CRA Insights: Life Sciences

CRA Charles River Associates

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Quantifying damages in life sciences cases

Competition inquiries, intellectual property disputes, and arbitration of commercial contracts all may require a quantification of damages. Assessing the potential harm often appears complex, although it need not be so. However, it is vital to avoid using 'standard' or 'canned' techniques that do not take into account the fundamental characteristics of the life sciences industry as a whole and the therapeutic category in particular. Our experience, gathered during the past 15 years working in global litigation and arbitration in the life sciences industry, suggests there are three key considerations:

- Grounding analysis in the context of the life sciences industry,
- Accounting for the regulatory context and its effect on business activities and
- Creating assessments that are consistent with commercial objectives and needs.

Here we review common situations that illustrate the importance of these considerations.

Creating a counterfactual scenario

Assessing potential harm often requires an explanation of how a marketplace would look if the behaviour at issue had not occurred. This 'counterfactual world' might include a marketplace that did not actually exist or has yet to come into existence. With the development of products and therapeutic classes occurring over decades in the life sciences industry, the counterfactual might require anticipation of changes over a long period of time.

For example, CRA had to consider a situation in which a company alleged that the failure of its business partner squandered the opportunity to launch a new innovative therapy. Our damages assessment required considering how the therapy would have performed commercially and how payors and competitors would have reacted to it. Our approach to this problem involved:

- Examining the commercial performance of other new products launched in the same category,
- Considering regulatory hurdles to determine the timing of the product's launch and any likely constraints imposed by marketing approval,
- Analysing the experience of the analogous situations in the country for pricing and competitor response,
- Evaluating information on the expected new or generic entry into the category and how that might change had the innovative product arrived as expected,
- Accounting for the additional costs and opportunities that would have arisen from supporting a new innovative therapy and
- Anticipating how a new therapy would affect physician practice and treatment patterns.

The impact of regulation in a mature marketplace

Assessing potential harm might instead require anticipating the development of an existing market. However, even in established pharmaceutical marketplaces, regulation and innovation create dynamic changes that need to be considered in the counterfactual. Recent examples have often involved projecting the impact of losing market exclusivity in different markets through entry of innovative or generic

alternatives. Although tempting to focus on a small number of 'close' analogue products, these situations benefited from our analysis of:

- The anticipated speed of entry for a particular therapeutic category,
- Regulatory decisions (such as forming reference price groups),
- The anticipated impact of entry on prices and market shares,
- Estimation of overall impact on sales, allowing for seasonality and
- Incorporation of regulatory price reductions into the commercial opportunities.

The life sciences industry is characterised by regular entry of new products, generics and frequent changes to the regulatory structures or pricing decisions. With such upheaval, disentangling the repercussions of particular events can prove challenging but is necessary for accurate assessment of harm.

Allowing for commercial realities

Although highly regulated, anticipating how commercial decisions would change in the counterfactual scenario is an essential component of assessing potential harm. The counterfactual needs to be consistent with decisions in the real world, economic logic and—above all—common sense. CRA has successfully challenged scenarios that failed to meet these conditions. Some examples of short-sighted damages approaches include:

- Failing to account for reduced promotional activity that would result from reduced sales,
- Assuming a price that was higher than any existing prices for a therapy while also assuming that neither payor activity nor competitive entry would lead to reduced prices or that parallel importers would not affect distribution,
- Suggesting that there would be no meaningful change in physician practice patterns, patient preferences or therapeutic options over several decades and
- Assuming prices that would be unprofitable for distributors or others in the distribution chain.

Conclusion

Assessing potential harm requires a comprehensive knowledge of how the relevant life sciences marketplaces function. Innovator and generic companies compete in therapeutic areas based on the business opportunities and regulatory systems. Understanding the commercial motivation guiding companies—both in what led to disputes and what would need to be present in a sensible counterfactual—ensures that the assessment of harm is reasonable and defensible and provides a real, recognizable underpinning to assessments of harm.

About CRA and the Life Sciences Practice

CRA is a leading global consulting firm that offers business, financial and economic consulting services to industry, government and financial clients. Maximizing product value and corporate performance, CRA consultants combine knowledge and experience with state-of-the-art analytical tools and methodologies tailored to client-specific needs. Founded in 1965, CRA now has offices throughout the world. The Life Sciences Practice works with leading biotech, medical device and pharmaceutical companies; law firms; regulatory agencies; and national and international industry associations. We provide the analytical expertise and industry experience needed to address the industry's toughest issues. We have a reputation for rigorous and innovative analysis, careful attention to detail and the ability to work effectively as part of a wider team of advisers.

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