Hogan Lovells

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Patent and exclusivity rights continue to demand global attention through the FDA various requirements and recent EMEA guidance documents.

Hogan Lovells attorneys can advise you on all aspects of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Hatch/Waxman Act, and guide you on patent submissions and listings under the FDA's June 2003 rules and new Form FDA 3542. We then work closely with you to obtain all appropriate patent term extensions and non-patent statutory exclusivity periods.

We can also advise you on pediatric testing requirements and pediatric marketing exclusivity provisions, as well as the complex marketing exclusivity provisions in U.S. and EU orphan drug legislation. We can then thoroughly assist in managing your patent and exclusivity rights to secure the maximum authorized life cycle protection.

Additionally, when pioneer companies need to assess the legal and scientific validity of possible generic versions of a pioneer product, we ensure that they are able to participate in the generic drug approval process and raise meritorious objections to potential generic products in a timely manner.

With many of these issues arising in Europe, we counsel pioneer companies on the impact of innovator rights of the 2004 EU Pharmaceutical Review Legislation and the effect of recent EMEA guidance documents on comparability of various forms of "biogenerics," European Court of Justice

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Practices

Pharmaceuticals and Biotechnology Regulatory

jurisprudence (the "generics cases"), relevant European Pharmacopoeia monograph activities, and opportunities and threats posed by parallel trade cases such as Bayer Adalat and Kohlpharma.

Representative experience

Submitted landmark citizen petitions to the FDA on bioequivalence standards for narrow therapeutic range drugs under sections 505(b)(2) and 505(j) of the Food, Drug, and Cosmetic Act.

Developed a strategy and drafted the necessary FDA documents for a protocol that our client, who sought “pediatric exclusivity” of a complex and toxic drug product, could complete within the statutory timeframe.

Counseled a client on the FDA orphan drug standard for "clinical superiority," allowing the same drug to go to market during another drug’s seven-year marketing exclusivity period.

Conduct due diligence for the likely outcome under the standards in EU orphan medicinal products law.

Interpreted Bolar laws, in result of the EU vs. Canada World Trade Organization (WTO) case.

Wrote policy papers and presentations on U.S. and WTO law in the area of regulatory data exclusivity to officials in Latin American and Asian countries on behalf of a major trade association and officials.

Helped persuade the Mexican government to stop approving generic products that infringe patents and/or exclusivity periods.

Latest thinking and events

News

Comment period ending for proposal to automatically sunset HHS/FDA/CMS regulations

News

Protecting biomedical innovation as a national security asset

News

FDA issues list of essential medicines and countermeasures required under Buy American Executive Order

News

Labeling carve-out does not shield generic drug makers from induced infringement claims, CAFC rules

News

UK post-Brexit regulation of medicines from 1 January 2021

Insights

The CRA: Schumer-led Senate Could Overturn Trump Deregulatory Legacy