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The following are two more cases involving Abbreviated New Drug Applications (ANDAs).

Otsuka Pharmaceutical v. Barr Laboratories

On December 5, 2008, Magistrate Hughes of the Federal District Court in New Jersey denied plaintiff's motion to amend the pleadings to update its ANDA infringement allegations by adding a willful infringement count against six defendants (Barr Laboratories, Sandoz, Sun Pharmaceutical, Teva Pharmaceutical, and Apotex), as well as adding an infringement allegation under 35 U.S.C. § 271(a) against three of the defendants (Apotex, Sandoz, and Teva) in Civil Action No. 07-1000 (MCL). Plaintiff also sought bifurcation of the willfulness issues and the 35 U.S.C. § 271(a) infringement issues from the liability issues after closing of the pleadings as well as stay of discovery as to the willfulness and 35 U.S.C. § 271(a) infringement issues.

In support of the motion to amend Otsuka argued that:

> Courts have clearly and consistently held that there can be willful infringement in the context of ANDA litigation, when the allegations point to more than just the bare ANDA filing.

In opposing the motion, the defendants argued that the requested amendment should be denied because the proposed amendments were futile. First, the defendants argued that willful infringement based on the filing of an ANDA is simply unavailable in a patent suit based solely upon 35 U.S.C. § 271(e)(1). Accordingly, Otsuka's allegations of deliberate copying, baseless Paragraph IV Certifications, baseless pleadings, and litigation misconduct, cannot change the statute. Defendants further argued that the Federal Circuit has repeatedly confirmed that a claim for willful infringement is simply not available in a patent infringement case based solely on an ANDA filing. [See *Glaxo Group Ltd. V. Apotex Inc.*, 376 F.3d 1339 (Fed. Cir. 2004); *see also Yamanouchi Pharm. Co. Ltd. V. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. ir. 2000).]

Janssen v. Apotex

In this ANDA case decided September 4, 2008, the Federal Circuit affirmed the order of the US District Court for the District of New Jersey dismissing the declaratory judgment action for noninfringement filed by Apotex against Janssen Pharmaceutica, N.V. and Janssen, L.P. (collectively Janssen).

In order to bring about early resolution of patent disputes between generics and pioneering drug companies, the Hatch-Waxman Act provides that the filing of a Paragraph IV Certification is an act of patent infringement. [35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S 661, 678 (1990).] The ANDA filer must provide notice to the patentee and NDA holder of the factual and legal bases for the Paragraph IV Certification. [21 U.S.C. § 355(j)(2)(B).] Upon such notice, the patentee and NDA holder have the option of suing on all, some, or none of the patents included in the Paragraph IV Certification.

Since late 2003, the Hatch-Waxman Act also has permitted the ANDA party to file a civil action under 28 U.S.C. § 2201 for a declaratory judgment that any NDA listed patent is invalid or will not be infringed by the drug for which the applicant seeks approval. [21 U.S.C. § 355(j)(5)(C)(i)(II).]

Specifically, the statute allows a Paragraph IV ANDA filer a right to bring a declaratory judgment action for noninfringement or invalidity of the relevant listed patents against the patentee and NDA holder, if the patentee has not brought an infringement action within the 45-day notice period. [21 U.S.C. § 355(j)(5)(C).]

Congress extended federal court jurisdiction over these declaratory judgment actions "to the extent consistent with the Constitution." [35 U.S.C. § 271(e)(5).] Therefore, federal courts have jurisdiction over these declaratory judgment actions to the extent that they present an Article III case or controversy. [*Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).]

Janssen holds an approved NDA for its drug Risperdal® Oral Solution. The Orange Book originally listed US Patent Nos. 4,804,663 ('663 patent), 5,453,425 ('425 patent) and 5,616,587 ('587 patent) in connection with this NDA. The '663 patent covers the compound risperidone, which is the active compound in the drug Risperdal®

Oral Solution. The '425 and '587 patents cover specific aqueous solutions of risperidone and methods for preparing these solutions. The '663 patent expired on December 29, 2007. However, the FDA granted Janssen an additional six months of pediatric exclusivity pursuant to 21 U.S.C. § 355a, making June 29, 2008, the effective expiration date of the '663 patent. The '425 and '587 patents expire in 2014.

The '663 patent had been the subject of prior litigation. Following a bench trial, it was found to be infringed, valid, and enforceable. The Federal Circuit later affirmed the judgment of the district court. Apotex was not a party to that trial. However, Apotex stipulated to infringement, validity, and enforceability of the '663 patent based on the Federal Circuit opinion.

On December 8, 2006, Janssen provided Apotex with a covenant-not-to-sue with respect to the '425 and '587 patents. After granting the covenant, Janssen requested that Apotex withdraw its counterclaims. Apotex refused. On October 11, 2007, the district court granted Janssen's motion to dismiss Apotex's counterclaims for lack of subject matter jurisdiction. The district court found "no case or controversy" regarding the '425 and '527 patents.

In the Federal Circuit, Apotex contended that *Caraco Pharm. Labs. v. Forest Labs.*, [527 F.3d 1278 (Fed. Cir. 2008)] in which this court held that despite the existence of a covenant-not-to-sue, a declaratory judgment claim brought under the Hatch-Waxman Act presents a justiciable Article III controversy, is controlling law.

The Federal Circuit agreed with the parties that if Apotex had not stipulated to the validity of the '663 patent, then *Caraco* would have been controlling. However, Apotex stipulated to the validity, infringement, and enforceability of the '663 patent on May 11, 2007.

Therefore, while the harm that created a justiciable Article III controversy in Caraco was present when Apotex filed its counterclaims on April 25, 2006, that harm ceased to exist upon Apotex's stipulation. As such, the harm that gave rise to jurisdiction over the declaratory judgment claims in Caraco was no longer present on October 11, 2007—the date the district court dismissed the case.

The key difference between *Caraco* and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in *Caraco* ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of the '663 patent. Therefore, unlike Caraco, Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a non-infringing product by an invalid patent—as it stipulated to the validity of the '663 patent.

Jurisdiction over a declaratory judgment action must be present "at all stages of review, not merely at the time the complaint is filed." [*Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974); *seeBenitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since."); *Intl Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed. Cir. 1986) ("[J]urisdiction over [ ] a declaratory judgment action [must have] existed at, and has continued since, the time the complaint was filed.").]

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