

Launch-at-Risk Analysis

Intensity worked with a generic pharmaceutical company to evaluate potential risks and rewards in an “at-risk” generic drug launch. Intensity’s complex, scenario-based modeling provided key insights and drove economically informed decision making.

Summary

A generic pharmaceutical company hired Intensity to evaluate a potential “at-risk” generic drug launch. An at-risk generic drug launch occurs when a company introduces a generic drug product while litigation contesting validity and infringement of patents is still ongoing. Evaluating the economic benefits of near-term profits against the risks of potential economic damages down the line can be complex and requires experience, expertise, and strong economic analysis. Intensity was hired to model the generic launch and help the company evaluate potential risk and rewards in making a sound decision.

Intensity delivered a highly customized and parameterized model forecasting the generic launch dynamics, including evaluation of multiple generic entrants, authorized generics, expected price deflation, generic take-over, and a variety of other economic factors. Intensity provided guidance in evaluating the trade-offs faced by the generic supplier under a variety of scenarios and offered advice on risk-mitigation strategies designed to increase potential profits while reducing exposure. Ultimately, the pharmaceutical company client utilized Intensity’s models to present the risk and potential rewards to its board of directors in making an economically informed decision on the launch.

Potential Lost Profit and Generic Profit

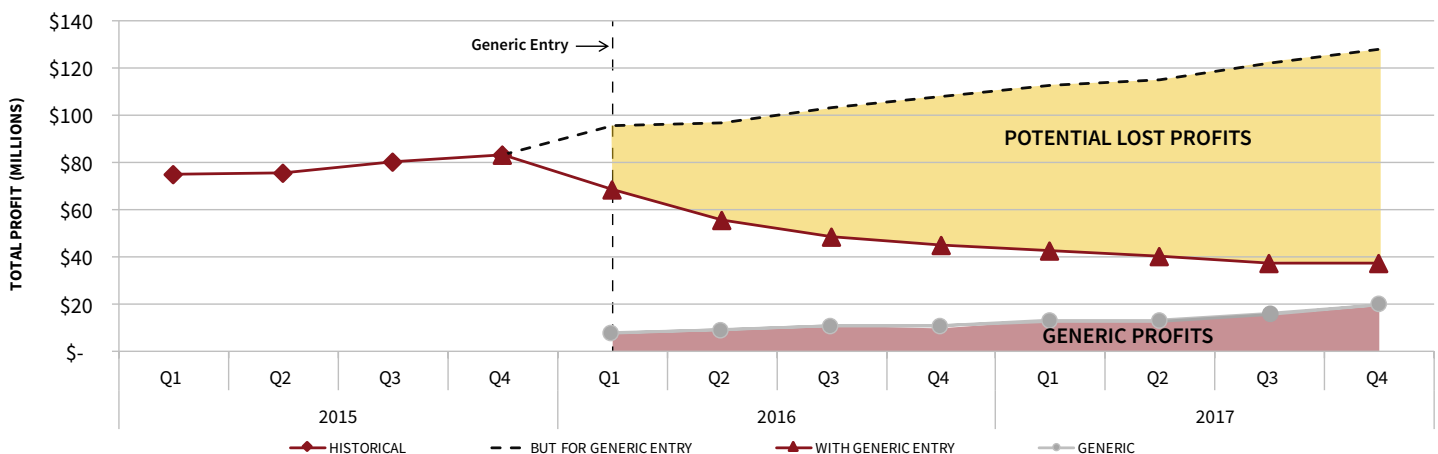


Figure 1 Potential economic damages owed to a patent holder can be multiples of actual revenues and profit earned by an infringing generic supplier. For example, if a generic earns profits of \$30 per prescription while the branded drug earns \$60 per prescription, potential exposure could be \$2 for every \$1 earned.

The Challenge

A decision to launch a generic drug at risk can be highly profitable, resulting in millions of dollars in potential revenue and profit. However, it also carries significant risk; an adverse court decision following a launch can easily wipe out millions of earned revenues and even represent exposure that are multiples of revenues earned. Evaluating the dynamics of the launch and the choices made in bringing a generic product to market frequently requires complex and nuanced understanding of pharmaceutical market dynamics and potential for economic damages. Intensity was hired to help the generic supplier navigate the potential risks and rewards in pursuing a generic launch under various scenarios.

