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IP, Licensing, M&A Trends To Watch In Life Sciences This Year

By **Christina MacDougall, Ben Pensak and Benjamin Stein** (February 5, 2025, 6:40 PM EST)


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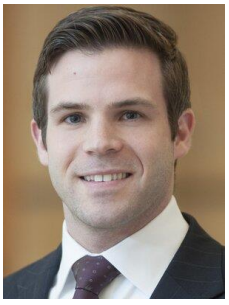
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The life sciences industry has long been at the forefront of innovation, and 2025 promises to continue this trajectory with exciting developments in intellectual property, licensing, and mergers and acquisitions.

As the sector navigates a dynamic landscape of scientific advancements, economic pressures and regulatory changes, stakeholders are increasingly leveraging strategic transactions to gain a competitive edge.

This article explores the trends shaping the life sciences space, focusing on the critical areas of IP, licensing and M&A. Data derived from potential product candidates and the IP that covers such product candidates drive the value of life science companies. These pillars not only highlight the challenges and opportunities facing the industry but also provide a look at how companies are preparing for the future.

How Evolving IP Strategies Are Reshaping Innovation in Life Sciences

Intellectual property remains a cornerstone of the life sciences industry, driving value creation and innovation. As the sector evolves, so too does the IP landscape, presenting both opportunities and challenges. Below are some of the key trends shaping IP in the life sciences space.

Patents for Biologics and Biosimilars

As biologic therapies and biosimilars continue to grow in prominence, there is a heightened focus on patenting strategies related to biologics, with an increasing number of patent disputes over biosimilars.

The IP landscape is also adjusting to the growing demand for robust patent protections for complex biologics, as well as the challenge of protecting biosimilars that are modeled after existing biologic drugs. Biologics and biologic-based targeted therapies are of significant interest.

Artificial Intelligence and Machine Learning in Drug Discovery

AI and machine learning are transforming drug discovery, with new tools for predicting protein

structures, identifying and enhancing drug compounds, and personalizing therapies.

IP protection is being sought for AI algorithms, data-driven innovations and software applications in the drug development process. The integration of AI into biotechnology raises questions about inventorship and ownership of inventions driven by AI.

The lines between IP covering traditional biologics versus AI and machine learning applications are likely to become increasingly blurred. Similarly, ownership of copyright in any original expressions, such as underlying source code created with the help of AI, is a developing area. Purely AI-created expression is not considered copyrightable, but human-authored contributions can be protectable to varying degrees.

Global Harmonization and IP Strategies

As the biotechnology industry becomes increasingly global, life sciences companies are focusing on harmonizing their patent strategies across jurisdictions.

These efforts are seen in the expansion of the Patent Cooperation Treaty (for example, the addition of Uruguay in January); the addition of the Unified Patent Court in Europe; and international collaborations aimed at streamlining patent examination processes.

Companies are also adapting to regional differences in patentability criteria, particularly in emerging markets such as China, India and Brazil. Similarly, life sciences companies are focused on harmonizing product names and branding strategies that require navigating the trademark clearance and regulatory approval issues that arise in different jurisdictions in connection with that effort.

Data Exclusivity and Trade Secrets

With the growing importance of data in drug development, life sciences companies are exploring the use of trade secrets and data exclusivity protections.

Regulatory exclusivity periods, such as those seen with new chemical entities, are also being scrutinized as companies seek to extend their market position through data protection strategies rather than relying solely on patents.

Additionally, there is rising interest in protecting proprietary biological data, such as clinical trial data and research outcomes, through nonpatent means.

Further, there are increasing considerations with regard to data protections. Companies with clinical trial data will need to navigate the evolving regulations around data storage and usage of patient information, given the global footprint of many entities.

Patentability of Artificial Organisms and Synthetic Biology

Advances in synthetic biology, which involves creating or altering organisms with novel functions, are raising complex patentability questions. The challenge of patenting artificial organisms, synthetic genomes and genetically modified organisms is pushing the boundaries of current patent laws, requiring regulators to update guidelines on the scope of patentable inventions.

Licensing as the Go-To Strategy for Collaboration and Growth in Life Sciences

Through economic ups and downs, licensing as a means for entities to access IP rights, while enabling other entities to realize an economic return without giving up all the rights to their IP, remains a viable and appealing strategy.

The following highlight how licensing is playing an increasingly important role in life sciences transactions.

Licensing as an Alternative to M&A

An acquisition is typically perceived of as the ultimate exit for a biotech and the final imprimatur of Big Pharma's buy-in on a therapy.

