

*Innovation in a Science-Based Sector: The Institutional Evolution behind China's Emerging Biopharmaceutical Innovation Boom**

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Abstract

Biologics are one of the fastest growing fields in the biomedical industry. Producing these innovative drugs has proven both technologically and politically challenging, however. Traditional strategies of technological catch-up employed by East Asian countries have remained remarkably ineffective at catalyzing their biotechnological development. Consequently, biopharmaceutical innovation has historically been concentrated in the hands of a few developed countries. After decades of stagnation, China's biopharmaceutical industry began experiencing marked growth in the 2010s. This article analyzes the institutional evolution of China's biopharmaceutical industry from the early market reform era to 2020 to explain the roots of China's surge in biological innovation. Specifically, we argue that biopharmaceutical innovation is highly dependent not only on scientific capacity and the existence of academia-industry ties, but also on the presence of regulatory regimes

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that are harmonized with global standards and capable of incentivizing innovation while protecting patients' needs. Consequently, our findings contrast with the previous research drawing on India's experience to argue that intellectual property regime harmonization damages domestic innovation capacity. Ultimately, this study suggests that biopharmaceuticals may present a unique window of opportunity for latecomers to biotechnology and offers lessons on fostering science-based high-tech innovation for developing countries.

Biologics, also referred to as biopharmaceuticals, are drugs based on large, complex molecules composed of proteins, nucleic acids, and/or living biological materials. Produced through complicated biomanufacturing processes and used in gene therapies, immunotherapies, and various other cutting-edge medical interventions, they constitute one of the fastest growing fields within the biomedical industry. Chinese companies are increasingly competitive and innovative in this field. Not only are Chinese biopharmaceutical companies increasing in number and creating new drugs for China's domestic markets, they are also quickly becoming global players with innovative products. In 2018, for instance, the Chinese drug regulatory authority approved 48 new drugs, the highest number in 20 years. Nine of these were globally novel molecular entities developed by Chinese companies.¹ Drugs created by Chinese companies are also increasingly garnering U.S. Food and Drug Administration (FDA) approval and being out licensed by established global leaders in the pharmaceutical industry. Such advances are surprising considering that until the 2010, Chinese pharmaceutical companies made minimal investments in research and development (R&D) and were largely focused on producing off-patent generic drugs exclusively for the Chinese market. Even when compared to other developing countries like India, China was long regarded as a laggard in pharmaceutical innovation. How, then, did China jumpstart its biopharmaceutical industry? From where does China's innovative capacity stem, and what lessons can we draw from China's experience for science-driven sectors in the developing world?

In his "New Structural Economics," Justin Yifu Lin argues that dynamic factor endowments such as natural resources, capital, and labor define the developmental stage—and thus industrial structure—of different nations.² Different industrial structures require corresponding forms of hard infrastructure—such as electric power and road networks—and soft