



November 20, 2012

U.S. Court of Appeals Denied Momenta Pharmaceuticals Petition for Rehearing En Banc in "Safe-Harbor" Case

Company Plans to File Petition for Rehearing to Supreme Court

CAMBRIDGE, Mass., Nov. 20, 2012 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that the United States Court of Appeals for the Federal Circuit (CAFC) denied its request for a rehearing *en banc* to reconsider its three-judge panel opinion in the case of *Momenta Pharmaceuticals vs. Amphastar Pharmaceuticals, Inc.*, which held that Amphastar's use of Momenta's patented method for processing enoxaparin sodium injection was protected by the "safe harbor" from patent infringement under 35 U.S.C. sec. 271(e)(1).

The request for all active judges of the court to reconsider a panel decision, known as rehearing *en banc*, is only granted upon a majority vote.

"We will continue to pursue our appellate options and we plan to file a petition for *certiorari*, asking the Supreme Court to review this case," said Craig Wheeler, President and Chief Executive Officer of Momenta. "We strongly believe that the CAFC panel decision in this case finds no support in the statutory text of the safe harbor provision of the patent law, or in Supreme Court precedent, and a final decision upholding this case could have wide-ranging, negative effects on drug development."

About "Safe Harbor" provision

Enacted as part of the Hatch-Waxman Act of 1984, the 'safe harbor' provision of the patent statute provides that it is not an act of patent infringement to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

About Momenta Pharmaceuticals, Inc. vs. Amphastar patent infringement case

Momenta sued Amphastar for infringement of Momenta's U.S. Patent No. 7,575,866, which claims methods for processing enoxaparin (the generic name for the active ingredient in Lovenox®). The patented methods assure that enoxaparin, a highly complex drug product, is reproducibly manufactured.

In October, 2011, the U.S. District Court for the District of Massachusetts granted Momenta a preliminary injunction, enjoining Amphastar from selling any of its enoxaparin product. According to the District Court, Amphastar's activity was not protected from infringement by the "safe harbor" provision because the alleged infringing activity involved use of Momenta's patented methods "on each commercial batch of enoxaparin that will be sold after FDA approval."

Amphastar appealed the grant of the preliminary injunction to the CAFC, and the CAFC stayed the preliminary injunction in January, 2012 without issuing a written opinion. In August 2012, The CAFC issued its written opinion. The opinion held that Amphastar's use of the patented methods was protected from infringement under the safe harbor, and remanded the case to the District Court for further proceedings consistent with this conclusion. The District Court proceedings are currently stayed pending resolution of the *en banc* appeal.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drug products, as well as to the discovery and development of novel drugs.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release.

Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names,

trademarks, or service marks are property of their respective owners.

Special Note Regarding Forward-Looking Statements

Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, including statements relating to its beliefs and intentions related to litigation with Amphastar and Watson, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "hope," "target," "project," "goals," "potential," "predict," "might," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors referred to in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Momenta from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. Momenta is providing the information in this press release as of this date and assumes no obligations to update the information included in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

CONTACT: Lora Pike

Senior Director, Investor Relations

and Corporate Communications

lpike@momentapharma.com

617-395-5189

Source: Momenta Pharmaceuticals

News Provided by Acquire Media