



October 5, 2017

U.S. Patent and Trademark Office Rules In Lilly's Favor On Alimta Vitamin Regimen Patent

INDIANAPOLIS, Oct. 5, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (PTO) has ruled in the company's favor regarding patentability of the vitamin regimen for Alimta[®] (pemetrexed for injection).

In the inter partes review (IPR) proceedings initiated by Neptune Generics, LLC and Sandoz Inc., the U.S. PTO found that the claims of the vitamin regimen patent are valid. If the patent is ultimately upheld through all remaining challenges, Alimta would maintain U.S. exclusivity until May 2022, preventing marketing of generic products for as long as the patent remains in force.

"We are pleased with today's ruling by the U.S. PTO finding the claims of the Alimta vitamin regimen patent are valid," said Michael J. Harrington, senior vice president and general counsel for Lilly. "This ruling largely confirms the earlier decision of the district court which was affirmed on appeal by a unanimous court."

Harrington continued, "The significant scientific research that Lilly performed in support of the vitamin regimen patent deserves intellectual property protection, which has been confirmed in every validity challenge to date. We continue to emphasize that protection of intellectual property rights is extremely important to the biopharmaceutical industry and the patients we serve. These rights help support the development of the next generation of innovative medicines."

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 www.lilly.com and <http://newsroom.lilly.com/social-channels>. 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, Lilly)

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