

# DISENABLEMENT: SCIENTIFIC IRREPRODUCIBILITY IN PATENT LAW

*Jacob S. Sherkow\**

Draft: July 24, 2015

Please direct all comments to: [jacob.sherkow@nyls.edu](mailto:jacob.sherkow@nyls.edu)

## ABSTRACT

Reproducibility—the verification of scientific results by outside researchers—lies at the heart of the scientific method. And yet, it forms little part of the law most connected with science and technology: patent law. To the contrary, the most salient patent law doctrine in this area—enablement—appears to mitigate or even actively dissuade litigation concerning reproducibility. This is critically problematic in the context of pharmaceutical patents, where some of the most valuable patents appear based on ultimately irreproducible data. This Article attempts to reconcile the enablement doctrine with irreproducibility by assessing some of the difficulties in enablement doctrine, generally, and exploring recent concerns with scientific irreproducibility. It also provides several concrete examples of irreproducibility in patents on blockbuster drugs— Prempro, Xigris, Plavix, and Avastin. Lastly, the Article provides several suggestions for encouraging reproducible data in patents, including clarifying the enablement doctrine, easing patent law’s statutory bars for empirically-based inventions, and mandating open access to testing data. These modifications would align patent law, scientific practice, and innovation policy, and prevent the current incentive structure of disablement.

---

\*Associate Professor, Innovation Center for Law and Technology, New York Law School. Thanks to Kevin Emerson Collins, Yaniv Heled, Dmitry Karshedt, Norman V. Siebrasse, Katherine Jo Strandburg, and participants at IPSC 2015 and PatCon V for their comments. Support for this paper was generously provided by New York Law School’s Summer Research Fund.