

# Cost of Hatch-Waxman Litigation Decreases (via tax deduction)

A photograph of a modern building with a curved glass facade, showing multiple floors and windows, set against a light blue sky.

1 MIN READ

November 6, 2023, 9:53 AM

By: Aziz Burgy

As Benjamin Franklin famously remarked, “nothing is certain except death and taxes.” Recently, the U.S. Court of Appeals for the Third Circuit provided more certainty about the latter by holding that legal expenses incurred by generic drug manufacturers in defending patent infringement suits brought under the Hatch-Waxman Act are deductible from the manufacturers’ federal taxes as ordinary and necessary business expenses. *Mylan, Inc. & Subsidiaries v. Comm’r of Internal Revenue*, 76 F.4th 230 (3d Cir. 2023).

In the appeal, the Commissioner of Internal Revenue argued that these expenses should be capitalized, under 26 U.S.C. § 263 and the associated regulations, as amounts paid to acquire approvals from the Food and Drug Administration (“FDA”). *Id.* at 243. The Third Circuit rejected the Commissioner’s argument noting that “ultimate FDA approval is never decided by the outcome of patent litigation under [35 U.S.C.] § 271(e)(2), even if it is delayed by such litigation.” *Id.* at 244. The Third Circuit concluded that “it makes no difference in deciding the question of deductibility whether the patent litigation expenses are incurred by the patentee or the alleged infringer. Nor does it matter that the deductibility question arises in the context of an ANDA suit.” *Id.* at 239-240.

Generic drug manufacturers can certainly leverage this ruling at corporate tax time. Companies should also consult with their tax advisors about the treatment of costs

associated with the preparation, assembly, and transmittal of notice letters required by the Abbreviated New Drug Application.

 [www2.ca3.uscourts.gov/...](http://www2.ca3.uscourts.gov/...)



## Related People

---



Aziz Burgy

## Related Services

---

Intellectual Property

To subscribe to our publications, [click here](#).

## TAGS

pharma

## News & Insights

- ACI 12th Annual Summit for Women Leaders in Life Sciences Law  
**SPEAKING ENGAGEMENT     INTELLECTUAL PROPERTY**
- National LGBTQ+ Bar Association Lavender Law Conference and Career Fair 2025  
**SPONSORSHIP**
- National Bar Association 100th Annual Convention and Exhibits  
**SPONSORSHIP     ANTITRUST**
- Keeping Pace: Updates in Cartel Enforcement  
**WEBINAR     ANTITRUST**
- Hanging in the Balance: Supreme Court Declines to Decide the Uninjured Class Member Question in Labcorp v. Davis  
**AXINN VIEWPOINTS     ANTITRUST**
- New Incentives, New Rewards: What You Need to Know About the Antitrust Division's First-Ever Whistleblower Rewards Program  
**AXINN VIEWPOINTS     ANTITRUST**
- Informa Antitrust Midwest  
**SPEAKING ENGAGEMENT**
- GCR Live: Law Leaders Europe 2025  
**SPEAKING ENGAGEMENT     ANTITRUST**
- How I Made Partner: 'Show Up and Build Rapport With Colleagues and Clients,' Says Michael O'Mara of Axinn Veltrop & Harkrider  
**MEDIA MENTIONS     ANTITRUST**

- Axinn Counsel Rebecca Clegg Named 2025 MCCA Rising Star

**AWARDS & RECOGNITIONS**

**INTELLECTUAL PROPERTY**

© 2025 Axinn, Veltrop & Harkrider LLP. All Rights Reserved