Regulatory Competitive Shelters—An Emerging Class of Administrative Properties

Yaniv Heled*

Georgia State University College of Law

Faculty profile: http://law.gsu.edu/directory/heled


In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) that paved the way for the regulation and approval of generic versions of already approved drugs. This legislation also instituted a novel benefit that was meant to be administered by the Food and Drug Administration separate from and independent of any patents covering the regulated pharmaceutical products. This new benefit was different from other types of administrative properties in that it did not manifest in a direct grant of a positive right by the regulating agency but rather in a temporary loss of the agency’s ability to similarly benefit subsequent potential beneficiaries—effectively, a shelter from competition. The competitive advantages that resulted from this benefit have proved as powerful as the benefit itself was successful in achieving its purpose: the incentivizing of technological innovation. Such regulatory competitive shelters (hereinafter “competitive shelters” or RCSs; also known as “regulatory exclusivities” and “statutory exclusivities”) have grown increasingly popular with industries acquainted with them. As a result, they have also become more prevalent in regulatory frameworks affecting such industries, both in the United States and Internationally. A prevalent recent example is the

* Assistant Professor, Georgia State University College of Law.
Biologics Price Competition and Innovation Act that was passed in March 2010 and which Act included significant competitive shelter periods of up to twelve years meant to benefit manufacturers of approved biologics. Despite their growing prominence, little has been written about RCSs per se. Supplementing the discussion in *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?* (18 Mich. Telecom. & Tech. L. Rev. 419 (2012)), in this article, I seek to (1) define and characterize RCSs as an increasingly prevalent class of administrative intellectual properties, (2) offer a taxonomy of the different types of RCSs instituted to date, and (3) elucidate their potential advantages as a public policy tool as well as their perils.