

Some Key Fabry dates

2001 August 3. TKT and Genzyme both receive EU marketing authority, 10 years Orphan exclusivity.

2003 April 24. Genzyme receives US marketing authority and 7 years of Orphan exclusivity in the United States.

2003 October 9. The United States Court of Appeals for the Federal Circuit (CAFC) affirms TKT's Replagal does not infringe Mount Sinai patent (which is licensed to Genzyme for Fabrazyme).

2007 Carl Icahn reportedly acquiring significant shares of Genzyme. Icahn is also a Trustee of Mount Sinai.

2009 Genzyme's manufacturing woes for Fabrazyme spin out of control. Genzyme introduces severe rationing for US patients. Less severe rationing for non-US patients facing competition from Shire's Replagal.

2010 February 22. Icahn, a 4.9 percent shareholder, begins Proxy battle for Genzyme Board.

2010 April 24. US Orphan drug exclusivity expires.

2010 June 9. Carl Icahn places two persons on Genzyme Board of Directors, including Steven Burakoff, a director of the Tisch Cancer Institute at the Mount Sinai Medical Center.

2010 August 2. Represented by Alan Black, Fabray patents Joseph M. Carik, Anita Hochendoner, and Anita Bova request NIH/DHHS to use Bayh-Dole March-In rights on Mount Sinai patent.

2010 Oct 22. European Medicines Agency recommendation to restore full doses of Fabrazyme or Replagal for EU patents. (US patients continue to be rationed into 2012).

2010 Mount Sinai seeking to enforce Fabry patent in Europe against Shire, asks for injunction in several countries, including order to destroy infringing Shire products. Shire asks for compulsory license in Germany.

2010 December 7. NIH denies US Fabry patient March-in petition.

2011 January 18. Mount Sinai obtains injunction from German court. NIH forces Mount Sinai to not enforce the injunction during the shortage.

2011 February 16. France based SanofiAventis announces agreement to acquire Genzyme for \$20.1 billion.

2011 August. EU Orphan Exclusivity ends.

2012. Spring. German compulsory license case scheduled to proceed.

2012 March 14. Shire withdraws Replagal US FDA BLA.

2012 May 9. Mount Sinai grants Shire a nonexclusive license to the patent in connection with the ongoing sales of Replagal in the European Union.

2015 September 27. Expiration of Mount Sinai patent on Fabrazyme in the United States

2016. August. Mount Sinai's European patent (based upon US Patent 5,356,804) expires in Europe.

Much more here: http://keionline.org/sites/default/files/Replagal_Fabrazyme_Timeline.pdf