Unpatenting Product Hops

Michael S. Sinha

Follow this and additional works at: https://scholarship.law.slu.edu/faculty

Part of the Commercial Law Commons, Intellectual Property Law Commons, and the Pharmaceuticals and Drug Design Commons
Unpatenting Product Hops

UC Irvine Law Review, Volume 15 (2025)
Saint Louis U. Legal Studies Research Paper No. 2024-03

Michael S. Sinha
Saint Louis University – School of Law

Abstract

On July 9, 2021, President Joseph R. Biden signed Executive Order 14036 (“Promoting Competition in the American Economy”), which directed the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (USPTO) to collaborate on new approaches to increasing competition and lowering prices in the pharmaceutical marketplace. In response, the USPTO outlined several new initiatives, among them an intent to improve the robustness and reliability of issued patents.

A major impetus for the Executive Order was the pervasive nature of pharmaceutical product hopping, which occurs when manufacturers introduce new follow-on versions of lucrative pharmaceutical products to the market, like extended-release forms of drugs or modifications to device components of combination therapeutics. Product hops are usually intended to mitigate lost market share due to generic competition or thwart generic competition entirely. Yet the small added value of these new products is usually far outweighed by excess costs to payers and patients alike. Product hops remain an essential part of product lifecycle management strategies due to patents, which discourage manufacturers from entering lucrative markets, encourage settlement and delayed generic entry, and undermine the fundamental constitutional intent of the patent system—a time-limited exclusive right.

Elevating patentability standards at the USPTO could mitigate product hopping through the rejection of weaker patents, which should eventually curtail patent applications from manufacturers that attempt to create “new,” yet arguably uninventive, products intended primarily to capture market share from would-be competitors.

This article evaluates the core elements of patentability and relevant case law, highlighting opportunities for the USPTO to strengthen its review of pharmaceutical patents. When coupled with regulatory reforms that further mitigate the impact of product hops, pharmaceutical research and development may pivot away from product life cycle management strategies and toward transformative innovation that accelerates the development of the next generation of therapeutics and cures.