

At A Glance

Intellectual Property Damages in the Life Sciences Industry

Overview

Pharmaceutical IP litigation takes many forms, for both small molecules and biologic products:

- The manufacturer of a brand-name pharmaceutical product may file a claim against a generic manufacturer for infringement of its intellectual property.
- A generic may challenge the validity of a brand's patent.
- A brand manufacturer may file a preliminary injunction against the generic, claiming that it will be irreparably harmed by generic entry.
- A former employee may allegedly misuse trade secrets to develop and market a pharmaceutical active ingredient.

Experts in NERA's Life Sciences Practice have been analyzing issues related to the infringement or misappropriation of intellectual property for decades, assisting companies with projects related to:

- Commercial Success
- Irreparable Harm
- Lost Profits Calculations
- Reasonable Royalty Calculations

NERA's experts provide in-depth knowledge of the economic complexities of the prescription pharmaceutical industry as well as experience in the required disciplines—including analyzing market-wide data using economic and econometric models—to address complex problems that arise in assessing nexus, causality, and calculating damages for pharmaceutical products.

This expertise includes:

- An understanding of how prescription drug formularies affect sales
- Experience working with large, third-party pharmaceutical datasets to project shares and responses to changes (such as entry and/or exit of a generic competitor)
- Experience quantifying lost profits and reasonable royalty damages

Key Areas of Expertise

The Role of Institutional Structures in Prescription Drug Markets

NERA has conducted analyses of prescription drugs—both small molecule and biologic products—for decades and has developed a deep understanding of the regulatory structures surrounding the development, marketing, and



sale of prescription drugs. This understanding extends to the unique relationship between doctors, patients, and payors, and the role of drug formularies, Medicare, and Medicaid in drug pricing and availability.

Through NERA's experience with prescription drug markets, our experts are able to demonstrate a deep knowledge of how these entities interact with each other and the roles they play in consumer choice, as well as the relationship they have with profitability, success, and competition among and across drug classes and individual products.

Evaluating the Commercial Success of a Patent

In the context of litigation in district court and in inter partes review, the question of patent validity is determined, in part, based on whether the patented invention would have been obvious to a person of normal skill in the art. NERA experts have extensive experience analyzing the relationship between the patented feature and the commercial success of a product (or products) used by courts to assess non-obviousness. For example, NERA experts routinely conduct analyses of the commercial success of pharmaceutical products and assess the existence (or absence) of a nexus to the claimed invention.

Assessing Whether Generic Entry Will Lead to Irreparable Harm

In cases where there are allegations of infringement or misuse of intellectual property, the owner of the intellectual property may file a preliminary injunction motion, enjoining the alleged infringer from entering or continuing to market its product. The success of such a motion depends critically on whether the owner of the intellectual property would be irreparably harmed by the infringement.

NERA's experts have extensive experience assessing the likelihood of irreparable harm in the life sciences, including in the pharmaceutical industry. These analyses focus on assessing the likely extent of harm from the allegedly infringing product, the ability to accurately evaluate the harm, and the extent to which the harm may or may not persist into the future.

Calculating Damages

NERA's experts have experience calculating both lost profits and reasonable royalty damages in litigation involving infringement of intellectual property, with expertise in pharmaceuticals, medical devices, and biotechnology. NERA's expertise also extends beyond the United States; NERA's experts have conducted lost profits and reasonable royalty damages calculations in Canada, the UK, and Europe.

About NERA

NERA Economic Consulting (www.nera.com) is a global firm of experts dedicated to applying economic, finance, and quantitative principles to complex business and legal challenges. For over half a century, NERA's economists have been creating strategies, studies, reports, expert testimony, and policy recommendations for government authorities and the world's leading law firms and corporations. We bring academic rigor, objectivity, and real world industry experience to bear on issues arising from competition, regulation, public policy, strategy, finance, and litigation.

NERA's clients value our ability to apply and communicate state-of-the-art approaches clearly and convincingly, our commitment to deliver unbiased findings, and our reputation for quality and independence. Our clients rely on the integrity and skills of our unparalleled team of economists and other experts backed by the resources and reliability of one of the world's largest economic consultancies. With its main office in New York City, NERA serves clients from more than 25 offices across North America, Europe, and Asia Pacific.

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