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United States
Hatch-Waxman declaratory judgments

The Drug Price Competition and Patent Term Restoration Act 1984 (commonly referred to as 'Hatch-Waxman') attempts to strike a balance between the interests of innovative drug manufacturers and generic manufacturers. As part of this balance, an innovator alerts the public and generic competitors as to which patents it believes cover its Food and Drug Administration (FDA)-approved drug product or methods of the product's use by listing the patents in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the 'Orange Book'). While an innovator may list several patents in the Orange Book, it may not assert all patents against the generic manufacturer (eg, if it concludes that the generic's product does not infringe certain patents). This can lead to uncertainty for generics, since nothing in Hatch-Waxman will stop an innovator from later asserting those same patents against the generic's product after market launch. As a result, generics often seek a declaratory judgment that an unasserted patent is invalid or not infringed, and recent Supreme Court and Court of Appeals for the Federal Circuit decisions have given more strength and structure to declaratory judgment actions in the area of Hatch-Waxman.

The Hatch-Waxman Act: balancing competition and innovation

In 1984 Congress enacted the Hatch-Waxman Amendments (Public Law 98-417, 98 Stat 1585 (codified at 21 USC §§ 350, 360cc and 35 USC §§ 156, 271, 282)). In this legislation Congress struck a balance between the divergent interests of innovative drug manufacturers and generic manufacturers by facilitating the rapid availability of safe, affordable generic drugs, while simultaneously incentivising and rewarding the research and development of novel drug therapies. Hatch-Waxman remedied any *de facto* extension of an innovator's monopoly by providing generics with a safe harbour to pursue drug product approval prior to expiration of an innovator's patent (see 35 USC § 271(e)(1)). In addition, a generic is required to conduct limited testing only to prove that its product is bioequivalent to the innovator's drug product before it files an abbreviated new drug application (ANDA) with the FDA (see 21 USC § 355(j)(2)(A)). To prevent the expedited application and approval process from unfairly prejudicing innovators, Congress included patent listing, certification, notice and challenge procedures to allow innovators to bring patent challenges that will stay regulatory approval of the generic's product.

Under Hatch-Waxman an innovator (or patentee in partnership with the innovator) submits information to the FDA for patents covering its drug product or approved methods of the product's use, which the FDA then publishes in the Orange Book (21 USC § 355(b)(1), (c)(2)). When a generic files an ANDA, it must certify whether each patent listed in the Orange Book (if any) has expired, will expire before the generic sells its product or is invalid, unenforceable or not infringed by the generic's product (ie, a Paragraph IV certification) (21 USC § 355(j)(2)(A)(vii)(I-IV)). As an incentive to file ANDAs and to challenge Orange Book-listed patents, the first generic to file an ANDA containing a Paragraph IV certification may be entitled to 180 days of marketing exclusivity during which no other similar ANDA can be approved (21 USC § 355(j)(5)(B)(iv)(II)(bb)). This exclusivity gives the first generic a significant competitive advantage with regard to other potential generics, allowing it to recoup its costs in seeking product approval and to acquire a significant portion of the relevant market.

As a part of the Hatch-Waxman *quid pro quo*, an ANDA applicant must notify and provide the patentee and NDA holder with the factual and legal bases of any Paragraph IV certifications within 20 days of receipt of notice from the FDA that its ANDA has been accepted for filing (21 USC § 355(j)(2)(B)(i)). Once notified, an innovator has the option of filing an infringement action under 35 USC § 271(e)(2) against the ANDA applicant.

If the innovator sues within 45 days of receipt of the notice, the FDA will stay approval of the ANDA for 30 months or until resolution of the infringement action in the ANDA applicant's favour, whichever is sooner (21 USC § 355(j)(5)(B)(iii)). If the innovator does not file suit, the FDA may approve the ANDA at any time upon completion of its review (*id*).

