

## *The Biologics Price Competition and Innovation Act (BPCIA): A Failed Experiment, Sham, or an Exercise in Futility?*

**Yaniv Heled**

In addition to “Obamacare,” the Patient Protection and Affordable Care Act (PPACA) also includes a set of legislative amendments of the Public Health Service Act that are known as the Biologics Price Competition and Innovation Act (BPCIA). Representing the culmination of a long and fervent legislative struggle, which was decisively won by the pharmaceutical industry lobby, BPCIA sets up a framework for the approval of follow-on versions of biological pharmaceuticals (a.k.a. biologics). It includes periods of market, data, and generic exclusivities in such products, as well as a very elaborate scheme for the resolution of related patent disputes. Despite the fact that BPCIA was passed in early 2010, it was only in July 2014 that the FDA accepted the first application for the approval of a follow-on biological product and only March 2015 that the first biosimilar product was approved; similarly, to date there have been only two litigations involving disputes arising under BPCIA. This dismal record is especially disturbing in comparison with the many dozens of follow-on applications filed pursuant to the passage of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in 1984. This disappointing level of legal and regulatory activity subsequent to the enactment of BPCIA begs the question: is there something wrong with BPCIA? The answer, I believe, is a resounding yes. Retracing the legislative origins of BPCIA, this article argues that BPCIA is, at best, a misguided attempt to reproduce the success of the Hatch-Waxman Act in the context of biologics; at worst it is a sham meant to derail efforts to bring to the market cheaper follow-on versions of already-approved biologics. Regardless, as many have observed from the outset, BPCIA is doomed to fail at facilitating the kind of savings in healthcare expenditures that many hoped it would bring. As this reality becomes increasingly apparent, this article argues that a genuine effort to make biologics more widely accessible would necessitate a reevaluation of the current intellectual property scheme that allows biologics manufacturers to “double dip” (if not “triple dip”) in protections for their products. The article thus calls for a paradigm shift in the way the FDA (and other similar regulatory bodies around the world) approve biologics and evaluate applications for follow-on biological products by, first, making all regulatory submissions related to biologics open to the public and, second, rendering patents covering biological products unenforceable against follow-on applicants upon the onset of market exclusivities in such products.