Our Analysis

Intensity modeled generic entry and potential damages under a variety of scenarios that included varying number of generic suppliers, whether or not an authorized generic was launched, whether or not demand increased as a result of lower generic prices, and a variety of other factors. Key elements of the model included:

- Projections of quarterly units, prices, sales, and profits with and without generic entry;
- Flexible model parameterization including the degree of generic price deflation, time-varying generic take-over, the number of generic entrants, and other factors;
- Evaluation of risk-reward under a number of customized scenarios;
- Analysis of the impact of risk-mitigation strategies.

Projected Units Post-Generic Entry

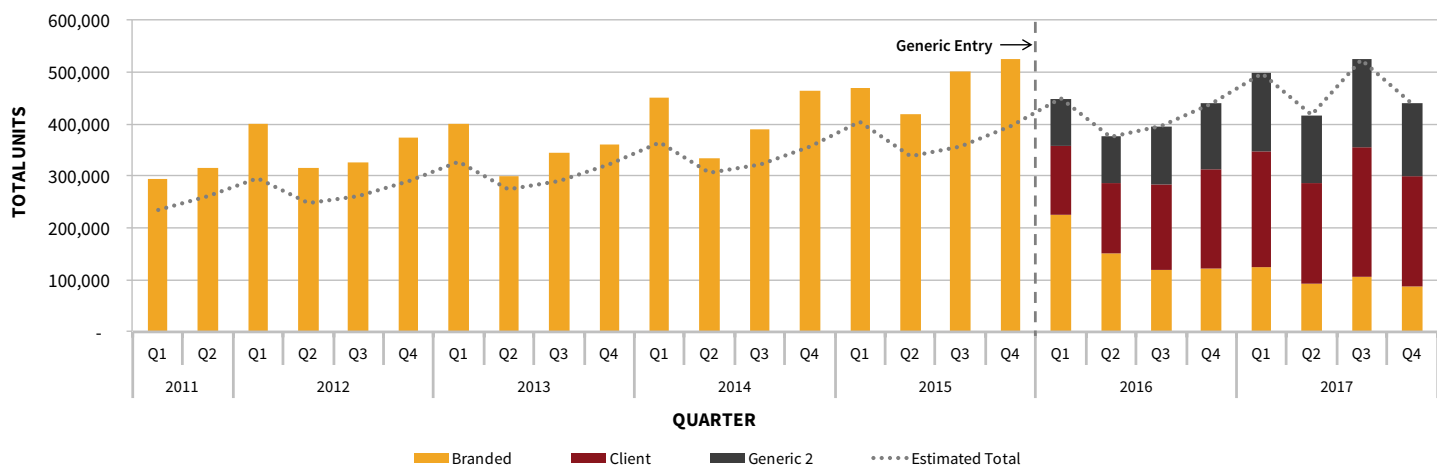


Figure 2 Projecting market dynamics based on branded generic units headed into generic entry, anticipated generic takeover, and number of competitors. Proper forecasting and evaluation of market dynamics requires unique evaluation and consideration of case-specific facts and economic circumstances.

Our Recommendations

Intensity provided evaluation of potential risk and reward under a variety of economic scenarios. We provided a detailed analysis and parameterized economic model to the client for its own evaluations. Economic benefits and potential costs were presented to the company's board of directors and evaluated based on probabilistic outcomes of success. Intensity further provided concrete guidance on risk-mitigation strategies related to generic pricing and take-over. We provided a flexible economic model that allowed the client to understand the market dynamics and utilize insights in its own analysis going forward.

Conclusion

Intensity offered economic insight and transparent evaluation of likely outcomes from a potential at-risk generic drug launch. Those insights and evaluations were used as direct inputs into the generic launch decision. These insights, coupled with Intensity's recommended risk-mitigation strategies, provided the client with the tools and ability to make an informed launch decision to maximize the trade-off between potential revenue gains and potential risk exposure from economic damages.

All figures described herein are for illustrative purposes only and have been altered to maintain client confidentiality.

About Intensity

Intensity generates excellence through powerful research, analysis, and expertise to solve the most complex challenges in the marketplace and courtroom. We consistently deliver reliable results that are built upon meticulous research, intense scrutiny, and scientific analysis.

Please contact us any time!

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