Originally, the 180-day exclusivity period could be triggered by the earlier of:

- the ANDA applicant's marketing of the generic product; or
- a court decision of non-infringement or invalidity with respect to all of the patents through which the first ANDA applicant qualified for exclusivity (21 USC § 355(j)(5)(B)(iv) (2000)).

The Medicare Prescription Drug, Improvement and Modernisation Act of 2003 (MMA) (Pub L 108-173, 117 Stat 2066) replaced the second prong of this triggering statutory scheme with forfeiture provisions which define when a first ANDA applicant forfeits its marketing exclusivity if it fails to market its product by a certain date (see 21 USC § 355(j)(5)(D) (Supp 2004)). These forfeiture provisions only affect ANDAs filed after December 8 2003, for which no Paragraph IV certification was made before December 8 2003 (MMA § 1102(b), 117 Stat at 2460).

Evolution of Hatch-Waxman declaratory judgment actions

Whether for strategic reasons or simply because a claim cannot reasonably be pursued, innovators do not always assert all Orange Book-listed patents against ANDA applicants despite receiving a Paragraph IV certification. While it may be unlikely that the innovator would later assert such a patent against the generic's product, innovators are not precluded from serially asserting Orange Book-listed patents against ANDA applicants, which creates uncertainty for the generic in launching its product. As a result, an ANDA applicant may elect to file a declaratory judgment action against the innovator alleging that any such patents are invalid or not infringed by its generic product.

Two statutes establish the jurisdictional requirements for declaratory judgment actions in patent cases:

- the Declaratory Judgment Act (28 USC § 2201); and
- the patent infringement statute (35 USC § 271).

The Declaratory Judgment Act requires an "actual controversy within [the court's] jurisdiction", which is derived from the general authority and jurisdiction for federal courts in the United States Constitution (Constitution Art III, § 2; *MedImmune, Inc v Genetech, Inc* 127 SCt 764, 771 (2007)). The statute also sets forth that courts have discretion over whether to exercise jurisdiction for declaratory judgment actions. Under 28 USC § 1338 the federal district courts have original jurisdiction in any case arising under the patent statute. So, a declaratory judgment action involving a patent claim is within the federal district court's jurisdiction, provided that there is an "actual controversy" in the case.

In conjunction with these statutory requirements, the Federal Circuit developed a two-part reasonable apprehension of suit test to determine whether a federal district court has jurisdiction over a declaratory judgment action in a patent case (*EMC Corp v Norand Corp*, 89 F 3d 807, 811 (Fed Cir 1996)). Based on this test, the Federal Circuit frequently found that Hatch-Waxman declaratory judgment actions lacked subject-matter jurisdiction. Thus, uncertainty remained for ANDA applicants when the innovator did not file an infringement action within 45 days of receiving a Paragraph IV certification for a particular patent listed in the Orange Book.

Congress attempted to remedy this uncertainty through the MMA by amending Hatch-Waxman to establish civil actions for patent certainty. The MMA expressly permits declaratory judgment actions when an ANDA applicant makes a Paragraph IV certification and is not sued for infringement of that patent by the innovator (see 21 USC § 355(j)(5)(C) (Supp 2004)). These amendments appear to indicate a broad Congressional endorsement of declaratory judgment actions by ANDA applicants. However, prior to the Supreme Court's decision in *MedImmune*, US district courts and the Federal Circuit were still reluctant to entertain Hatch-Waxman declaratory judgment actions (see *Teva Pharmaceuticals USA, Inc v Pfizer, Inc*, 395 F3d 1324 (Fed Cir 2005) (abrogated by *MedImmune*)).

