Buchanan
Ingersoll·Rooney

Buchanan's Drug Target Analysis for Brand Name Drugs

Developing a Strategy for Patent Expiration

Impending patent or market exclusivity expiration for a brand name drug creates many questions and considerations for manufacturers before generics hit the market. What does the timing of generic competition look like? How will my sales be impacted by new competition? Is there anything that I can do to protect my drug product now? Your strategy depends on proactive measures as much as it does on reactive decisions.

Buchanan's Drug Target Analysis Includes both Intellectual Property + FDA Perspectives

Creating a customized Drug Target Analysis requires a strong combination of both Intellectual Property (IP) and Food and Drug Administration (FDA) knowledge. Our firm is unique in that we have deep bench strength in both practices, with attorneys who collaborate for our Life Sciences clients on a daily basis. This rare combination allows for a comprehensive work product without the time and cost of obtaining analyses from two boutique firms.

We have helped drug companies:

- Assess and identify gaps in drug product patent portfolios
- Manage expiring patents by taking advantage of drug product changes that can be patented, and obtain FDA approvals for those changes
- Manage expiring regulatory exclusivity by considering new product uses that can receive additional exclusivity protection
- Defend patents in Hatch-Waxman litigation
- Think "outside the box" about complementary strategies, including strategic drug product acquisition and identification of foreign market products for introduction into the U.S.

Our Comprehensive Solution

Assessing the options companies have available to them when facing impending generic drug competition involves complex and time-consuming research and analysis. With our Drug Target Analysis, we do the heavy lifting for you, layering in our extensive IP and FDA knowledge to map out the legal, regulatory and business landscape. Our detailed report helps you address barriers and maximize opportunities for continued product protection, successful new drug applications, product acquisitions, and/or market launches and re-launches.

With our Drug Target Analysis, you get:

- A Deep-Dive Analysis that includes:
  - A situational overview of the post-patent landscape
  - A competitive analysis of the generic market and where vulnerabilities may lie
  - A comprehensive breakdown of FDA regulatory barriers and opportunities, including exclusivity or bioequivalence requirements
  - A summary of clinical trials being conducted that suggest activity within the drug's product category
  - A patent review of Orange Book-listed patents (or an entire patent portfolio), including patents filed and any ongoing patent litigation
  - Mapping various market entry scenarios for generics, including potential timing
- An easy-to-digest Executive Summary of our review
- A final customized Drug Target Analysis Report based on your company's needs – a unique offering that combines all of our insights and analysis and is directed to your goals.
- And, if you choose to move forward, we can assist with all aspects of the post-patent and NDA process, patent prosecution and litigation, and due diligence.

Our Work in Action

Working with a company looking to acquire branded products, we helped our client assess remaining patent and exclusivity life and identified companies with interest in the particular product space. We assessed patents for their vulnerability to legal challenge, addressing the most and least likely scenarios to generic market entry. We delivered an analysis on each product that allowed the client to make strategic recommendations to management about continued product viability and new protection strategies.

The Buchanan Advantage

To conduct a customized analysis of this depth and acuity requires a strong, seamless blend of IP and FDA prowess. Our patent and FDA lawyers collaborate on a daily basis, working together to serve clients under our multi-practice Life Sciences umbrella.

Our dedicated FDA practice understands both the business and the science of developing and marketing FDA-regulated products. Our relationships and experience working with the FDA can be paramount to a drug company's success. Few firms can match the level of knowledge, scientific understanding and FDA experience we offer, including having a team member who was the former FDA associate chief legal counsel. In addition, we have appeared before most of FDA's drug-reviewing divisions within the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). Our Life Sciences IP team has extensive experience in patent-portfolio development, strategic patent prosecution and patent litigation, as well as counseling clients on potential FDA implications. Our team includes pharmaceutical patent lawyers who have worked at the United States Patent and Trademark Office (USPTO), as well as individuals who have worked within FDA's Office of Generic Drugs.

Looking for your own Drug Target Analysis? We're Here to Help.

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