M&A also requires alignment between the parties on the value of all assets, the absence of any assets that the acquirer does not desire to acquire, and navigating the complexities of an acquisition transaction.

In contrast, licensing allows two parties to focus on a specific technology of interest, while enabling the licensing party to continue developing its IP, frequently using proceeds received from the licensee.

Key Developments in Licensing Deals

In the weeds of contracting terms, we are seeing (1) licensees begin seeking royalty adjustments in the event that a product becomes subject to price negotiations in the U.S., (2) more sensitivity in clinical milestones to relevant indications and clinical plans, and (3) ever-increasing attention to the rights each party gets to use arising from such data and results.

Biotech Sensitivity to High Research and Development Costs

Today's high-cost environment has all interested entities focusing more on research and development costs and responsibility for budget overages. Licensors want licensees to compensate for prior R&D investments to develop technology to where it is and then, depending on the licensing arrangement, expect a licensee to continue covering development costs.

Licensees who are funding ongoing activities have an interest in ensuring funds are spent on their intended target and to keep an eye on the solvency of their licensors.

Contracting parties need to be sensitive to financing arrangements and accounting treatment to ensure no surprises. The more funding that one party provides, the more it expects to reap the commercial benefits.

A licensor that is willing to share costs with its licensee may seek a profit share, whereas a licensee that is funding all development may expect to pay lower milestones and royalties.

Cross-Border Licensing

Licenses are taken globally to access IP wherever it may be developed. In particular, Big Pharma and other well-funded licensees are accessing novel molecules being developed in China, with the China-based developer sometimes looking to retain Chinese rights.

There are also countries trying to support and encourage their local life sciences industry. At the same time, licensing remains essential to getting fully developed products into countries and to specific markets and patient populations that can benefit from targeted therapies.

What's Fueling a Surge in Life Sciences M&A Activity for 2025

There is significant optimism that traditional M&A activity in the life sciences space will carry the momentum from 2024 into 2025. Several factors contribute to this optimism.

New Entrants

Big Pharma M&A tends to be driven more by strategic priority than depressed value. Traditionally, an acquisition has largely depended on whether the target and assets fit into an acquirer's strategic goals and product portfolio.

However, there has been a significant increase in nontraditional financial participants in the life sciences M&A space, which we expect will help to accelerate deal activity. These financial sponsors are much less concerned with strategic shifts and instead on whether they can take advantage of depressed values.

Dry Powder

Even without these new entrants, we expect there to be a material increase in activity from strategic buyers. While reports on the specific number vary, it has been widely reported that larger pharmaceutical companies collectively have over a trillion dollars to deploy in dealmaking efforts.

If Day 1 of the J.P. Morgan Healthcare Conference this year is any indication, we expect strategic industry participants to utilize their war chests to complement existing asset portfolios or to expand into new ones, particularly as revenues from existing assets could sour.

Patent Expirations

According to a recent report from EY, within the next three years, patent expirations could affect approximately $300 billion in industry revenues.[1]

Accordingly, Big Pharma will likely expand significant resources to not only continued R&D efforts but also to acquisitive growth, particularly with respect to later-stage and precommercial assets.

We also expect to see an increased focus and investment in branding strategies and trademark protection for products in order to maximize market share and value after the relevant products expire.

Regulatory Landscape

The regulatory landscape will be shifting under the second Trump administration. The most obvious example is the new leadership at the Federal Trade Commission. With the appointment of Andrew Ferguson to replace Lina Khan, the expectation is that the FTC and similar anticompetition agencies will put less focus on deal activity generally, including within the life sciences industry.

Additionally, if Marty Makary is confirmed as the new U.S. Food and Drug Administration commissioner,

a comparable reset of agency priorities and focus is likely, especially in the area of vaccines and the use of AI in drug development.

Conclusion

As the life sciences industry continues to evolve, the interplay of IP, licensing strategies and M&A activity will remain critical in shaping its future.

Companies that effectively navigate these trends — by staying ahead of IP challenges, leveraging innovative licensing structures and pursuing strategic acquisitions — will be best positioned to capitalize on emerging opportunities.

As we move into 2025, the sector's adaptability and resilience will surely fuel continued growth and innovation, ensuring its pivotal role in addressing global health challenges and advancing medical breakthroughs.

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[1] https://www.ey.com/en_gl/insights/life-sciences/why-licensing-deals-are-a-powerful-source-of-growth-in-life-sciences.