

OCA Limitations Imposed by ANDA Filer Provided a Basis for Filing Suit

BY BRUCE M. WEXLER, DAVID M. CONCA AND JASON K. PANDA

On March 12, 2010, *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, the District of Delaware found that it was permissible for a patent holder to file suit under 35 U.S.C. § 271(e)(2)(A) where an ANDA filer had placed unreasonable conditions on the Offer of Confidential Access for pre-suit receipt of information about the ANDA. No. 09-2118, 2010 WL 902552 (D. Del. March 12, 2010).

This case could be useful for innovator patentees faced with OCA restrictions by ANDA filers. The court's opinion does not describe the details of the restrictions. We therefore describe below certain facts we obtained from the available files.

Plaintiffs Eurand, Inc and Anesta AG ("Plaintiffs") sued Defendants Anchen Pharmaceuticals and Anchen, Inc. ("Anchen") for infringement of two patents listed in the Orange Book for the drug AMRIX[®] (cyclobenzaprine hydrochloride extended-release capsules).

As part of its ANDA Notice Letter, Anchen made an Offer of Confidential Access ("OCA") to the confidential information contained in Anchen's ANDA. Anchen's offer had various restrictions, including (D.I. 51, Exhibit D-3):

- Access was to attorneys from one outside law firm representing Requestor, provided such attorneys do not engage, formally or informally, in patent prosecution, any FDA counseling, litigation, or other work before or involving FDA or citizen petitioning activity for any Requestor.
- The attorneys shall not disclose any Confidential Anchen Information to any other person or entity, including any of Requestor's employees, outside scientific consultants, and/or other outside counsel retained by a Requestor, without the prior written consent of Anchen's outside litigation counsel.

Plaintiffs refused Anchen's OCA as unreasonable and attempted without success to negotiate the terms. *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 2010 WL 902552, at *2. Defendants also declined the Plaintiffs' offer to accept Anchen's ANDA on an outside counsel eyes only basis under Delaware Local Rule 26.2. *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 2010 WL 902552, at *6. Because the parties did not agree on the OCA terms, Plaintiffs were unable to access Anchen's ANDA. *Id.* at **5-6. Plaintiffs sued

anyway, alleging in the Complaint facts relating to non-access to Anchen's ANDA, as follows (Complaint ¶ 30):

Since receiving Anchen's First and Second Paragraph IV Notice Letters and the accompanying Anchen Offers, Plaintiffs have negotiated with the Anchen Defendants to procure a copy of ANDA No. 91-281 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful. For example, the Anchen Defendants' most recent proposal continues to unreasonably limit the fields of practice and other activities of any person, including outside counsel, who accepts access to the ANDA. The Anchen Defendants have refused to modify these restrictions despite Judge Robinson's June 23, 2009 Order in two other AMRIX® cases pending in the District, CIV-08-889 and CIV-09-018, rejecting similar proposals made by the defendants there. In addition, the Anchen Defendants have refused to provide their ANDA to Plaintiffs under Delaware Local Rule 26.2.

Anchen moved to dismiss for lack of subject matter jurisdiction and also for Rule 11 sanctions arguing that the Complaint admitted that Plaintiffs had insufficient basis for suit. *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 2010 WL 902552, at *4.

Subject Matter Jurisdiction

The court found subject matter jurisdiction. The court noted that Plaintiffs could not determine, without examining the confidential information contained in Anchen's ANDA, whether Anchen's ANDA products are likely to infringe. *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 2010 WL 902552, at *5. The court also noted that in ANDA cases, the usual methods of supporting an allegation for infringement (securing and evaluating the accused product) were not immediately available to the patentee. *Id.* The court then noted that Hatch-Waxman's scheme permitted Plaintiffs to "avail themselves of the artificial act of infringement" found in § 271(e)(2)(A) and because Defendants did not contest the fact that the ANDA was submitted to the FDA, submission of the ANDA was an act of infringement sufficient to create a case or controversy supporting Article III subject matter jurisdiction. *Id.*

Rule 11 Sanctions

Anchen also argued that, by filing suit, Plaintiffs were improperly attempting to obtain discovery in order to satisfy the pre-suit obligations of Fed. R. Civ. P. 11. *Id.* The court noted that in some instances it was permissible to file suit if the complete facts concerning infringement were unavailable. *Id.* at **5-6. The court explained that the Federal Circuit in *Hoffman La Roche, Inc. v. Invamed Inc.* had found that Rule 11 may not prohibit a patentee from bringing an infringement action even though the patentee "is unable to obtain and set forth in its complaint facts showing infringement." 213 F.3d 1359, 1364 (Fed. Cir. 2000) (approving "resort to the judicial process" following defendant ANDA filer's refusal to disclose its manufacturing process in a case involving alleged infringement of a process patent).

The court rejected Anchen's argument that Plaintiffs had not been refused access to Anchen's ANDA but only refused to accept Anchen's offer of access. *In re: Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 2010 WL 902552, at *5. The court recognized that Plaintiffs had made several attempts to obtain confidential access to Anchen's ANDA and expressed a willingness to observe the restrictions and limitations of the Protective Order existing in the other consolidated

cases. *Id.* at *6. Defendants not only refused these efforts, but did not respond to Plaintiffs' final request to receive the entire ANDA under the Delaware Local Rules providing outside counsel access to confidential information prior to entry of a protective order. *Id.*, citing Delaware Local Rule 26.2. The court further stated that permitting an ANDA filer to place onerous restrictions on its OCA would frustrate the Hatch-Waxman system and give defendants unfettered ability to preclude access to confidential information necessary to assess infringement until the 45-day window for filing suit lapsed. *Id.* at *5. For these reasons, the court found that Plaintiffs did not run afoul of Rule 11 in bringing the infringement action. *Id.* at *6.

Other Issues of Interest

The court also addressed other issues of interest in Hatch-Waxman cases involving claims against parents, personal jurisdiction and venue.

- A parent corporation that is actively involved in preparing ANDA was deemed to have submitted the ANDA, regardless of whether it is the named applicant. *Id.* at *6.
- A parent corporation's contacts were attributable to its subsidiary under an agency theory where the companies were two arms of the same business group, operated in concert with each other, and entered into agreements with each other that were nearer than arm's length. *Id.* at *9.
- A corporation's substantial revenues from drug sales in the forum state were relied upon to establish general personal jurisdiction. *Id.* at **9-10.
- Protective suits are not a sufficient reason to transfer a litigation when plaintiffs have otherwise chosen a proper forum. *Id.* at *10.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

David M. Conca
212-318-6406
davidconca@paulhastings.com

Jason K. Panda
212-318-6521
jasonpanda@paulhastings.com

Bruce M. Wexler
212-318-6020
brucewexler@paulhastings.com