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Ritika Malik · Mar 13, 2025 · 3 min read

Merck Faces Fierce Patent Dispute Over Injectable Keytruda



The biopharma sector is no stranger to complex legal conflicts, particularly on patents and licensing rights. In a new dispute involving Merck & Co.'s new injectable version of its blockbuster cancer drug, **Keytruda**, the company faces patent infringement claims from Halozyme Therapeutics.

Merck vs. Halozyme

Keytruda, a widely used immune checkpoint inhibitor, has revolutionized cancer care, especially for patients with lung and skin tumors. Merck has been developing a **subcutaneous (SC) version** to make the drug more convenient for patients, and extend the drug's commercial lifecycle. However, this development has drawn the attention of Halozyme Therapeutics, which alleges that Merck's new formulation infringes on its patented **Enhance** drug delivery technology.

Halozyme contends that Merck must secure a licensing agreement before bringing the injectable version of Keytruda to market. In response, Merck has challenged these claims, disputing the validity of Halozyme's patents. The company has filed petitions with the U.S. Patent and Trademark Office to review and potentially invalidate seven of Halozyme's patents.



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Additional [court filings](#) indicate that Halozyme has initiated legal action to prevent Merck from proceeding without a formal agreement. This legal maneuver underscores the increasing role of intellectual property protection in drug delivery innovation.

The Stakes for Merck

Merck's existing formulation of Keytruda is administered as an intravenous (IV) infusion, requiring patients to visit hospitals or infusion centers for treatment. A subcutaneous version would provide greater convenience, shorter administration times, and potential cost savings for both patients and healthcare systems.

Beyond patient benefits, this new formulation is a key part of Merck's [long-term strategy](#) to extend Keytruda's patent exclusivity. With the IV formulation's primary patents set to expire in 2028, Merck is seeking ways to maintain its stronghold in the lucrative oncology market. If Halozyme's claims hold up in court, Merck may be forced into a licensing agreement or risk delays in launching its new formulation.

Implications for the Industry

This case underscores larger issues in biotech patent law, particularly concerning drug reformulations and delivery mechanisms. Pharmaceutical companies often face challenges when developing improved versions of existing drugs, as these innovations may overlap with technologies patented by smaller biotech firms.

A similar situation arose in 2022 when [Anylam Pharmaceuticals sued Moderna and Pfizer](#), claiming that their mRNA vaccine delivery systems infringed on its proprietary lipid nanoparticle technology. These disputes highlight the delicate balance between innovation, intellectual property protection, and commercialization.

What's Next?

If the courts side with Halozyme, Merck may have to negotiate a licensing deal or redesign its delivery method to avoid infringement. However, if Merck successfully defends its position, it could pave the way for broader use of subcutaneous immunotherapies, reshaping how cancer treatments are administered. The outcome of this legal battle will be closely watched, as it may set precedents for future patent disputes in the biotech industry.

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