



June 25, 2015

UK Court Rules in Favor of Lilly in Alimta Vitamin Regimen Patent Lawsuit

INDIANAPOLIS, June 25, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the Court of Appeal has ruled that the Alimta® (pemetrexed disodium) vitamin regimen patent would be indirectly infringed by a generic competitor that had stated its intent to market certain alternative salt forms of pemetrexed in the United Kingdom prior to the UK patent's expiration in June 2021.

Specifically, the Court of Appeal held that commercialization of these alternative salt forms in the products as proposed would constitute indirect infringement by supplying an essential means for putting the patented invention into effect. The decision came in the case of *Actavis v. Eli Lilly and Company*.

The Court of Appeal also held there was no difference between the law in the UK and that in France, Italy and Spain as it relates to indirect infringement, and so reversed the High Court's decision granting declarations of noninfringement over the Alimta vitamin regimen patents in those countries.

Actavis may seek permission to appeal the decision to the UK Supreme Court. In addition, Actavis has stated it may ask the High Court to decide whether a different proposed product would infringe the patent. The Court of Appeal has ruled that the High Court will need to decide whether it will hear this new claim. If the High Court decides to hear Actavis' case on the different proposed product, Lilly will defend the case vigorously.

In Europe, the compound patents for Alimta remain in force and are expected to provide exclusivity through December 2015. This decision increases the likelihood that the vitamin regimen patents for Alimta will provide exclusivity in the UK, France, Italy and Spain through June 2021.

"We are pleased with the UK Court of Appeal's ruling that confirms the Alimta vitamin regimen patent would be infringed by the entry of these generic pemetrexed products in the United Kingdom prior to June 2021. We are also pleased the ruling has cancelled the declarations of noninfringement with respect to France, Italy and Spain," said Michael J. Harrington, senior vice president and general counsel for Lilly.

Harrington continued, "We continue to emphasize that protection of intellectual property rights is extremely important to the biopharmaceutical industry and the patients we serve. Intellectual property rights provide assurances of market exclusivity that help support the development of the next generation of innovative medicines to treat unmet medical needs."

In a separate appeal earlier this year, the Dusseldorf Court of Appeal ruled the Alimta vitamin regimen patent would not be infringed by a generic competitor that has stated intent to market pemetrexed dipotassium in Germany after the compound patent expiration in December 2015. Lilly has asked for permission to appeal this ruling.

Lilly's vitamin regimen patents were upheld in a prior ruling by the Opposition Division of the European Patent Office. An appeal is pending before the Technical Board of Appeal of the European Patent Office.

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 UK and German 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 resolution of this litigation. 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)

Refer to:

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