Mylan Wins District Court Decision Against Biogen's Tecfidera® Patent

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Mylan achieves key milestone to provide U.S. multiple sclerosis patients with more affordable generic version of Biogen's Tecfidera® capsules

Biogen's asserted claims of ’514 method patent found invalid

Win clears legal pathway to launch upon FDA approval

HERTFORDSHIRE, England and PITTSBURGH, June 18, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced that the U.S. District Court for the Northern District of West Virginia invalidated Biogen's Tecfidera® patent, U.S. Patent No. 8,399,514, for lack of written description. The ’514 patent claimed methods of treating multiple sclerosis (MS) using a dose of 480 mg/day of dimethyl fumarate delayed release capsules. Today's decision clears the way for Mylan's launch of its dimethyl fumarate product upon the receipt of FDA approval. The '514 patent could have otherwise delayed generic competition until 2028.

Mylan CEO Heather Bresch commented: "Today's win is significant in that it brings Mylan one step closer to providing expanded treatment options for the thousands of Americans living with relapsing forms of MS. The District Court decision clears the legal pathway for us to bring our dimethyl fumarate product to market, and we are working with the FDA to accelerate our regulatory approval target action date, which currently is November 16. Once approved and launched, we believe our generic Tecfidera will potentially be the first generic of any MS treatment in an oral solid dosage form available to patients in the U.S., further advancing our commitment to provide a broad portfolio of central nervous system medicines, which already includes glatiramer acetate injection."

Mylan President Rajiv Malik commented: "Mylan continues to address unmet patient needs across the value chain. Bringing a product like generic Tecfidera to market requires not only our extensive scientific and commercial expertise, but also our unwavering commitment to access through overcoming potential legal barriers to reach patients. We look forward to bringing this important medicine to market as soon as possible, pending final FDA approval."

Tecfidera (dimethyl fumarate) delayed-release capsules are used to treat adults with relapsing forms of MS. Mylan believes it is one of the first companies to have filed a substantially complete Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification for a dimethyl fumarate product and expects to be eligible for 180 days of marketing exclusivity in the U.S. upon final FDA approval. Mylan's ANDA is pending with the U.S. Food and Drug Administration (FDA).

Biogen's total IQVIA sales in the U.S. for the 12 months ending April 30, 2020, were approximately $3.78 billion for Tecfidera.

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 portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 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.

Forward-Looking Statements
This press release includes statements that constitute "forward-looking statements," including with regard to today's decision clearing the way for Mylan's launch of its dimethyl fumarate product upon the receipt of FDA approval; that today's win is significant in that it brings Mylan one step closer to providing expanded treatment options for the thousands of Americans living with relapsing forms of MS; that the District Court decision clears the legal pathway for us to bring our dimethyl fumarate product to market, and we are working with the FDA to accelerate our regulatory approval target action date, which currently is November 16; that once approved and launched, we believe our generic Tecfidera will potentially be the first generic of any MS treatment in an oral solid dosage form available to patients in the U.S., further advancing our commitment to provide a broad portfolio of central nervous system medicines, which already includes glatiramer acetate injection; that we look forward to bringing this important medicine to market as soon as possible, pending final FDA approval; and that Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for a dimethyl fumarate product and expects to be eligible for 180 days of marketing exclusivity in the U.S. upon final FDA approval. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; 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 and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and

changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; 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.

View original content to download multimedia:http://www.prnewswire.com/news-releases/mylan-wins-district-court-decision-against-biogens-tecfidera-patent-301079843.html

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