show:

- (1) an explicit threat or other action by the patentee that would create a reasonable apprehension of an imminent infringement suit; and
- (2) that it was presently involved in or taking steps toward activity constituting infringement (see *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997)). This test became known as the reasonable-apprehension-of-suit test.

*Teva v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005), provides a good illustration how the Federal Circuit applied the first part of this test to ANDA filers.<sup>1</sup> Pfizer listed two patents in the *Orange Book* for Zoloft (sertraline):

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<sup>1</sup> The second part of the test rarely was an issue because the submission of an ANDA was sufficient to satisfy that inquiry.

the '518 patent (2006 expiration) and the '699 patent (2010) *Id.* at 1326. Ivax filed an ANDA for sertraline, along with a paragraph III certification for the '518 patent and a paragraph IV certification for the '699 patent. *Id.* at 1329-30. Ivax was the first to file an ANDA with a paragraph IV certification and, therefore, was entitled to 180-days exclusivity. *Id.* at 1330. After Pfizer sued Ivax for infringement of the '699 patent, Ivax and Pfizer settled, with Pfizer granting Ivax a license under the '699 patent which allowed Ivax to market its product upon expiration of the '518 patent. *Id.*

Teva filed its ANDA for sertraline after Ivax. *Id.* at 1330. Like Ivax, Teva submitted a paragraph III certification for the '518 patent and a paragraph IV certification for the '699 patent. This time, however, Pfizer did not sue Teva. *Id.* Because of Ivax's 180-day exclusivity period, Teva could not gain FDA approval until 180 days after (1) Ivax began to commercially market its product or (2) a court issued a judgment of invalidity or noninfringement of the '699 patent. Teva filed a declaratory judgment action, seeking a determination that the '699 patent was invalid and not infringed. *Id.*

The Federal Circuit concluded that Teva failed to meet the reasonable-apprehension-of-suit test, holding that:

- “We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.” *Id.* at 1333.
- Pfizer's suit to enforce the patent against Ivax and general history of enforcing patent rights is relevant to the analysis but not dispositive. *Id.* at 1333.
- Pfizer's refusal to grant a covenant not to sue Teva also is relevant but not dispositive. *Id.*
- The court was not persuaded by Teva's argument that the reasonable-apprehension-of-suit test is “subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly . . . .” *Id.* at 1337-38.
- “The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer.” *Id.* at 1338.

The Federal Circuit, therefore, affirmed the dismissal of Teva's declaratory judgment suit.

## B. The Supreme Court Criticizes the Federal Circuit Approach in *MedImmune*

The Supreme Court espoused a more expansive view of declaratory judgment jurisdiction in *MedImmune Inc. v. Genentech Inc.*, 127 S. Ct. 764 (2007). *MedImmune* involved a dispute over whether a newly issued patent was covered by a license from Genentech to *MedImmune*. *Id.* at 768. *MedImmune* took the position that the new patent was not covered by the license, while Genentech asserted that it was. *Id.* Rather than risk an infringement suit, *MedImmune* chose to pay royalties on the patent under protest and then filed a declaratory judgment suit, seeking a ruling that the new patent was invalid or not infringed. *Id.* The narrow issue in *MedImmune* was whether a licensee could bring a declaratory judgment suit against the patentee while

still paying royalties, because the payment of royalties meant that there was no imminent threat that the patentee would sue the licensee for infringement.

In the process of resolving this narrow issue, the Supreme Court more broadly addressed the case-or-controversy requirement for declaratory judgment jurisdiction. The court held that the existence of a case or controversy is to be judged under the “all the circumstances” test:

Basically, the question in each case is whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

*Id.* at 771 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The court expressed its view that:

The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is a “dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.”

*Id.* at 773 (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967)). The Supreme Court went out of its way to criticize the Federal Circuit's reasonable-apprehension-of-suit test, noting that it “contradicts” and “conflicts” with the Supreme Court's approach. *Id.* at 774 n.11.

