Stop Drug Manufacturers From Abusing the Patent System and Engaging In Anti-Competitive Practices

Over the past two decades, drug manufacturers have abused the patent system to extend monopolies for biologics and brand-name prescription drugs far past the exclusivity period as permitted under the law. How?

Drug manufacturers submit hundreds of patent requests on the same drug, a practice called "***obviousness-type double patenting.***" Then, these same drug manufacturers use "terminal disclaimers" to claim "non-patentably distinct patents" across multiple patents, creating large, duplicative "patent thickets."

"***Patent thickets***" – and the use of "***non-patently distinct patents***" – allow drug manufacturers to build large patent portfolios that shield their current patents from scrutiny as a mechanism to delay generic and biosimilar market entry by relying on the significant cost associated with challenging numerous patents.

- Specifically, the cost associated with challenging multiple "***non-patentably distinct patents***" is prohibitive for generic and biosimilar drug makers wanting to enter the market.
- For example, a biosimilar company must invalidate every single "***non-patentably distinct patent***" for freedom to launch, and cannot use the invalidation of one "***non-patentably distinct patent***" as grounds to dismiss another patent in the same cluster. A biologic drug manufacturer only needs to prove that one of the patents in a cluster is valid and infringed in order to block the biosimilar from entering the market.

To resolve these issues, Congress must pass the following bills from the 118th Congress that would promote competition in the market as well as address "***patent thickets***" and "***obviousness-type double patenting***," and "***terminal disclaimers***":

- **S. 113** – The Prescription Pricing for the People Act
  S. 150 – The Affordable Prescriptions for Patients Act
  S. 3583 and **H.R. 6986** – A Bill to Address Patent Thickets

The bottom-line: The United States is the only country that allows "***obviousness-type double patenting***" through the use of "***terminal disclaimers,***" which creates "***patent thickets***." These abusive, anti-competitive practices block generic and biosimilar drugs from entering the market to compete with patented drugs. This keeps the cost of patented drugs high, and it robs patients and health care payers like employer-sponsored self-insured health plans from accessing lower-costing alternatives.

It's time for Congress to step in to stop these abusive, anti-competitive practices.

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