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Intellectual Property

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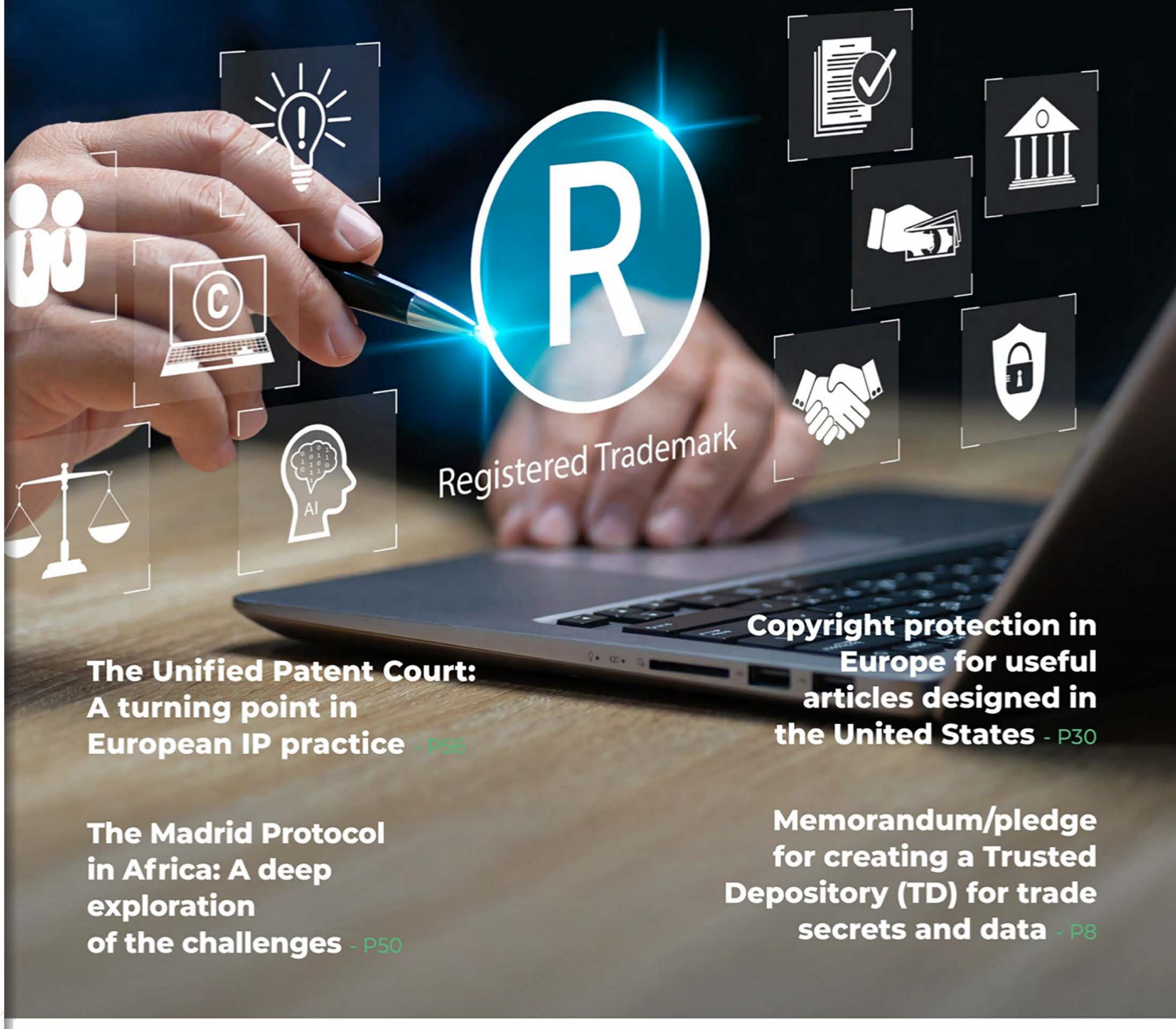

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IP DUE DILIGENCE IN THE PHARMACEUTICAL INDUSTRY:

EVALUATING HATCH-WAXMAN LITIGATION

By Yuval Marcus & Jordan Garner

Hatch-Waxman litigation plays a critical role in the pharmaceutical industry, creating a legal framework where brand-name drug manufacturers and generic companies navigate the complex interplay of intellectual property (IP) law and regulatory policies. For branded pharmaceutical companies, defending market exclusivity is vital, while generic manufacturers seek opportunities to challenge patents and introduce affordable alternatives. In this high-stakes environment, IP due diligence is essential for evaluating risks, protecting innovation, and guiding strategic decisions.

