

At A Glance

Life Sciences Biologics and Biosimilars

Overview

The 2009 passage of the Biologics Price Competition and Innovation Act (BPCIA) laid the groundwork for biosimilars to be approved using a shortened pathway to approval. Since the first approval of a biosimilar in 2015, the rate of FDA biosimilar approvals and the introduction of new products in the United States has increased rapidly. The impact of biosimilars on the evolving biologics market was enhanced by the FDA's 2019 release of guidelines on interchangeability. These guidelines have provided a pathway to allow biosimilars to be substituted for reference products without the involvement of the prescriber.

NERA's experts have experience analyzing issues related to biologics, including:

- Calculating lost profits and reasonable royalties for alleged infringement of patent rights
- Identifying irreparable harm to IP owners and balancing public interest
- Analyzing pricing
- Assessing competitive effects in potential mergers and acquisitions
- Determining harm from trademark infringement

Experts in NERA's Life Sciences Practice have extensive knowledge of the pharmaceutical industry and the nuances and complexities involved in the economics of the field, including determining the value of patents and other intellectual property, navigating complex litigation such as alleged reverse payment settlements, assessing commercial success, and calculating damages from lost profits and reasonable royalties.

Key Areas of Expertise

Calculating Damages

NERA's experts have experience calculating lost profits and reasonable royalty damages in litigation involving infringement of intellectual property, with expertise in many life sciences areas, including biologics and biosimilars. NERA was involved in the first BPCIA litigation, *Amgen v. Sandoz*. That case resulted from the introduction of the first FDA-approved biosimilar, a biologic that was directed to Amgen's Neupogen and

Neulasta blockbuster anti-infection products. NERA's expert opined on the appropriate monetary and injunctive remedies for the alleged infringement of Amgen patents involved in the recombinant DNA manufacturing process. NERA also assisted in determining appropriate remedies as a result of an alleged contract breach resulting in purported delays in research, development, and approval of a monoclonal antibody.

Irreparable Harm and Public Interest

NERA economists worked with a biosimilar manufacturer to analyze and understand the likely impacts of the introduction of a biosimilar product on pricing and sales of the reference product biologic and other treatments. NERA's work helped lead to a settlement, the result of which will enable the biosimilar product to launch in the United States prior to the end of the reference product's patent life.

Analyzing Pricing

The pricing of biologics and biosimilars is not straightforward. NERA's experts understand the potentially elevated costs associated with developing and manufacturing biosimilar products and related regulatory hurdles that affect the ability to price biosimilars with discounts similar to generic drugs. There are many complicating factors, including the different reimbursement structures connected with medical benefits for biosimilars, as well as multi-firm IP licensing, manufacturing, and marketing. In one pricing case, NERA was retained in an international arbitration to estimate the appropriate supply price for a biologic used to treat various inflammatory diseases. The arbitration tribunal issued a ruling in favor of NERA's client. In another matter involving biologic product pricing, a NERA team was retained by the Canadian pharmaceutical pricing regulator, the Patented Medicine Prices Review Board (PMPRB), to assess whether the pricing of a particular biologic product had been excessive. NERA's analysis and testimony were used in the PMPRB's fact-finding and adjudication of the question.

Assessing Competitive Effects in Potential Mergers & Acquisitions

NERA economists have extensive experience in all phases of merger and joint venture analysis. Our experts provide thorough economic analysis of market definition, competitive effects, entry, and efficiencies. For example, NERA assisted Merck in achieving antitrust clearance of its acquisition of Avecia Biologics (from the UK), assessing the transaction's competitive effects in the supply of process development, scale-up, and contract manufacturing services for biologics and the supply of innovator and follow-on biologics.

Trademark Infringement Analyses

Branding can be an important element of pharmaceutical marketing, and trademark infringement can be a significant area of dispute. Unlike many small-molecule generics, biosimilars often have their own branding apart from the reference drug. NERA economists have extensive experience in trademark infringement cases, including the evaluation of potential and actual trademark confusion by market participants. For example, in a trademark dispute between two pharmaceutical companies, NERA experts were called upon to respond to survey evidence allegedly demonstrating confusion by market participants and supported multiple industry experts offering testimony regarding the likelihood of confusion among market participants.

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. 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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