U.S. Court of Appeals Rules in Favor of Lilly in Alimta Alternate Salt Form Patent Lawsuit

August 9, 2019

INDIANAPOLIS, Aug. 9, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Court of Appeals for the Federal Circuit ruled in favor of Lilly, confirming that the Alimta® (pemetrexed for injection) vitamin regimen patent would be infringed by competitors that had stated their intent to market alternative salt forms of pemetrexed prior to the patent's expiration in May 2022.

The ruling came in the appeals of U.S. District Court decisions in the cases of Eli Lilly and Company v. Dr. Reddy's Laboratories and Eli Lilly and Company v. Hospira, Inc. Previous rulings in Lilly's favor had precluded the generic companies from launching the alternative salt forms until the patent expires.

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're pleased with this decision," said Michael J. Harrington, Lilly's senior vice president and general counsel. "Lilly's extensive research to discover this patent deserves intellectual property protection, which has been confirmed in every challenge in the U.S. to date."

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 alternative salt form of pemetrexed prior to the patent's expiration. The district court found the generic product would 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.

Both Dr. Reddy's and Hospira had appealed the district court's decisions, leading to today's ruling.

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.

Separately, Lilly announced in April 2019 that the U.S. Court of Appeals for the Federal Circuit ruled in the company's favor regarding patentability of the vitamin regimen for Alimta, upholding an October 2017 decision by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office.

About Eli Lilly and Company

Lilly is a global health care 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 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 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.

Alimta® (pemetrexed for injection, Lilly)

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