The Next Step in the Pharmaceutical Patent Wars: Will Congress Act?

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From pay-for-delay to product-hopping, pharmaceutical companies have a history of pushing their patent protections to the legal edge, and often beyond, all in an effort to maximize their ability to sell name-brand drugs without interference from generic competitors. Indeed, Allergan went so far as transferring certain patents to the Saint Regis Mohawk Tribe, who could then claim sovereign immunity to dismiss a patent challenge and then promptly license the drug back to Allergan.

Given these longstanding efforts to evade patent expiration, it is no surprise that litigation in this area has been fierce, both in the private litigation and government spheres. New efforts from Congress show that they may now be stepping into the maw as well. Last month, for example, the Terminating the Extension of Rights Misappropriated Act, or TERM Act, H.R. 3199, was introduced in the House, with bipartisan sponsorship.

The TERM Act aims to stop "trivial" changes to a drug from gaining entirely new patent protection, which members of Congress hope will stop the ability of brand name drug company to simply apply for a new patent on an old drug, sometimes repeatedly, and thereby gain additional years of patent exclusivity. Under the proposed bill, once a company files an application to introduce a generic version of a drug and challenges the patents protecting the drug, the brand name drug maker "shall be presumed to have disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires." That is, any new patents on a drug would be presumed to expire at the same time the first patent expires. The burden would then be on the brand name company to demonstrate that the later patents were "distinct inventions."

Because TERM has bipartisan support, it may not be as dead-on-arrival as many other bills that start in the House. In fact, Republicans have introduced at least two bills in the Senate just this year that take aim at different aspects of the current patent-extension scheme. There may now be a consensus that the status quo regime simply allows too much regulatory manipulation, leading to too long of an exclusivity period for many critical drugs—which, of course, has resulted in higher pharmaceutical costs for patients.