Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?

Yaniv Heled[1]

On March 23, 2010, President Obama signed into law the Biologics Price Competition and Innovation Act (BPCIA) as part of the Patient Protection and Affordable Care Act (PPACA). BPCIA sets up a framework for the approval of generic biological pharmaceuticals and provides for up to 12.5 years of market exclusivity for such FDA approved products. The exclusivity period is intended to run in parallel and in addition to any patents that may apply to such approved biological pharmaceutical products, which would also grant the developers of these products monopolies in the underlying technologies on which such products are based. This seeming "double dipping" raises questions regarding the need and justification, if any, for such parallel, double protection of this particular class of biological products.

In my presentation I will make the following arguments: (1) protection of biological pharmaceutical products under both statutory exclusivities and patent regimes would lead to waste of societal resources and carries an increased risk of patent abuse that might curb public access to such products; (2) the average length of a patent term covering biological pharmaceutical products is (only) about 5-11 months longer than the market exclusivity period afforded under BPCIA; (3) for various reasons, having mostly to do with the shortcomings of patent law in general and as it pertains to biologics in particular, statutory exclusivities under BPCIA would provide better protection to the interests of developers of biological products than patents; thus, (4) at the onset of the market exclusivity period in a biological pharmaceutical product under BPCIA, primary patents covering the relevant product should become unenforceable against generic applicants under BPCIA for the same product.

[1] Assistant Professor, Georgia State University College of Law; J.S.D. 2011, Columbia Law School; LL.M. 2004, Columbia Law School; LL.B. 2000, Tel Aviv University; Undergraduate Diploma in Biology 2000, Tel Aviv University. This presentation is based on a forthcoming article which is expected to be published in Volume 18 of the Michigan Telecommunications and Technology Law Review.