The Supreme Court's decision in *MedImmune* focused on the totality of the parties' legal interests when determining whether there is an Article III case or controversy, and signalled the demise of the reasonable apprehension of suit test. The Supreme Court stated that the 'case of actual controversy' requirement of 28 USC § 2201(a) refers to, and is co-extensive with, the limits of justiciability under Article III of the Constitution (*MedImmune*, 127 S Ct at 771 (citing *Aetna Life Inc Co v Haworth*, 300 US 227, 240 (1937)). According to the Supreme Court, "the question in each case is whether the facts alleged, under all 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" (*MedImmune*, 127 S Ct at 771 (citation omitted)). Citing *MedImmune*, the Federal Circuit subsequently found jurisdiction in the Hatch-Waxman declaratory judgment context (eg, see *Teva Pharmaceuticals USA, Inc v Novartis Pharmaceuticals Corp*, 482 F3d 1330 (Fed Cir 2007)).

Hatch-Waxman declaratory judgment actions and covenants not to sue

The interaction of the Article III case or controversy requirement and the patent challenge provisions of Hatch-Waxman sparked the development of a significant body of precedence related to declaratory judgment jurisdiction. The Supreme Court's decision in *MedImmune*, ostensibly relaxing the Article III standard, added fuel to that fire. Prior to the *MedImmune* decision, the Federal Circuit frequently refused to find subject matter jurisdiction, citing the lack of a justiciable controversy under the reasonable apprehension of suit test. However, the Supreme Court's criticism in *MedImmune* and the Federal Circuit's subsequent abandonment of that standard paved the way for finding broad declaratory judgment jurisdiction in Hatch-Waxman cases. Federal Circuit precedence has now established that even the absolute lack of any apprehension of suit is not dispositive of the existence of an Article III controversy.

In *Caraco Pharm Labs v Forest Labs* (527 F.3d 1278 (Fed Cir 2008)) the Federal Circuit found that in the context of the Hatch-Waxman framework, a covenant not to sue does not necessarily eliminate Article III subject matter jurisdiction. In *Caraco* Forest, the innovator, had listed two patents, the '712 and '941 patents, in the Orange Book for Lexapro (*id* at 1286). Ivax filed the first ANDA for Lexapro, which contained Paragraph IV certifications for both patents (*id*). As such, Ivax was entitled to 180 days of exclusivity. Forest sued Ivax only for infringement of the '712 patent, and Forest ultimately prevailed (*id* (citing *Forest Labs, Inc v Ivax Pharms, Inc*, 501 F 3d 1263 (Fed Cir 2007)). As a result, Ivax could not market its product until after the '712 patent expired (*id* at 1287).

Caraco filed a second ANDA for Lexapro, which also contained Paragraph IV certifications for both patents (*id* at 1288). Forest again sued Caraco only for infringement of the '712 patent and granted a covenant not to sue on the other unasserted patent (*id*). As the second ANDA applicant, Caraco was prevented from marketing its product by the existence of Ivax's 180-day exclusivity. However, if Caraco could trigger Ivax's exclusivity by obtaining a judgment of non-infringement or invalidity with regard to both the '941 and the '712 patents, Caraco would be free to market its product once Ivax's exclusivity expired (*id* at 1287). To this end, Caraco filed a declaratory judgment counterclaim seeking a declaration of non-infringement of the '941 patent (*id* at 1288). Perhaps recognising the possibility that Caraco could trigger Ivax's exclusivity through favourable judgments on both the '941 and the '712 patents, Forest subsequently gave Caraco a covenant not to sue on the '941 patent, eliminating any apprehension of suit on that patent. Thereafter Forest filed a motion to dismiss Caraco's counterclaim, which the district court granted (*id*).

On appeal, the Federal Circuit reversed the district court's dismissal of Caraco's counterclaim, finding that an actual Article III controversy was present despite Forest's covenant not to sue on the unasserted patent (*id* at 1291). Applying the "all the circumstances" standard set forth in *MedImmune*, the Federal Circuit concluded that there was an actual Article III controversy between Forest and Caraco over the '941 patent (*id* at 1291-1294). First, should Caraco win in its challenge to the '712 patent, it would still be prevented from entering the market by Ivax's 180-day exclusivity, even if Caraco's product did not infringe the '941 patent (*id* at 1291-1292). This preclusion, reasoned the court, constituted an injury in fact (*id*). Second, this injury was traceable to Forest through Forest's conduct of listing the '712 and '941 patents in the Orange Book (*id* at 1292-1293). Finally, Caraco's injury was capable of being addressed through judicial intervention (*id* at 1293). Thus, the court found that Caraco had standing to bring its counterclaim with regard to the '941 patent.

