

Generic Co. Lobs Antitrust Suit To Access Brand-Name Meds

By **Jeff Overley**

Law360, New York (April 01, 2013, 6:33 PM ET) -- Generic-drug maker Accord Healthcare Inc. on Monday sued Acorda Therapeutics Inc. in Florida federal court for allegedly trying to stave off competition by refusing to sell samples of multiple sclerosis drug Ampyra to rival companies looking to introduce a lower-cost version of the medicine.

Accord, a unit of Indian drugmaker Intas Pharmaceuticals Ltd., is aiming to apply for U.S. Food and Drug Administration approval in January and says it needs to acquire samples by next month if it's going to meet that target.

No generic version of Ampyra exists, and because of an FDA-imposed safety framework, distribution of the drug is strictly policed, giving Accord no other option but to seek access through Acorda's distribution company, H.D. Smith, the complaint says.

"Acorda's refusal to sell samples of Ampyra at market prices to Accord Healthcare for bioequivalence testing is intended to, and will, thwart the entry to market of any competing products, thereby extending its monopoly power in the relevant market," the lawsuit asserts.

In a March 20 letter filed as an exhibit in the case, Accord asked Acorda for 600 units of Ampyra, or dalfampridine, and warned it against using a so-called risk evaluation and mitigation strategy imposed by the FDA to block access.

One week later, Acorda replied by rejecting the notion it has any responsibility to assist with development of a competing product, saying that is it "under no legal obligation to fulfill Accord's purchase request and declines to do so."

A similar debate is playing out in a New Jersey federal court case where Apotex Inc., Roxane Laboratories Inc. and Actavis Elizabeth LLC accuse Actelion Pharmaceutical Ltd. of hiding behind FDA risk-reduction rules to prevent generics companies from getting their hands on active ingredients needed to conduct testing.

Actelion is seeking to have the suit thrown out, but it recently encountered a powerful foe when the Federal Trade Commission filed a brief opposing dismissal. While the FTC didn't take a position on the merits, it did warn against barring the allegations as a matter of law, saying U.S. Supreme Court precedent and the Hatch-Waxman Act leave the door open for claims that branded-drug makers are gaming the system by using FDA-mandated safety restrictions to indefinitely extend their monopoly over a patented treatment.

The central question is whether the consumer interest in obtaining affordable medicines warrants a carve-out in refusal-to-deal law, which generally gives companies wide berth when deciding not to do business with someone.

Accord's lawsuit contends that Ampyra sells at the "extremely expensive" wholesale price of \$10,000 per year and that delayed entry of a generic will force consumers to pay an "artificially high" price for the drug.

Acorda said it had not seen the lawsuit and had no immediate comment.

The plaintiffs are represented by Devang B. Desai of Gaebe Mullen Antonelli & Dimatteo PA and B. Jefferson Boggs, Matthew L. Fedowitz, Christopher J. Sorenson and Aaron M. Johnson of Merchant & Gould PC.

Counsel information for Acorda was not immediately available.

The case is Accord Healthcare Inc. et al. v. Acorda Therapeutics Inc. et al., case number 0:13-cv-60742, in the U.S. District Court for the Southern District of Florida.

--Additional reporting by Melissa Lipman. Editing by Richard McVay. _____

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