WEBINAR SUMMARY

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Informa Pharma Intelligence

Leveraging Your Life Science and Pharmaceutical Portfolio: Driving M&A and Target Identification Through Research-Driven Strategies

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KEY TAKEAWAYS

- Patents have important implications for life sciences and pharmaceutical companies.
- Knowledge of FDA regulatory requirements is key to planning a strategy and anticipating challenges.
- The interplay between IP and FDA insights drives deal value.

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OVERVIEW

Understanding the role that intellectual property (IP) and FDA regulatory issues play in a life sciences or pharmaceutical portfolio is essential to identifying investment or acquisition targets, driving deal value in acquisitions and divestitures, focusing on strategic growth, and "looking around corners" to assess the competition. With these goals in mind, gaining insights that maximize the value of IP and FDA factors is crucial to strong portfolio management.

Practical benefits of a joint IP and FDA approach include spotting vulnerabilities and red flags early, asking the right questions in the case of an investment or acquisition, articulating the value of a product in the case of a divestiture, and making an informed business decision under any scenario.

CONTEXT

Presenters from Buchanan Ingersoll & Rooney discussed how life sciences and pharmaceutical companies can leverage IP and FDA regulatory insights to identify market openings, and to assess patent, exclusivity, and other regulatory issues to help optimize the value of their portfolios, critique potential targets, and close successful deals. Although focused on drug products here, these concepts are integral to any deal involving FDA-regulated products, including biologics, medical devices, and others.

KEY TAKEAWAYS

Patents have important implications for life sciences and pharmaceutical companies.

When considering an asset investment, acquisition, or divestiture, the first thing companies and investors must look at is an asset's patent portfolio and value. Specifically, they should look at the breadth and strength of the patents and, in the case of an acquisition, should examine:

- **Sufficiency:** Is there enough diversity of patents that cover different aspects of the product or does a single patent cover the product?
- **Weaknesses:** Are the claims too narrow for a potential competitor to get around them?
- **Vulnerabilities and design-around possibilities:** Are there any gaps that may allow a competitor to invalidate or circumvent the asset's patents?

Similarly, in the case of a divestiture, additional criteria to be considered include diversity of the patent claims and the value of the product compared to competitors' products.

In both scenarios, it is critical to model out:

- If and when generic competition may emerge.
- What the regulatory hurdles are for potential generic competitors.
- What legal and regulatory obstacles those competitors may face if they decide to challenge the asset's patents.
- The likely challenge strategy of a potential competitor.

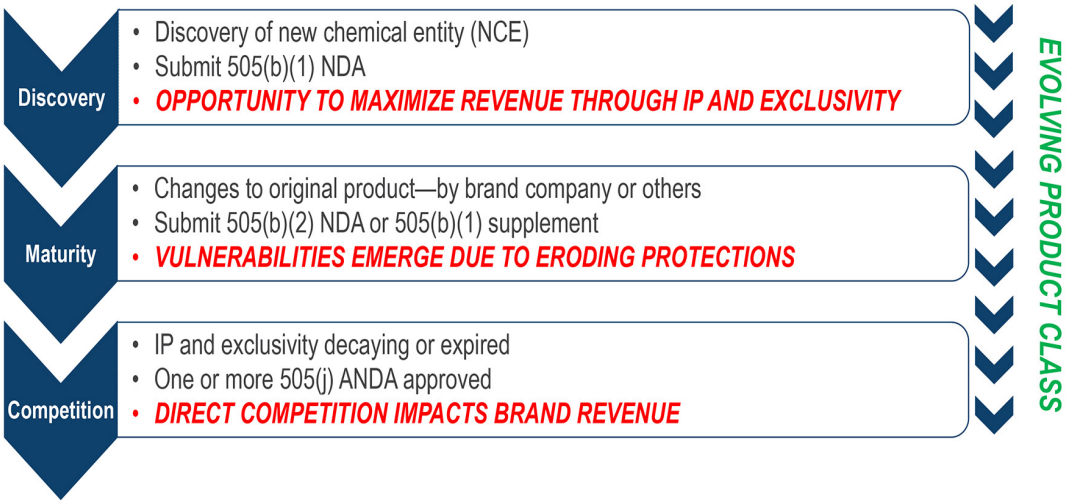
> Asset acquisition is like selecting a car and kicking the tires and getting under the hood to see what the issues are. To do that with regard to an IP portfolio, you need to look at the patents that cover the products.
>
> *Matthew Fedowitz, Buchanan Ingersoll & Rooney*

The key place to start is the Orange Book, the FDA's official compilation of approved drugs, the patents covering those drugs, and the regulatory exclusivity periods to which they are entitled. In general, the exclusivity period is five years for new chemical entities (NCEs) and seven years for orphan drugs, with six additional months for pediatric adaptations of either category. The goal of the exclusivity period is to promote a balance between new drug innovation and future generic competition.

Knowledge of FDA regulatory requirements is key to planning a strategy and anticipating challenges.

Beyond IP, the regulatory aspects of managing a life sciences or pharmaceutical product portfolio can also have a significant impact on deal value. Those impacts can be both positive and negative and they manifest in the three main phases of the drug product lifecycle: discovery, maturity, and competition.

Figure 1. Phases of the drug product lifecycle



The positive regulatory impacts typically coincide with the product's discovery and maturity phases, when revenue potential is at its highest upon approval of a 505(b)(1) new drug application (NDA) and when exclusivity periods may be extended via filing additional 505(b)(1) supplements or 505(b)(2) NDAs.

