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RAKOCZY MOLINO MAZZOCHI SIWIK LLP

PRIMARY SERVICES

FDA and Hatch-Waxman Counseling & Litigation

For years, pharmaceutical manufacturers have profited from changes in the law brought about by the 1984 amendments to the patent laws and the Federal Food, Drug, and Cosmetic Act (commonly known as the Hatch-Waxman Amendments, or "Hatch-Waxman"). The benefits of the Hatch-Waxman statutory compromise include, among others, patent term extensions; non-patent exclusivity periods for new drugs (NCE, new clinical investigation, pediatric and orphan drug exclusivities); expedited FDA approval of generic and branded drug products; and generic marketing exclusivity. The attorneys at **Rakoczy Molino Mazzochi Siwik LLP** have the experience and know-how to assist their clients in reaping such benefits, while overcoming the hurdles brought about by the rise in patent infringement litigation stemming from the submission of Abbreviated New Drug Applications ("ANDAs") and Section 505(b)(2) applications/paper NDAs.

Rakoczy Molino Mazzochi Siwik LLP is the place to turn for guidance about Hatch-Waxman and the FDA.

Advising Clients from Product Development to Commercial Marketing

Our lawyers are intimately familiar with the statutory and constantly changing regulatory guidelines set in place by Hatch-Waxman and the FDA that are crucial to the approval and market entry of any new drug. We advise our clients through the entire process of taking a drug product to market, whether a true generic pursuant to an ANDA or a new drug pursuant to a Section 505(b)(2) application, including: counseling our clients on potential opportunities and market strategies for generic and new drug products; counseling our clients on design-around and patentability opportunities; providing opinions of counsel on patent noninfringement or invalidity; assisting with the filing and submission of ANDAs or Section 505(b)(2) applications, patent certifications, and notice letters; prosecuting and defending patent infringement lawsuits; and protecting our clients' approval and exclusivity interests before the FDA.

Our lawyers are registered to practice before the U.S. Patent and Trademark Office. They have technical skills, clinical research and engineering experience, and understanding of analytical techniques in a variety of fields, including: pharmaceuticals; organic, inorganic, and industrial chemistry; biochemistry; biotechnology; and genetics. This "real world" experience enables us to assist with virtually any legal issue surrounding our clients' product development without losing sight of the science behind the product.

The firm's guidance includes counseling on all aspects of the design, development, patenting, approval, exclusivity, and market entry of new and generic drugs:

- Counseling clients on FDA regulatory issues and broad strategies for development and market authorization of new (Section 505(b)(2)) and

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generic (ANDA) drugs

- Reviewing U.S. and foreign patents, applications and related file histories directed at our clients' proposed drug products, preparations, or methods of use, and counseling clients on potential design-around opportunities
- Conducting targeted prior art searches to locate related art and counseling clients on potential invalidity challenges
- Advising our clients on freedom to operate and providing independent opinions of counsel on patent validity and infringement
- Providing individualized strategies for preparing and filing an ANDA or Section 505(b)(2) application in light of possible regulatory exclusivities and patent hurdles
- Drafting, preparing or reviewing all documents necessary to obtain approval of and exclusivity for new and generic drugs, together with providing legal strategy for the various approval pathways
- Counseling our clients on the bioequivalence studies or clinical trials necessary to support FDA approvals
- Reviewing labeling to ensure it meets regulatory requirements and counseling our clients on various carve-out, promotion, and "off-label" use issues
- Resolution of complications arising during FDA application review
- Providing unparalleled expertise and guidance on the FDA's Orange Book and preparing appropriate patent certifications and notice letters
- Assisting with all aspects of ANDA or Section 505(b)(2) application preparation and submission
- Monitoring patent issuances and publication of patent applications at the PTO, FDA listings of new Orange Book patents, paragraph IV certifications filed by other generic drug manufacturers, and related pending litigation that might affect our clients' interests
- Enforcing and defending our clients' interests in high-stakes Hatch-Waxman patent litigation
- Representing and advocating our clients' interests before the FDA and, if necessary, litigating approval and exclusivity issues against the agency.

The preeminent interest of any pharmaceutical manufacturer is to secure, protect and maintain market entry. The attorneys at **Rakoczy Molino Mazzochi Siwik LLP** are uniquely poised to assist their clients in negotiating the minefield of Hatch-Waxman statutory, regulatory and litigation hurdles to secure ultimate freedom to operate in the marketplace.

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