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A REVIEW OF LEGAL FINANCE

The biopharmaceutical industry's Covid-influenced evolution

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2020 was a transformative year for all businesses, but pharmaceutical companies in particular were challenged to innovate, collaborate and generate results directly connected to solving a public health crisis.

From the outset, it was clear that the industry's response to the Covid-19 pandemic would define pharmaceutical companies' perceived efficiency, efficacy and ethics. Many biotech and pharmaceutical companies moved quickly toward a singular goal—perhaps signaling a broader shift in how the industry is thinking about the allocation of resources for new investments and development. The pandemic mobilized many companies into new and expanded research and development (R&D), with valuable results including multiple therapeutic solutions and breakthrough technologies for the future.

Below we explore how this change has led to a reevaluation of investment in R&D, an increased interest in parallel therapies and an evolution in how companies manage associated legal risks. It was encouraging to see large and small pharmaceutical companies alike aim to solve a common and global problem in response to Covid-19. In the pharmaceutical industry there is a long tradition of companies carving out market niches for their products, which are rigorously protected by patents and intellectual property rights. Market exclusivities and high prices tend to be justified by the massive expense of R&D and high rates of failure at early and clinical development stages for these products.

R&D for Covid therapies and vaccines prompted notable collaboration.

Companies like Pfizer and BioNTech worked collaboratively to develop effective therapies and vaccines for Covid-19.[1] Failure by one company even led to collaboration with a competitor: After Merck discontinued development of its own vaccine candidate it teamed up with Johnson & Johnson to ramp up production of theirs.[2]

The rousing success of many pharmaceutical companies' parallel efforts may be a spark that ignites further interest in biosimilars and parallel therapies. But while it is promising to see companies' parallel efforts, litigation over patents and market share remains inevitable between competitors and copycats alike. The industry's successful collaboration to solve a global pandemic will have lasting benefits for the world, but a return to competition is inevitable.

> **"By preemptively securing finance for litigation, companies can redirect funds that would otherwise have been set aside for litigation costs to the early stages of product development."**

PARALLEL THERAPIES ARE ON THE RISE

In the 11 years since the Biosimilars Price Competition and Innovation Act (BPCIA) was enacted, the United States has seen the 29th biosimilar approved by FDA[3] and the 20th biosimilar product commercially launched.[4] This is an impressive start, even though there currently are no interchangeable biosimilars on the market. While we are still in the early phases of observing market trends in the US (the first biosimilar product approved in Europe predates the first US biosimilar product by about a decade), the legal environment of biosimilars has only become larger and more complex.

As the biosimilar industry continues to grow and companies compete for market share, we will inevitably see an uptick in patent litigation. According to Bloomberg, manufacturing and formulation patents, which protect all aspects of the manufacture of biologics, continue to play a central role in biosimilar litigation, as biosimilar makers obtain patents to protect their products and gain a competitive edge.[5]

BIOPHARMACEUTICAL COMPANIES ARE REEVALUATING BUSINESS OPPORTUNITIES

There is a widely held perception that innovative pharmaceutical companies survive and thrive by reinvesting profits from existing drug sales back in R&D pipelines to fuel new discoveries for the next generation of medicine. In 2020, we saw more companies looking beyond existing product sales and critically assessing where future funds could come from, how their funds are being spent and their risk tolerance for new investments.

Thank you for your interest in Burford.

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