

Regulatory Competitive Shelters—An Emerging Mechanism for Encouraging Technological Innovation

Yaniv Heled*

Georgia State University College of Law

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

SSRN page: http://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=1375263

Since the early 1980s the regulation of pharmaceuticals and medical devices in the United States has seen the emergence of a new kind of mechanism for encouraging technological innovation: regulatory competitive shelters (RCSs; also known as “regulatory exclusivities” and “statutory exclusivities”). These regulatory institutions create a novel class of benefits that are separate from and independent of any patents covering the regulated technologies. These benefits also differ from patents in that they do 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. Notable examples of such RCSs are the orphan drug exclusivity under the 1983 Orphan Drug Act and the “new chemical entity” (NCE) exclusivity under the 1984 Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). The competitive advantages that result from these RCSs and others have proven as powerful as the RCSs themselves were successful in achieving their purpose of incentivizing technological innovation. Thus, since their introduction into the regulation of pharmaceuticals and medical devices in the early 1980s, RCSs have grown increasingly popular with industries acquainted with them and policymakers alike. Also, as a result of their success, they have become more prevalent in regulatory frameworks affecting the pharmaceutical and biomedical industries, including the Biologics Price Competition and Innovation Act in 2010 and the Generating Antibiotic Incentives Now (GAIN) Act in 2012. It is

* Assistant Professor, Georgia State University College of Law.

prudent to assume that with their increasing popularity RCSs will find their way into additional regulatory frameworks pertaining to pharmaceuticals, medical devices and, perhaps even other technologies. This presentation will (1) define and characterize RCSs as an increasingly prevalent class of regulatory benefits for technological innovation, (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.