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Buying the Future: How Patent Cliffs are Driving Biotech

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Introduction
In the next four to five years, the pharmaceutical industry is at risk of losing $200 to $400 billion in revenue. Nearly 200 drugs, including Merck's Keytruda and Bristol Myers Squibb and Pfizer's Eliquis, will lose exclusivity, leading to the rapid entrance of generics and biosimilars into the market. This is known as the patent cliff, a key driver of biopharma strategy. To offset the loss of revenue associated with the patent cliff, Big Pharma turns to the biotechnology sector, where innovative therapies can replenish pipelines and provide new periods of exclusivity and commercial growth [1].

The need to look externally for innovation is rooted in the economics of drug development itself. Bringing a new therapy to market is an expensive, multi-stage process that often takes more than a decade to complete [2]. Furthermore, each stage carries a great risk with a very low probability of success. Only one or two out of every 10,000 compounds discovered in the lab reach the market despite a 10 to 15 year research and development (R&D) process that costs up to $1 to $2 billion [3,4].

Patents and regulatory exclusivities are provided to allow companies to recover from these costs. In the United States, patents last 20 years from the date of filing, which occurs early in a drug's development, meaning much of a drug's exclusivity is consumed during the long clinical development process before it even reaches patients. However, upon U.S. Food and Drug Administration approval, biologics receive 12 years of exclusivity, rare disease drugs receive seven years, and medicines with previously unapproved active moieties receive five years. Some drugs have both patent and exclusivity protection, while others have just one or neither [5].

Methods
To understand the long-term implications of the patent cliff for both industry and patients, trends in pharmaceutical patent expirations, drug development economics, biotechnology valuation, and strategic partnerships were analyzed. Industry reports, clinical development statistics, and recent dealmaking trends were evaluated to assess how large pharmaceutical companies are adapting through acquisitions, licensing agreements, and external innovation strategies. Regulatory protections, R&D success rates, and business decision-making continue to shape the industry.

Results
These protections allow pharmaceutical companies to generate revenue from their new therapies, but upon expiration, new entrants reduce market share, and the technology enters the public domain. For small-molecule drugs, the introduction of generics can reduce sales by 80 to 90% within the first year. Biologics often face slower competition due to manufacturing complexity and regulatory hurdles, but their revenues still decline substantially over time [1]. As a result, pharmaceutical companies must identify new sources of revenue well before their leading assets lose market share.

A potential solution is to focus on internal R&D, which many companies do by investing in their own pipelines, but high costs and risks persist. From 2015 to 2021, the top 20 pharmaceutical companies by sales developed 138 drugs, which is roughly one drug per company per year. However, this output reflects the scale of large, diversified pipelines rather than high per-drug success rates. Companies advance dozens of candidates in parallel, accepting that most will fail. The primary risk occurs when advancing from Phase II to Phase III clinical trials, when therapies must demonstrate safety and efficacy in large patient populations. Less than 50% of Phase II drugs successfully reach Phase III, meaning companies often lose significant money and time when trials fail. As a result, this solution exposes Big Pharma to major uncertainty [6].

On the other hand, small biotechs are increasingly focusing on early-stage discovery, often using advanced technologies like artificial intelligence and machine learning to de-risk and accelerate the process. These companies can specialize in specific scientific platforms or modalities, allowing them to pursue new approaches that might be otherwise difficult in larger pharmaceutical settings. However, biotech companies

often encounter significant challenges when advancing to later-stage clinical trials, which require large patient populations and substantial financial resources. This is where Big Pharma can provide the infrastructure to run expensive trials through partnerships and acquisitions after the drug has been considerably de-risked. By the time promising drugs generate strong Phase II data, their value increases dramatically. Competition grows among potential acquirers, further driving up valuation by billions [6].

The primary factor that separates biotech valuation from other industries is the immense risk. Years of high R&D costs must occur before any revenue is generated, and there is always a possibility that clinical trials will fail. As a result, biotech companies are typically valued using risk-adjusted models that incorporate the probability of success at each stage of development. When one phase succeeds, the risk decreases, and the value increases dramatically. Even if a pharma company does not need to spend on early-stage R&D, the cost is shifted to the increased valuation and premium when acquiring biotechs. These dynamics have begun to shape the strategic goals of biotechs. Many are now structuring themselves for acquisition by developing sought-after modalities, such as oncology and GLP-1 assets, to de-risk early [7].

Looking ahead, recent shifts in dealmaking activity offer insight into how these strategies may evolve. Deal volume suffered after COVID-19, leading to fewer partnerships with risky, early-stage assets. However, the market has gradually begun to recover as companies navigate external innovation, shifting from large acquisitions to early-stage partnerships. Codevelopment agreements and licensing deals allow for access to promising technologies at lower cost and with shared risk. Also, advances in AI may assist in identifying high-potential assets early in development, leading to more strategic investment decisions. Identifying winning assets before they become unavailable or overpriced is becoming the primary goal of Big Pharma, potentially outperforming full acquisitions. By combining scientific expertise with business strategy, Big Pharma can streamline dealmaking and maximize the value of external innovation [8].

Conclusion

As the next wave of patent expirations approaches, the ability to identify and integrate new scientific breakthroughs will become increasingly important. Modern drug development now extends beyond the lab, as investment decisions increasingly shape which therapies reach patients. Ultimately, the companies that most effectively identify, acquire, and integrate innovation may be best positioned to navigate the next wave of patent expirations while continuing to deliver new therapies to patients.

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