

## Biotech Insights - Spring 2026

---

April 15, 2026

---

**PRACTICES** Healthcare Transactions and Regulatory, Life Sciences, Pharmaceuticals, Patents, Mergers and Acquisitions, FDA Regulatory and Compliance, Biotechnology, Intellectual Property

---

Welcome to Haynes Boone's Biotech Insights! This newsletter is your go-to resource for staying informed on the latest legal developments in biotechnology. Each edition will feature expert analysis of key topics impacting the biotechnology industry, a spotlight on one of our talented team members and details about where to connect with our team at upcoming industry events. We are committed to keeping you informed in this important and rapidly evolving field. This month's edition features:

### [Regulatory Overview: Post-Approval Changes to Marketed Drugs](#)

As GLP-1 drugs continue to expand, post-approval changes are no longer routine. The FDA's approval of Wegovy in tablet form underscores a key challenge: The same type of product update can fall into entirely different regulatory categories. Some changes require prior approval before launch, while others can proceed with notice or later reporting. Misjudging that line can create real regulatory and commercial risk. This article outlines how the FDA evaluates post-approval changes and what sponsors need to get right.

### [Federal Circuit's Holding on Patent Eligibility for Engineered Host Cells Dovetails With PERA](#)

Years after the Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.* and *Alice Corporation Pty. Ltd. v. CLS Bank International*, patent eligibility in the life sciences remains unsettled. Nowhere is that uncertainty more pronounced than in claims involving nucleic acid sequences. A recent Federal Circuit decision begins to draw a clearer line, with significant implications for biotech innovation and the future of patent eligibility reform.

### [Key California M&A Considerations for Life Sciences Businesses: Part 2](#)

In California M&A transactions, certain legal constraints can significantly impact how deals are negotiated and executed. This second article in our two-part series focuses on dispute resolution provisions, the enforceability of non-competition and non-solicitation covenants, and key tax considerations that commonly influence deal structure and negotiations.

Read the full [Spring 2026 Biotech Insights here](#).