## C. Federal Circuit's Reaction to *MedImmune*

The Federal Circuit initially held that “[t]he Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test.” *San Disk Corp. v. STMicroelectronics Inc.*, 480 F.3d 1372, 1380 (Fed. Cir. 2008); see also *Teva*, 482 F.3d at 1339 (reasonable-apprehension-of-suit test overruled by *MedImmune*). More recently, however, the Federal Circuit has tempered that view, holding that *MedImmune* “did not completely do away with the relevance of a reasonable apprehension of suit,” *Prasco LLC v. Medicis Pharm. Corp.*, 2008 U.S. App. LEXIS 17329, No. 06-cv-313, \*10 (Fed. Cir. Aug. 15, 2008), and that its post-*MedImmune* decisions were intended to “reshape[] the contours” of the Federal Circuit's test. *Cat Tech LLC v. Tube Master Inc.*, 528 F.3d 871, 880 (2008).

The Federal Circuit has been reluctant to provide clear guidance “on the outer boundaries of declaratory judgment jurisdiction” post-*MedImmune*. *San Disk*, 480 F.3d at 1381. The court has been careful to include qualifying language in its opinions and has declined to set a standard:

There is . . . no facile, all-purpose standard to police the line between declaratory judgment actions which satisfy the case or controversy requirement and those that do not.

*Cat Tech*, 528 F.3d at 879. Nevertheless, over the course of several decisions, the Federal Circuit has elucidated several “circumstances” that it will consider when determining whether declaratory judgment exists. These circumstances fall broadly into three categories:

- (1) whether the patentee has taken an affirmative act or a position adverse to the ANDA filer in connection with the patent in suit;

- (2) whether the patentee has caused economic harm to the ANDA filer; and
- (3) the purposes of the Hatch-Waxman Act.

### I. An Affirmative Act or Statement of Adverse Position

*Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.* (Novartis), 482 F.3d 1330 (Fed. Cir. 2007), is the starting point for any discussion of declaratory judgment jurisdiction in the Hatch-Waxman context. In *Novartis*, Teva filed an ANDA for Famvir (famcyclovir), for which Novartis had listed five patents in the *Orange Book*. *Id.* at 1334. Teva submitted a paragraph IV certification for all five of the *Orange Book* patents. *Id.* Novartis, however, brought suit only on one patent, which was sufficient to trigger the automatic 30-month stay under the Hatch Waxman Act. *Id.* at 1335. Teva then filed a declaratory judgment action on the four remaining patents. *Id.* The district court dismissed Teva's action, holding that Teva failed to establish a reasonable-apprehension-of-suit on the four patents. *Id.*

After first noting that *MedImmune* controlled the analysis, the Federal Circuit reversed, holding that the following "circumstances" were sufficient to support declaratory judgment jurisdiction:

- Novartis listed its patents in the *Orange Book*. This, the court said, did not establish an Article III controversy in itself but should be considered in the totality of the circumstances. *Id.* at 1341.
- The very act of submitting an ANDA with a paragraph IV certification is an act of infringement and that "if such an action creates a justiciable controversy for one party [i.e., Novartis], the same action should create a justiciable declaratory judgment controversy for the opposing party [i.e., Teva]." *Id.* at 1342.
- Novartis's strategy enabled it to claim the benefits of a 30-month stay, while insulating the other four patents from challenge. This frustrated the objective of the Hatch-Waxman Act, which was to have all potential patent issues resolved during the period of regulatory review. *Id.* at 1342-43.
- Novartis had pending litigation on one of the *Orange Book* listed patents. *Id.* at 1344-45.
- There was a "possibility of future litigation that Novartis created by electing to challenge Teva's ANDA on only one of the five *Orange Book* listed Famvir patents." *Id.* at 1345.

The Federal Circuit concluded that, "[although] several of Teva's grounds alleging an 'actual controversy' when standing alone might not be sufficient, if taken as a whole these circumstances establish a justiciable controversy with Novartis that can be resolved by allowing Teva to bring a declaratory judgment." *Id.* at 1341 (emphasis added).

