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Due Diligence: Intellectual property

Beyond checklists: a framework for biopharma startup

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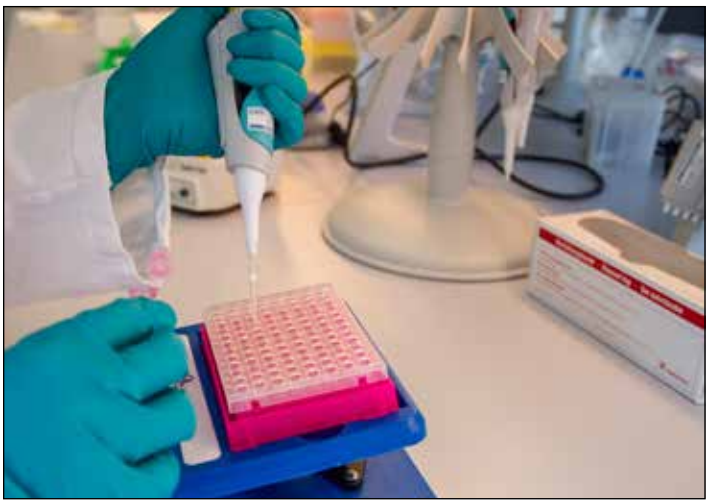
When conducting a due diligence investigation, the primary goal is to provide information that is of strategic value to the client. However, many intellectual property attorneys begin diligence projects by dusting off their favorite checklists of specific tasks to perform. In the process of marching through the various tasks, the goal can get lost. When the target of a diligence project is a biopharma startup, getting lost in the weeds of a checklist can waste critical time and money. Worse, it can delay or prevent deals, and consequently potentially life-saving medicines, from moving forward.

Conducting a thorough diligence investigation using certain key questions as a framework can liberate IP attorneys from the minutiae of diligence checklists, but still ensure that they provide their clients with the information necessary to assess a deal opportunity. IP attorneys provide the most value to their clients when they can answer the following three key questions in diligence:



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When the target of a diligence project is a biopharma startup, getting lost in the weeds of a checklist can waste critical time and money.

Does the target startup's patent portfolio align with its (and your client's) strategic commercial objectives? Will the startup (and your client) be free to actually implement those commercial objectives? And what are some solutions to the above questions if the answer to either is no?

Assessing patent portfolio alignment

Here's what you need to do.

Understand the lead commercial product. It may sound self-evident, but the first step should be to obtain a clear and complete understanding of the lead product and the startup's path to commercialization. Obtain the chemical structure of the product and dig into the details on the dosage form and formulation, the lead indication, and the mechanism of action of the product. Ask to review the draft drug label, if available. Look carefully at the clinical status and available clinical trial information. Realistically assess the timeline for FDA approval. This in-depth analysis of the product is necessary before any review of the patent portfolio.

Conduct a critical analysis of the pending and issued claims in the startup's patent portfolio as compared to the lead product. Review the portfolio for claims that cover the lead commercial product and the lead indication generically and specifically. Genus claims can be useful as defensive claims to provide deterrence to innovator competitors, while narrow, focused claims provide stronger protection of the lead product from generic entry. Assess the strength of both types of coverage, reviewing the file histories and specifications to get an understanding of any claim construction or estoppel issues. Review the prior art cited during prosecution and the arguments made to distinguish the lead product. Perform a patentability analysis on the lead product. Determine if backup programs have been pursued and/or life cycle patents directed to formulations, polymorphs, or dosage regimens have been filed. Determine if any identified holes in claim

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coverage can be plugged with continuation applications or new filings.

Review platform cases carefully, particularly for their effects on the commercial lead cases. Platform cases are typically filed before a clinical lead product is identified. These cases often benefit from an early stage of research and a consequent lack of prior art, and can therefore have broad coverage of a subsequent commercial product. The strength of such broad claims often relies on the written description and enablement support provided in the application. On the other hand, the disclosures in these initial applications may also act a primary source of prior art against any subsequent patents, including those that more closely cover the commercial product. Assess the impact of the earlier patent applications on the patentability and patent term of the later patent applications, particularly those that cover the lead product.

Confirm ownership and clear title for the portfolio. This step involves more than simply confirming the proper execution and recordation of assignments. Ask questions about collaborations or relationships with academic institutions, contract research organizations (CROs), and consultants. Look at inventorship carefully. Compare the timing of employment of key scientists and inventors with dates of early patent filings to assess whether former employers might assert an ownership stake. Evaluate license agreements, particularly to platform technologies, and assess whether they impact inventorship or ownership of new filings.

Making sure the value proposition aligns with the patent portfolio

A number of factors come into play when determining whether the value proposition aligns with the patent portfolio. Timing can have a significant effect on this calculation. Consider some of the following factors:

- What are the terms of the patents in the portfolio? How do these terms align with the expected date of FDA approval and commercial entry? How do they align with regulatory exclusivities, including new chemical entity, Orphan, and method of use?
- Are there terminal disclaimers filed in any of the patents that adversely affect term? Have all appropriate terminal disclaimers been filed or considered?
- Are there pending continuations in any of the parent families? Can continuations be filed to obtain better or stronger claim sets? Do applications need to be accelerated to issuance with Track 1 or other acceleration mechanisms?
- Are there any life cycle patents that extend the exclusivity for the product? For example, does the portfolio contain patents directed toward dosage regimens, formulations, combinations, polymorphs, pharmacokinetics, or clinical trial results? Can new applications be filed?
- What are the most likely challenges (invalidity, noninfringement) that could be raised by a generic competitor?

Answering the above questions can provide a detailed picture of the commercial product and the scope of patent and regulatory exclusivities. If you identify problems, however, don't simply point them out to your clients. Your clients certainly want an understanding of how such problems impact the value proposition, but they also need an understanding of how you might fix or minimize any such issues.

Live free or die

Could the startup be blocked from commercialization by third-party patents? Knowing the freedom-to-operate landscape for the lead product is crucial to assessing its commercial value and any potential delays of commercial launch.

Evaluate the searches performed to date and conduct new searches. Critically assess any searches that have been conducted and determine whether additional searches need to be performed. It may be important to search not only the commercial product itself, but also aspects of the formulation, the molecular target, and the indication. Assess the strength of any identified blocking patents, the nature of the assignee, and any impact on commercial entry timing. Determine if any opinions of invalidity or noninfringement could be warranted.

Identify key competitors and evaluate their patent portfolios. The client or the startup are generally the best sources of information as to potential competitors. Once a list of potential competitors is compiled, it is worth the time to evaluate their patent portfolios and clinical candidates to determine if problematic claims covering the startup's lead product could be obtained. Competitive analysis can provide useful insights into how the startup's commercial objectives could be hindered. Determine if the startup's portfolio can be mined to cover competitor products and provide flexibility in a cross-licensing situation.

Using the above framework to perform diligence on a biopharma startup can focus an attorney's attention on those IP aspects of most significance to clients in a deal setting. Importantly, changing the emphasis from only identifying potential problems to also highlighting potential solutions will provide real value to your client, should they decide to move forward with the deal. While checklists are useful, they can lend themselves to focusing on administrative minutiae, and ultimately prevent the big-picture analysis of the opportunity.

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