
June 20th, 2017

Fingolimod Hydrochloride wins Patent Infringement Lawsuit in the U.S. District Court

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka) announced today that on June 9, 2017, the United States District Court for the District of Delaware ruled that the U.S. Patent covering the active ingredient of fingolimod ("Patent") is valid and enforceable, and no generic drug of fingolimod hydrochloride shall be approved in the U.S. earlier than February 18, 2019, the expiration date of the Patent, together with any period of pediatric exclusivity that may be awarded under 21 U.S.C. §355a.

In December 2014, Mitsubishi Tanabe Pharma Corporation brought a patent infringement lawsuit in the U.S. concerning fingolimod hydrochloride (Trade Name in the U.S.: GILENYA[®]; Trade Name in Japan: IMUSERA[®]/GILENYA[®]) jointly with Novartis Pharma Corporation ("Novartis"; the holder of the new drug application for fingolimod in the U.S.), and Mitsui Sugar Co., Ltd. (joint patent holder) in the U.S. District Court for the District of Delaware against six generics manufacturers (Actavis, Inc., Apotex, Inc., Aurobindo Pharma Ltd., Ezra Ventures, LLC., HEC Pharm Co., Ltd., and Mylan Pharmaceuticals Inc.).

The decision entered by the U.S. District Court for the District of Delaware finds that the Patent is valid and enforceable against above six generics manufacturers who filed Abbreviated New Drug Applications with the U.S. Food and Drug Administration alleging the invalidity and unenforceability of the Patent.

Fingolimod hydrochloride is a sphingosine 1-phosphate (S1P) receptor modulator for the treatment multiple sclerosis, which has been marketed in the U.S. since 2010. Currently, fingolimod is approved in over 80 countries and regions worldwide, including Canada, Europe and Japan.

Mitsubishi Tanabe Pharma sees intellectual property as one of its most important corporate asset, and intends to take appropriate legal actions against infringements or the risk of infringement of our intellectual property in the future.

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