#### a. *Orange Book Listings and Paragraph IV Certifications*

Although an explicit threat of suit is no longer required, the Federal Circuit still looks to determine if the patentee has taken "some affirmative act" or "position" that puts the declaratory judgment plaintiff "in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk Corp. v. STMicroelectronics Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007). The court in *Novartis* did not expressly address the existence of an "affirmative act" or "adverse position" by the patentee, but the con-

duct of the patentee nevertheless featured prominently in the Court's decision:

A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the *Orange Book*, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

*Novartis*, 482 F.3d at 1344 (emphasis added).

Left unanswered in *Novartis* is whether the first two of these three circumstances—the patentee's listing of a patent in the *Orange Book* and the ANDA filer's paragraph IV certification for that patent—would be sufficient. The majority opinion relies on the existence of already pending litigation, see *id.*, but Judge Friedman in his concurrence suggests that the first two circumstances may be sufficient. *Id.* at 1347; see also *3M v. Barr Cabs*, 289 F.3d 775, 784 (Fed. Cir. 2002) (Gajarsa, J., concurring) (*Orange Book* listing and submission of ANDA are sufficient for jurisdiction).

#### b. *Prior Litigation Filed by the Patentee*

"Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy." *Prasco*, 2008 U.S. App. LEXIS 17329 at \*24; see also *Novartis*, 482 F.3d at 1344. It is clear from *Novartis* that litigation pending on one *Orange Book* patent is sufficient to create declaratory judgment jurisdiction over other *Orange Book* patents. *Novartis*, 482 F.3d at 1344 ("[R]elated litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on the other related patents"). It seems equally clear that prior litigation between the ANDA filer and the patentee over unrelated patents covering a different drug is not sufficient. *Prasco*, 2008 U.S. App. LEXIS 17329 at \*24.

It remains unclear how the Federal Circuit will weigh other litigation that falls between these two extremes, such as where a patentee files suit against one ANDA applicant for violation of an *Orange Book* patent but does not file a similar suit against a subsequent ANDA applicant on the same patent (see *Pfizer*, 395 F.3d at 1333). Also, the Federal Circuit has not ruled on whether a suit on an *Orange Book* patent is sufficient to establish declaratory judgment jurisdiction related to a non-*Orange Book* patent covering the same drug.

#### c. *Perceived Threat of Patent Infringement Litigation May Not Be Enough*

"[J]urisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patents to pose a risk of infringement, without some affirmative act by the patentee." *Id.* at \*18 (quoting *SanDisk*, 480 F.3d at 1380-81). In *Prasco*, *Prasco* marketed a generic benzoyl peroxide product OSCION, which competed with Medicis' TRIAZ product. *Prasco*, 2008 U.S. App. LEXIS 17329 at \*2. TRIAZ was marked as being covered by four patents. *Id.* *Prasco* filed an action seeking

a declaratory judgment that its product did not infringe the four patents covering TRIAZ. *Id.* at \*1. The district court dismissed Prasco's declaratory judgment action because Prasco failed to establish a case or controversy. *Id.* at \*2.

The Federal Circuit affirmed, holding that the district court's decision was correct under *MedImmune*. In reaching that decision, the court weighed the following circumstances:

- A purely subjective fear that the patentee may bring an infringement action in the future is not does not cause a justiciable injury. Prasco actually launched its product despite the existence of the four patents. *Id.* at \*18.
- Medicis did not accuse Prasco of infringement, assert any rights to OSCION, or take any actions which would imply such claims. *Id.* at \*21.
- Medicis previously sued Prasco for infringement of unrelated patents covering different products. "[O]ne prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that Medicis will also take action against Prasco regarding its new product." *Id.* at \*24.
- Medicis failed to sign a covenant not to sue Prasco after Prasco sent them samples of OSCION. *Id.* at \*25-\*26.

