Abstract and Keywords

This article reexamines the sources of exclusivity for drugs, considers their limitations, and evaluates exclusivity under the new biologics legislation in light of these limitations. The current overlapping legal protections for exclusivity in the pharmaceutical marketplace reflect a series of political compromises, repeatedly renegotiated to correct for unintended consequences in the previous version of the rules. Patents and patent challenges play a central role in this system of protection, and many of the patents at stake are ultimately held invalid in litigation. It is not easy to untangle a complex legal regime that allocates billions of dollars of profits. But it makes little sense for lawmakers and trade negotiators to extend this Byzantine system into new legal regimes, either by duplicating the Hatch–Waxman Act for biosimilars or by binding US trading partners to adopt similar systems in their national laws. A simpler and more effective legal regime would rely less on patent protection and more on well-designed regulatory exclusivity to support incentives for new drug development.

Keywords: drug exclusivity, patents, patent challenges, Hatch–Waxman Act, drug policy, biosimilars, regulation

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