A critical component of IP due diligence is the evaluation of Orange Book-listed patents. The Orange Book, maintained by the FDA, lists patents that protect approved drugs. Generic manufacturers frequently challenge these patents through Paragraph IV certifications, asserting that they are invalid or will not be infringed. These challenges trigger Hatch-Waxman litigation, placing the burden on brand-name companies to either bring suit on their patents or forgo an automatic 30-month stay of approval of the generic product by the FDA. Careful analysis of the Orange Book listings can help companies anticipate challenges, assess the strength of their defense, and prepare for potential litigation.

At times, an acquisition or financing transaction can take place during the pendency of a Hatch-Waxman litigation. For example, a generic manufacturer may seek investment or acquisition to fund the launch of their generic product. Likewise, a branded company may seek investment, the value of which is predicated on anticipated revenues of a new drug product. Understanding the relevant exclusivity time frames and handicapping potential outcomes are important considerations during IP due diligence in this context.

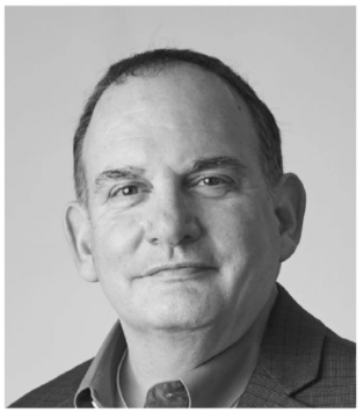
Whether prior to the institution of a Hatch-Waxman litigation or during, a critical component of IP diligence is an assessment of the patent strength of the Orange Book listed patents. Patent strength forms the foundation of IP due diligence in Hatch-Waxman litigation. Assessing a patent's validity and enforceability involves analysing the scope of its claims, the likelihood of infringement, and the likelihood that the patent will survive invalidation challenges. Patents with broad claims offer significant protection but are more vulnerable to validity disputes. In contrast, narrowly crafted patents may be easier to defend but can limit the range of covered innovations. Due diligence investigations may involve examining patent prosecution histories,

conducting a search of earlier patents and scientific literature, and analysing whether the descriptive portion of a patent is legally sufficient to support the claims. A detailed examination of prior art is often necessary to determine whether existing patents or scientific publications could undermine the novelty or non-obviousness of the claims. Furthermore, understanding patent expiration dates is crucial, as they define the period of exclusivity a company can rely on before generic competition arises.

Regulatory exclusivities, which operate independently of patents, also play a key role in Hatch-Waxman litigation. These exclusivities, granted by the FDA, provide additional protection for new drugs. New Chemical Entity (NCE) exclusivity, for example, offers a five-year period during which generics cannot file for approval. These regulatory protections often overlap with patents, creating a layered defense against generic competition. Effective IP due diligence requires mapping the interplay between patent life and regulatory exclusivities to identify potential vulnerabilities in a drug's market exclusivity.

Market factors also influence the value of intellectual property in Hatch-Waxman litigation. Understanding the competitive landscape, market dynamics, and pricing pressures helps companies prioritise which patents to defend vigorously. Additionally, litigation costs must be weighed against the financial benefits of maintaining exclusivity. In some cases, settlements with generic manufacturers, such as authorised generics or licensing agreements, may offer a more practical resolution.

Ultimately, understanding the nuances of Hatch-Waxman litigation is a cornerstone of effective IP due diligence in transactions involving pharmaceuticals. By thoroughly evaluating patent portfolios, regulatory protections, and market conditions, companies can mitigate risks, defend their innovations, and maintain a competitive edge. As the pharmaceutical industry continues to evolve, the ability to anticipate challenges and adapt strategies remains critical for long-term success.



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Yuval H. Marcus is the managing partner and the Co-Chair of the Litigation Practice Group at Leason Ellis. With more than 25 years litigating intellectual property disputes in federal courts throughout the country, he implements a practical, business-driven, results-oriented approach for his clients in all types of IP disputes, including patent, trademark, trade dress, copyright, and false advertising matters.

With a litigator's perspective, Yuval also conducts IP due diligence on behalf of investors and companies relating to investments and M&A transactions (totaling more than $1 billion), including in connection with life sciences and medical technology companies. Yuval helps buy-side clients evaluate and understand the IP litigation risks inherent in each investment or acquisition opportunity.

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Jordan conducts IP due diligence on behalf of investors and companies relating to investments, debt and alternative financing arrangements and M&A transactions (totaling more than $1 billion), including in connection with life sciences and medical technology companies. Utilizing his hands-on patent prosecution experience, Jordan enables clients to evaluate and understand the scope and strength of the patents and other IP assets that form the basis for the investment or acquisition opportunity.