



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

April 26, 2019

INDIANAPOLIS, April 26, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Court of Appeals for the Federal Circuit has ruled in the company's favor regarding patentability of the vitamin regimen for Alimta® (pemetrexed for injection). The decision upholds an October 2017 decision by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (PTO).

In the inter partes review (IPR) proceedings initiated by Neptune Generics, LLC and Sandoz Inc., the U.S. PTO found on October 5, 2017 that the claims of the vitamin regimen patent are valid. Neptune, Fresenius Kabi and Mylan filed an appeal, which was decided today.

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 Appeals Court 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 confirms the earlier decision of the both the PTO and the district court, which was affirmed on appeal by a unanimous court.

"Lilly's extensive research to discover the Alimta vitamin regimen patent deserves intellectual property protection, which has been confirmed in every validity challenge in the U.S. to date," Harrington said. "We depend on strong and effective intellectual property protection to help support the development of the next generation of innovative medicines."

On June 22, 2018, Lilly announced that the U.S. District Court for the Southern District of Indiana ruled in favor of Lilly that the Alimta vitamin regimen patent would be infringed by the use of Dr. Reddy's Laboratories alternative salt form of pemetrexed prior to the patent's expiration in May 2022. The district court found that use of Dr. Reddy's product will infringe under the doctrine of equivalents.

In a separate decision on June 15, 2018, the District Court also ruled in favor of Lilly in the case of Eli Lilly and Company v. Hospira, Inc., denying Hospira's motion for summary judgement and granting Lilly's cross-motion for summary judgment.

These rulings mean Dr. Reddy's Laboratories and Hospira will be prevented from launching their alternative salt forms of pemetrexed until the patent expires. Dr. Reddy's Laboratories and Hospira have appealed the district court's decisions. The hearing on those appeals is scheduled for June 2019.

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 create medicines that 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](http://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 litigation or appeal. Also, the company cannot predict whether generic pemetrexed will be marketed in the U.S. 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. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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Alimta® (pemetrexed for injection, Lilly)

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