Mylan Defeats Allergan's Maneuver to Rent Tribal Sovereign Immunity to Avoid Restasis® Patent Challenge

February 26, 2018

U.S. Patent Trial and Appeal Board denies St. Regis Mohawk Tribe's motion to terminate Restasis patent challenge
Decision finds that Tribal sovereign immunity does not apply to inter partes review proceedings
Federal District Court previously held patents invalid

HERTFORDSHIRE, England and PITTSBURGH, Feb. 26, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced that the U.S. Patent Trial and Appeal Board (PTAB) has denied the St. Regis Mohawk Tribe's (Tribe) motion to terminate Mylan's patent challenge regarding six patents related to Allergan's Restasis®.

Mylan CEO Heather Bresch commented, "Mylan has always been vocal in its efforts to challenge and break down barriers to access. The PTAB's ruling reinforces our belief that Allergan's maneuvers to engage the St. Regis Mohawk Tribe for patent protection were a sham. We will continue to be steadfast in our efforts on both the legal and regulatory fronts to bring a generic version of Restasis to patients as quickly as possible."

In a move admittedly designed to protect the Restasis® patents from cancellation by the PTAB, Allergan announced last September that it had assigned the rights of six patents to the Tribe. The Tribe immediately moved to dismiss the proceedings, arguing that its tribal sovereign immunity prevented the PTAB from reviewing the patents.

On Feb. 23, the PTAB denied the Tribe's motion on multiple grounds. The PTAB held that the Tribe did not establish that the doctrine of tribal sovereign immunity applied to inter partes review (IPR) proceedings. Alternatively, the PTAB held that even if tribal sovereign immunity did apply, the IPR proceedings could continue without the Tribe because Allergan retained ownership interests in the patents.

The PTAB tentatively scheduled an oral hearing on the merits for April 3, 2018, and stated that it would render a final written decision on the patentability of the challenged patents by June 6, 2018.

Mylan previously announced that the Eastern District of Texas held Allergan's patents invalid after a trial on the merits. The case is currently on appeal before the U.S. Court of Appeals for the Federal Circuit.

This press release includes statements that constitute "forward-looking statements," including with regard to the outcome of litigation and that Mylan will continue to be steadfast in its efforts on both the legal and regulatory fronts to bring a generic version of Restasis to patients as quickly as possible. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market, including generic Restasis; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings, including any appeal of the Court's decision invalidating the Restasis patents, and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

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