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.

**Contacts**

**Dr. David Blackburn**
Director
Washington, DC: +1 202 466 9264
david.blackburn@nera.com

**Dr. Stephanie Demperio**
Senior Consultant
White Plains, NY: +1 914 448 4153
stephanie.demperio@nera.com