

## Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201

### Comments of Knowledge Ecology International

#### 11. The agency's investigation, enforcement and remedial processes.

In 2014, KEI asked the FTC to investigate collusion between Sanofi and Shire, relating to the 2012 decision by the Icahn School of Medicine at Mount Sinai (ISMMS) to license Fabry patents to Shire in Europe, and the subsequent decision by Shire to withdraw an FDA biologic license application (BLA) for Replagal (agalsidase alfa). Our letter setting out the basis for the complaint is here: <https://www.keionline.org/22538>. KEI believes there was strong evidence of collusion to limit competition between Sanofi, which sells Fabrazyme, and Shire, whose treatment Replagal is Fabryzyme's direct competitor. To our knowledge, the FTC's investigation was brief and shallow, and did not involve discovery. There is simply no other reason than collusion to understand why Shire's Replagal has not entered in the U.S. market for the treatment for Fabry's disease, a serious illness with an enormous price tag for the treatments. Fabrazyme and Replagal were both invented on NIH grants, and both products are now owned by European firms. The U.S. prices for Fabrazyme are extremely high, and would be lower if Sanofi and Shire were acting as competitors, rather than companies managing a global cartel.

We are anxious to see investigations of potential pricing collusion in the markets for insulin and drugs for multiple sclerosis (MS), two areas where prices and price increases have clearly moved in concert.

The attached figure prepared by Daniel Hartung and Dennis Bourdette at Oregon Health and Science University illustrates how a series of drugs to treat MS have seen price escalations<sup>1</sup> to match the ever-increasing rollout prices of new drugs. R&D costs are clearly not a factor. In the figure, the highest price for a drug and the one with the largest increase for a rollout price was Zinbryta, a repurposed drug licensed from the NIH to Biogen for modest consideration. Zinbryta was later withdrawn from the market over concerns regarding its safety,<sup>2</sup> but the fact that the NIH allowed its own patent to be licensed for a product sold at such a high price illustrates the extent that the federal government has failed to exercise its own leverage to curb excessive prices. The FTC could fruitfully engage in advocacy, not only to influence the terms of licenses on government-owned patents, but to set norms for the use of Bayh-Dole march-in or royalty-free rights in drugs invented on federal grants or research contracts.

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<sup>1</sup> Hartung, Daniel M. et al. "The Cost of Multiple Sclerosis Drugs in the US and the Pharmaceutical Industry: Too Big to Fail?" *Neurology* 84.21 (2015): 2185–2192. PMC. Web. 20 Aug. 2018.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4451044/pdf/NEUROLOGY2014614974.pdf>

<sup>2</sup> <https://www.fda.gov/Drugs/DrugSafety/ucm600999.htm>

**Figure 1: Price increases for drugs treating multiple sclerosis**

