The Licensing Journal, *Staying IP Due Diligence Ready: A Practical Guide for In-House Counsel Introduction*, (Apr. 1, 2026)

The Licensing Journal

Staying IP Due Diligence Ready: A Practical Guide for In-House Counsel Introduction

Jean Ge and Phil Hamzik

Jean Ge specializes in protecting high-value, complex biotherapeutics. She develops sophisticated IP strategies designed to protect enterprise value and support long-term business objectives. Jean's counsel is grounded in a deep understanding of each client's unique technology and market position. She translates this insight into actionable legal strategy across the full spectrum of patent practice, including global patent portfolio development, freedom-to-operate analyses, and third-party risk management. She regularly guides clients through complex IP due diligences integral to corporate transactions, including financings, mergers, and acquisitions.

Phil Hamzik is a shareholder at Wolf Greenfield, where he counsels pharmaceutical and biotech clients on patent strategy and other aspects of their intellectual property. From protecting key platform technologies to advising on drug product lifecycle management, Phil works closely with life sciences companies of all sizes to develop and implement IP strategies aligned with their business goals. In addition to global patent prosecution and portfolio management, Phil provides strategic advice related to freedom-to-operate, competitive landscape, and validity/invalidity. Defending and conducting IP due diligence is also a significant focus of his work. As a trained medicinal chemist, Phil brings a discovery mindset and years of practical scientific experience to his IP practice.

Introduction

For in-house counsel, IP due diligence is not simply a checklist exercise—it is a real-time test of the company's long-term intellectual property strategy. With transaction timelines often compressed, there is little room for error or last-minute remediation. The most effective approach is to build a culture of IP due diligence readiness well before a deal is on the horizon. Whether preparing for a potential financing, strategic partnership, or acquisition, the following ten practices can help ensure that your IP portfolio is organized, defensible, and clearly connected to the company's broader strategy.

1. Align IP Strategy with Business Objectives

At its core, IP due diligence evaluates whether the portfolio meaningfully supports the company's commercial objectives. In-house counsel should understand the R&D pipeline, product roadmap, and regulatory timelines, and ensure that patent strategy is synchronized with key commercial milestones. Regular communication with leadership about IP risks and opportunities allows the company to articulate a clear and credible narrative about the strength and value of its portfolio.

2. Maintain a Current Executive Summary of Programs and IP Position

Once strategic alignment is clear, the next step is ensuring that it can be communicated efficiently. Diligence proceeds more efficiently when the reviewing party can quickly understand the company's IP landscape. Maintaining a concise executive summary of key programs and assets—and how each is protected—can significantly streamline the process. This summary may include core patent families, geographic coverage, and projected loss of exclusivity (LOE). Clear, organized materials reduce unnecessary follow-up questions and demonstrate disciplined portfolio management.

3. Prepare and Pressure-Test Loss of Exclusivity (LOE) Analyses

After presenting the structure of the portfolio, diligence focus often turns to durability. Projected LOE dates are often central to valuation, particularly for life sciences companies. Counsel should prepare defensible analyses that account for regulatory exclusivity and patent exclusivity, taking into consideration patent term adjustment (PTA), patent term extension (PTE), and any relevant disclaimers, including terminal disclaimers. Where multiple patent families protect a product, the analysis should address how those families interact.

Working with outside counsel to pressure-test LOE assumptions can identify vulnerabilities early and support more informed exclusivity planning.

4. Develop and Document a Reasoned Freedom-to-Operate (FTO) Position

Durability of exclusivity is only part of the analysis; diligence also evaluates potential third-party constraints and infringement risk. Being surprised by a third-party patent during diligence can undermine credibility. A proactive FTO strategy should involve initial clearance analysis and periodic monitoring of the patent landscape, with scope and timing calibrated to the company's risk profile and resources.

The goal is not simply to identify risks, but to document reasoned positions—whether based on non-infringement, invalidity, design-arounds, licensing strategies, or a combination thereof. During diligence, presenting identified risks together with mitigation strategies in a clear and organized manner builds confidence.