Meanwhile, vulnerabilities begin to emerge during the maturity phase as patent and exclusivity life wanes or real-world evidence prompts changes to the original product to enhance its value. However, new drugs are most vulnerable during the competition phase, when exclusivity periods or patents expire and the threat of generic manufacturers filing 505(j) abbreviated new drug applications (ANDAs) becomes more palpable.

> If you are approaching year four and five of your exclusivity, you can be sure that there may be generic companies looking at developing a competitor to your product.
>
> *Barbara Binzak Blumenfeld, Buchanan Ingersoll & Rooney*

Each of these application types—505(b)(1) NDAs, 505(b)(2) NDAs, and 505(j) ANDAs—have different exclusivity periods, as well as different Orange Book patent listing and certification requirements. "Listing more patents is advantageous to the brand," Binzak Blumenfeld said. She noted that the Orange Book is not the be-all-end-all, however, as the relevant patent estate for a product may be much broader than what is listed there. Companies must therefore always do their own due diligence to ensure they have a complete product picture.

The interplay between IP and FDA insights drives deal value.

From a business development perspective, an understanding of the IP and FDA regulatory frameworks that govern life sciences and pharmaceutical product portfolios unlocks a new way of assessing deals. Developing such an understanding generally begins with an IP asset review.

An IP asset review achieves three things:

1. **Equips leaders to think offensively and defensively,** from the perspective of both maximizing the value of assets they already own and identifying potential vulnerabilities with other companies' products that may be assets of interest.
2. **Builds awareness of the need to "look around the corner"** for impending competition, even when that competition is indirect—for example, when it comes not from a generic manufacturer, but from within the larger product class.
3. **Helps answer questions about the strengths of a portfolio** and where it might need reinforcement, as well as prepare questions for investment or acquisition targets while identifying lurking issues that may be red flags.

"It's imperative that those in business development have that information in hand prior to the deal and throughout to leverage their side of the deal," Fedowitz said. He highlighted the importance of understanding the probability of a competitor moving into a space before an acquisition ever takes place: "[y]ou need to understand the likelihood of this happening up front by modeling out the potential competition." A favorably structured deal would be risk managed by accounting for hidden IP risks or unrecognized value, evaluating third-party licenses, evaluating sufficiency and strength of each IP portfolio, and articulating the risks of supply chain and distribution chain factors.

Once the IP asset review is complete, an FDA regulatory review provides a critical additional layer to any due diligence. An FDA review assesses hidden business risks in the same way that an IP review does for hidden IP risks. For example, when considering an acquisition, an FDA regulatory review would look at the asset's post-marketing history for warning signals of potential problems down the road, such as a history of FDA warning letters or other enforcement actions, manufacturing problems, or incomplete post-marketing studies. Such a review would also consider relevant FDA guidance and changes in the larger product class, such as emerging generic competition for other therapeutic class members.

CONCLUSION

To maximize the value of their investments or acquisitions, or to reach an optimal, risk-mitigated deal for a product they are divesting, companies must think strategically about leveraging their IP and product portfolios. They can be successful in these efforts by considering how IP and FDA factors influence each other and together drive deal value beyond what either individual set of factors separately can achieve. Executing on that approach requires a company to undertake a targeted IP and FDA review and seek guidance for strengthening portfolios if weaknesses or vulnerabilities are detected. Specialized advisors such as Buchanan Ingersoll & Rooney can support life sciences and pharmaceutical companies on that journey by doing a deep dive on the technical aspects and producing a clear analysis and recommendations.

"The individuals driving the deals are not going to need the hyper-technical details that are going to be identified during the IP and FDA regulatory reviews. What is important to them is to [have] easily understandable conclusions that convey the significance and impact of those conclusions," Binzak Blumenfeld noted.

BIOGRAPHIES

Barbara A. Binzak Blumenfeld, PhD, MA, Esq.
Shareholder, FDA & Life Sciences, Buchanan Ingersoll & Rooney

Barbara helps clients make and execute on strategic decisions about FDA-regulated product approvals. She leverages her unique background, integrating science and biomedical ethics into her legal practice to create true value for her clients. Barbara frequently works alongside Buchanan's IP attorneys to create a holistic IP/FDA strategy that takes into account the company's patent portfolio, FDA Orange Book listings, and FDA-granted regulatory exclusivity.

Barbara assists clients with FDA regulatory matters arising before, during, and after product approval and marketing. She has worked with clients on virtually all types of FDA-regulated products, including drugs (human and veterinary), biologics, regenerative medicine (cell and gene therapies), medical devices, foods (human and veterinary), and combination products.

Matthew Fedowitz, PharmD, Esq.
Shareholder, Intellectual Property & Life Sciences, Buchanan Ingersoll & Rooney

Matthew is a life sciences industry lawyer who focuses his practice on achieving the business goals of clients. This includes IP-related mergers and acquisitions; strategic patent prosecution; counseling with regard to FDA regulatory issues and their intersection with intellectual property; litigation in federal district court; and inter partes proceedings before the Patent Trial and Appeal Board.

Matthew has a particular expertise in the pharmaceutical, life science and medical device fields. He draws on this experience to assist clients in the identification of products as business development opportunities and to obtain and maneuver through intellectual property hurdles by coordinating due diligence, preparing patent validity, freedom-to-operate and non-infringement opinions, and resolving disputes in Federal District Court and before the U.S. Patent and Trademark Office.