The constant theme running throughout *Prasco* is the "bed-rock rule" that a case or controversy "must be based on a *real and immediate* injury or threat of injury that is *caused by the defendants*." *Id.* at \*18 (emphasis original).

#### d. Patentee's Refusal to Grant Covenant Not to Sue

The Federal Circuit has held that a patentee's refusal to grant a covenant not to sue is not sufficient to create a justiciable controversy:

[T]hough a defendant's failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy—some affirmative actions by the defendant will also generally be necessary.

*Prasco*, 2008 U.S. App. LEXIS 17329 at \*25-\*26. The statement that a covenant not to sue is "one circumstance to consider" is also consistent with the Federal Circuit's opinion in *SanDisk*, where, despite a promise not to sue, the Court found a justiciable case or controversy because the patentee had taken an adverse position and an "affirmative act" indicating a willingness to file suit (see *SanDisk*, 480 F.3d at 1381).

## II. The Actions of the Patentee Have Caused Other Economic Harm

An ANDA application also may be able to establish declaratory judgment jurisdiction if it suffers a real and immediate injury caused by the patentee. *Caraco Pharm. Labs. Ltd. v. Forest Labs. Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). In *Caraco*, Forest Laboratories listed two patents in the *Orange Book* for Lexapro (escitalopram), the '712 patent, (expiration 2012), and the '941 patent (2023). *Id.* at 1286. Ivax was the first to file an ANDA for escitalopram and submitted paragraph IV certifications for both *Orange Book* listed patents, asserting that they were invalid. *Id.* Ivax, therefore, was entitled to 180-days exclusivity. Forest brought an infringement suit against Ivax on the '712 patent only. *Id.*

Forest obtained a judgment that its patent was valid and infringed by Ivax's drug. *Id.* Ivax, therefore, was barred from marketing its product until the expiration of the '712 patent in 2012. *Id.* at 1287.

Caraco filed its ANDA for escitalopram after Ivax and submitted paragraph IV certifications for the '712 and '941 patents. *Id.* at 1288. As it did with Ivax, Forest responded with an infringement suit for the '712 patent, but declined to sue Caraco on the '941 patent. *Id.* Caraco filed suit seeking a declaratory judgment of invalidity or noninfringement of the '941 patent. Forest unilaterally granted Caraco a covenant not to sue for infringement of the '941 patent, which, Forest argued, eliminated any controversy between the parties. *Id.* at 1289-90. The district court agreed, and dismissed Caraco's complaint. *Id.* Caraco appealed.

By granting Caraco the covenant not to sue, Forest removed the possibility that Caraco would be required to launch at risk. Instead, Caraco was faced with a delayed launch due to its inability (in the absence of a declaratory judgment) to market its product until the expiration of Ivax's 180-day exclusivity period. *Id.* at 1288; see also *Pfizer*, 395 F.3d at 1334-35. The Federal Circuit determined that the covenant not to sue did not render Caraco's declaratory judgment action moot because, although it did eliminate any reasonable-apprehension-of-suit, the injury of being denied entry into the market was still present. *Id.* at 1296-97 (but see *Merck & Co. Inc. v. Apotex Inc.*, 2008 U.S. App. LEXIS 18378 at \*7 (Fed. Cir. Aug 21, 2008)) (affirming dismissal of declaratory judgment suit challenging disclaimed patents because final judgment could not be provided in time to have a meaningful impact on first filers' exclusivity rights).