5. Articulate a Clear Patentability Narrative and Maintain Disclosure Discipline

In parallel with assessing external risk, diligence teams evaluate the strength and defensibility of the company's own patents. Diligence may require identifying the closest prior art and explaining the patentability of key inventions. For pending applications, diligence teams may inquire about anticipated prosecution strategies; for issued patents, they may probe potential validity challenges. Thorough prior art searches and a well-developed patentability narrative help anticipate these discussions.

Counsel should also ensure compliance with the duty of disclosure under 37 C.F.R. § 1.56. Regular audits to confirm that Information Disclosure Statements (IDSs) are complete and current can reduce vulnerability and reinforce credibility.

6. Maintain Strong Portfolio Hygiene

Even strong patents can lose value if foundational ownership and formalities are not in order. Diligence frequently exposes gaps in inventorship, chain of title, or basic formalities. Although often viewed as administrative, these issues can affect valuation and delay transactions. Portfolio hygiene is therefore part of protecting enterprise value.

Counsel should periodically confirm accurate inventorship for pending and issued patents, ensure assignments and declarations are executed and recorded promptly, and maintain clear documentation of ownership—particularly before inventors depart. Maintenance fees should be current in relevant jurisdictions, and inventions developed with U.S. government support must be tracked for Bayh-Dole compliance.

7. Review Third-Party Agreements for IP Impact

Beyond the patents themselves, the value of an IP portfolio can be shaped by contractual rights and obligations. During diligence, inbound and outbound licenses, collaboration agreements, joint research agreements, material transfer agreements, and related contracts will be scrutinized. In-house counsel should ensure in advance that these agreements are organized, internally understood, and consistent with the company's intended IP ownership and commercialization strategy.

Key considerations include the scope of license grants, field and territorial limitations, sublicensing rights, and ownership of improvements or jointly developed IP. Employment and consulting agreements should confirm that IP has been properly assigned to the company. Agreements involving U.S. government funding warrant particular scrutiny due to Bayh-Dole obligations and potential manufacturing requirements.

8. Treat Trade Secrets as a Managed Asset

For many companies, trade secrets—including unpatented know-how, proprietary data, manufacturing processes, and other confidential business information—are often core assets. Because their protection depends on reasonable steps to maintain secrecy, diligence focuses on whether those measures are clearly defined and consistently implemented.

Counsel should identify key trade secrets on an ongoing basis, confirm enforceable confidentiality and assignment provisions in employment and contractor agreements, and ensure robust NDAs with third parties. Access controls, employee training, and structured onboarding and offboarding procedures demonstrate that trade secrets are actively managed and legally defensible.

9. Implement Structured Open Source and AI Governance

Modern diligence increasingly scrutinizes open source software (OSS) and artificial intelligence practices. Certain "copyleft" licenses may impose source code disclosure obligations, making structured OSS management essential.

In-house counsel should maintain a current inventory of third-party code, implement a formal OSS policy distinguishing pre-approved and high-risk licenses, and conduct regular internal reviews to identify and remediate compliance issues. Diligence teams may also assess AI governance, including risks of confidential information leakage and ownership or infringement concerns related to AI-generated content. A clear written AI policy—prohibiting input of confidential information into public tools and defining approved uses—signals that emerging technology risks are being managed deliberately.

10. Conduct a "Practice" Diligence

Finally, even a well-managed portfolio benefits from rehearsal. Preparing for diligence before a live transaction can reveal gaps on a manageable timeline. Reviewing sample diligence questionnaires or conducting a mock diligence with outside counsel can highlight weaknesses in portfolio management or documentation and allow corrective action before deal pressure intensifies. Treating diligence preparation as a rehearsal—rather than a reactive exercise—helps ensure that when an actual transaction arises, the company can respond efficiently and with confidence.

Final Thoughts

IP due diligence readiness is not a one-time project. It is an ongoing discipline that integrates legal, technical, and business considerations. By approaching portfolio management proactively—and engaging outside counsel strategically—companies can reduce transaction risk, strengthen valuation narratives, and move more efficiently when opportunities arise.