The court also found that the covenant not to sue granted to Caraco did not render the case moot. The Federal Circuit noted that although the covenant not to sue clearly eliminated any apprehension of suit, the case was nonetheless live and not moot because Caraco was still prevented from entering the Lexapro market (*id* at 1296). This barrier was created "in a manner that is unique to the Hatch-Waxman context" (*id*). In other words, listing the '941 patent in the Orange Book "constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment'" ((*id* at 1297, citing *MedImmune*, 127 S Ct at 771).

Caraco illustrates the significant impact that *MedImmune* has had on the analysis of Hatch-Waxman declaratory judgment jurisdiction. A broad reading of the *Caraco* opinion supports the idea that the mere listing of a patent in the Orange Book coupled with an ANDA containing a Paragraph IV certification to the patent can create an Article III controversy. However, this

conclusion has been tempered by another recent Federal Circuit decision, *Janssen Pharmaceutica, NV v Apotex, Inc* (No 2008-1062 (Fed Cir Sept 4 2008)), which suggests that an Article III controversy will no longer exist if the ANDA applicant stipulates to infringement, validity and enforceability of a patent listed in the Orange Book.

In *Janssen* Apotex was not the first ANDA applicant for risperidone oral solution (Risperdal Oral Solution) (*id* at *6). Apotex filed an ANDA with Paragraph IV certifications for all three patents listed in the Orange Book, but Janssen sued Apotex on only one of the patents, the '663 patent (*id* at *7-8). That same patent was subsequently affirmed in another case as valid, enforceable and infringed (*id* at *6, citing *Janssen Pharmaceutica, NV v Mylan Pharm, Inc,* 456 F Supp 2d 644, 671 (DNJ 2006), aff'd 233 Fed Appx 999 (Fed Cir 2007)). Although that action did not include Apotex, Apotex nevertheless stipulated to the infringement, validity and enforceability of the '663 patent (*id* at *6-7).

Prior to the stipulation, Apotex had counterclaimed to seek a declaratory judgment of non-infringement with respect to the two other patents listed in the Orange Book (*id* at *8). As in *Caraco*, Janssen provided Apotex with a covenant not to sue and the district court subsequently dismissed Apotex's counterclaims for lack of subject matter jurisdiction (*id*). Unlike *Caraco*, however, the Federal Circuit affirmed the district court, rejecting Apotex's argument that *Caraco* was controlling. The court found that while there had been harm that created a justiciable Article III controversy when Apotex filed its counterclaims, "that harm ceased to exist upon Apotex's stipulation" (*id* at *11). The court reasoned that Apotex was not being excluded from the market by an invalid patent (it had stipulated as to the patent's validity), but rather was being excluded from the market by the first ANDA applicant's 180-day exclusivity (*id* at *13).

Conclusion

Recent case law supporting Hatch-Waxman declaratory judgment jurisdiction provides generics with the opportunity to have greater certainty prior to market launch of a generic product. These same actions may also be exploited by later ANDA applicants to cause the first ANDA applicant to bring generic products to market sooner or risk forfeiting its 180-day exclusivity. In such circumstances, innovators may have an incentive to grant covenants not to sue to ANDA applicants to attempt to eliminate declaratory judgment jurisdiction. However, under *Caraco*, courts might nevertheless find that an Article III controversy exists, but this jurisdiction may be compromised if the ANDA applicant stipulates to the validity and infringement of patents listed in the Orange Book. Thus, innovators and generics alike must carefully evaluate their strategic positions in the market, taking into additional consideration the likelihood that an ANDA applicant will be able to maintain declaratory judgment jurisdiction under Hatch-Waxman.

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