In contrast to *Caraco*, the Federal Circuit held in *Janssen* that an ANDA applicant cannot establish declaratory judgment jurisdiction where market entry might be delayed, not by the patentee, but by a first filer who holds the 180-day exclusivity period. *Janssen Pharmaceutica NV v. Apotex Inc.*, 2008 U.S. App. LEXIS 18822, No. 06-cv-1020, (Fed. Cir. Sept. 4, 2008). *Janssen* originally listed three patents in the *Orange Book* for Risperdal (risperidone), the '663 patent (2008 expiration), the '425 patent (2014) and '587 (2014). *Id.* at \*8-\*9. Teva was the first filer. *Id.* at \*10. Teva submitted a paragraph III certification for the '663 patent and paragraph IV certifications for the '425 and '587 patents. *Id.* *Janssen* did not sue Teva on either the '425 or '587 patents, meaning that FDA could approve Teva's ANDA in 2008 upon expiration of the '663 patent. *Id.* As the first to submit a paragraph IV certification to the '425 and '507 patents, Teva was entitled to 180-days exclusivity. *Id.*

Apotex submitted its ANDA after Teva. *Id.* at \*11. Apotex initially submitted paragraph IV certifications for the '425 and '587 patents only. *Id.* It subsequently amended its ANDA to provide paragraph IV certification for the '663 patent. *Id.* *Janssen* brought suit against Apotex for infringement of the '663 patent but did not bring suit on the '425 and '587 patents. *Id.* In its answer to *Janssen's* suit, Apotex sought a declaratory judgment of noninfringement of the '425 and '587 patents. *Id.* Apotex subsequently stipulated to validity, infringement and enforceability of the '663 patent after the Federal Circuit ruled in favor of *Janssen* in other Risperdal litigation involving Mylan. *Id.* at \*9. After *Janssen* provided Apotex with a covenant not to sue on the '425 and

'587 patents, the district court dismissed Apotex's declaratory judgment claim as lacking a justiciable controversy. *Id.* at \*12.

The Federal Circuit distinguished Apotex's injury from that suffered by Caraco:

Caraco wanted to be able to challenge both patents and if successful, this would trigger Ivax's 180-day exclusivity period *at a time when Ivax could obtain FDA approval and then launch its product*. Hence, if Caraco was successful, Ivax would get its 180-day exclusivity sooner and Caraco would be able to obtain FDA approval earlier—resulting in greater competition at an earlier time. Without a declaratory judgment, Caraco could be excluded from selling a noninfringing product even if the asserted patent was proven to be invalid.

*Id.* at \*19 (emphasis original). Unlike Caraco, Apotex was not excluded from selling its product due to an allegedly invalid patent—it stipulated to the validity and infringement of the '663 patent. The Federal Circuit stated that “Apotex [was] excluded from the market by Teva's 180-day exclusivity period—a period which Teva [was] entitled to under the Hatch-Waxman Act.” *Id.* at \*20. The court then held that “Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act.” *Id.*

### III. The Purpose of the Hatch-Waxman Act

In addition to weighing the factual circumstances, the Federal Circuit often considers the purpose of the Hatch-Waxman Act when determining whether to assert declaratory judgment jurisdiction. In *Novartis*, the

court was concerned that the patentee could take undue advantage of the Hatch-Waxman Act:

By filing a lawsuit on only one [of] its five patents certified under paragraph IV in Teva's ANDA, Novartis has tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities.

*Id.* at 1330. The court found that Novartis was attempting to gain a 30-month stay without allowing Teva to obtain certainty of the validity or infringement of four of the patents. *Id.* This weighed in favor of allowing the ANDA filer to proceed with a declaratory judgment action. In contrast, the Federal Circuit held in *Janssen* that Apotex's exclusion from the market by Teva's 180-day exclusivity period was a result envisioned by the Hatch-Waxman Act and, therefore, not a justiciable injury. *Janssen*, 2008 U.S. App. LEXIS 18822 at \*20.

## Conclusion

Although *MedImmune* has spurred the Federal Circuit to relax some aspects of the reasonable-apprehension-of-suit test, that test remains a significant factor in the court's analysis of declaratory judgment jurisdiction in patent cases. There appears to be some tension within the Federal Circuit as some judges view *MedImmune* as a repudiation of the reasonable-apprehension-of-suit test, while others take a less expansive view of *MedImmune*. In the future, ANDA applicants will be required to show some conduct by the patentee, or injury caused by the patentee, to support declaratory judgment jurisdiction absent an explicit threat of suit.