Buchanan
Ingersoll·Rooney

Buchanan's Drug Target Analysis for Generic Drugs

Helping Your Strategy Hit the Mark

In the Generic Drug Marketplace, product strategy is the name of the game. You need a strategy that is informed, proactive, competitive and nuanced based on informed insight. Whether patent expiration is opening the door to generic drug competition or you are thinking of acquiring generic products for your portfolio, your company needs to invest in a sound strategy before spending its business development dollars.

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

Building 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 generic drug companies:

- Research, analyze and create customized drug-acquisition strategies
- Investigate and take action on drug shortages
- Identify foreign-market products for introduction into the U.S.
- Develop an approval and marketing roadmap that includes timing of generic drug approval, IP litigation strategies, and possible barriers to market entry

Our Comprehensive Solution

Assessing the generic drug market landscape involves nuanced, 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 successful product development, acquisition and/or market launch.

With our Drug Target Analysis, you get:

- A Deep-Dive Analysis that includes:
  - An overview of the drug, its uses and history
  - A summary of clinical trials being conducted that suggest activity within that 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
  - A comprehensive breakdown of FDA-regulatory barriers and opportunities, including exclusivity or bioequivalence requirements
  - A competitive analysis to determine who else might be interested in the drug
  - Mapping various market-entry scenarios and 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 that is directed to your goals.
- And, if you choose to move forward, we can assist with all aspects of the generic drug approval process, patent prosecution and litigation, and due diligence.

Our Work in Action

Working with a generic drug company, we helped our client assess the remaining patent and exclusivity life on numerous products that it was considering pursuing for generic development. Some products were drug/device combinations that raised specific and unique questions about the pathway to generic entry. We delivered an analysis on each product that included a discussion of the most likely scenarios and timing to generic product market entry. We briefed our client on each product, allowing them to make strategic recommendations about future development activities to the board of directors.

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 a former FDA associate chief legal counsel. In addition, we have appeared before most of FDA's drug review 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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