



U.S. District Court Rules in Favor of Lilly in Alimta Vitamin Regimen Patent Lawsuit

December 30, 2019

INDIANAPOLIS, Dec. 30, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. District Court for the Southern District of Indiana ruled in favor of Lilly that the Alimta® (pemetrexed for injection) vitamin regimen patent would be infringed by a competitor that had stated its intent to market alternative salt forms of pemetrexed prior to the patent's expiration in May 2022.

The ruling came in the case of Eli Lilly and Company v. Apotex Inc.

"We are pleased with today's District Court ruling finding the Alimta vitamin regimen patent would be infringed by the competitor's proposed products," said Michael J. Harrington, Lilly's senior vice president and general counsel. "Lilly's extensive research to discover the Alimta vitamin regimen patent deserves intellectual property protection. We depend on strong and effective intellectual property protection to support our investment in the next generation of breakthrough medicines."

On August 9, 2019, the U.S. Court of Appeals for the Federal Circuit Court ruled in favor of Lilly in appeals by Dr. Reddy's Laboratories, Ltd. and Hospira, Inc., affirming the June 2018 district court's decisions finding infringement of Lilly's patent under the doctrine of equivalents.

Today's ruling means Apotex will be prevented from launching its alternative salt form of pemetrexed until the patent expires. Lilly expects Apotex to appeal.

In October 2017, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office ruled in the company's favor regarding patentability of the vitamin regimen for Alimta.

In March 2014, the U.S. Court for the Southern District of Indiana upheld the validity of the vitamin regimen patent. In August 2015, the same court ruled in Lilly's favor regarding infringement of the vitamin regimen patent. The U.S. Court of Appeals for the Federal Circuit confirmed these rulings in a unanimous decision in January 2017, finding the patent is valid and would be infringed by the generic challengers' proposed products.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at lilly.com and lilly.com/newsroom. C-LLY

This release contains forward-looking statements regarding the U.S. Alimta patent litigation. These statements are based on management's current expectations, but actual results may differ materially. There can be no assurance that the company will prevail in any appeal. Also, the company cannot predict whether generic pemetrexed will be marketed prior to the expiration of the vitamin regimen patent. Other risk factors that may affect the company's results can be found in the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission.

Alimta® (pemetrexed for injection, Lilly)

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