

Navigating A Key Inflection Point In Biosimilar Sector M&A

By **Rachel Turow, Samuel Cammer and Leslie Demers** (September 30, 2026, 3:31 PM EDT)

A significant uptick has occurred in mergers and acquisitions in the biosimilars sector, with deal value approximating \$13 billion in the first nine months of 2026 alone, and mimicking the 15% year-over-year increase since 2025 in the biopharmaceutical sector's average transaction size.

This increase is due in large part to U.S. Food and Drug Administration regulatory reforms, a maturing patent litigation framework, and a looming patent cliff — with \$200 billion of branded products facing patent expiration by 2030.

These converging trends have reignited interest in the value of biosimilar assets and platforms, particularly for companies diversifying into the higher-growth biologics space.

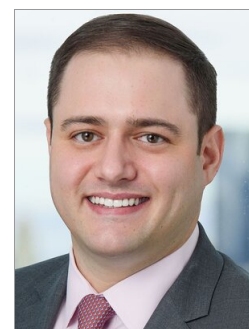
Aligning regulatory, intellectual property and transactional strategy will be critical to capturing the biosimilar opportunity before the window narrows.

Below are some major illustrative transactions:

- Sun Pharma of India's \$11.75 billion **acquisition** of New Jersey-based Organon — announced April 26, closing early next year, and framed as a shortcut to becoming a top global biosimilar amid greater regulatory certainty and lower potential development costs;
- Specialty-generics company Amneal Pharmaceuticals' \$1 billion-plus **buyout** of biosimilars development partner Kashiv BioSciences — announced April 30, with a goal to become an end-to-end supplier and with management citing the U.S. regulatory inflection point;
- Korean biopharmaceutical firm Celltrion's acquisition of Gifrer of France — announced May 12 and vertical commercial-channel M&A deal tied to substitution policy; and
- Biocon Biologics of India's \$3 billion **acquisition** of partner Viartis Inc.'s global biosimilars business — announced Feb. 27, 2022.



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We expect to see more activity in this space because while the business case for biosimilars — generic equivalents of biologics, or medications made from living organisms — took many years to build, it is now firmly established and catching the attention of dealmakers across the pharmaceutical industry.

In this article, we look at some of the factors that are influencing the surge in M&A, including FDA reforms, a settlement-friendly patent litigation environment and the 2030 patent cliff.

We also discuss making biosimilars a real business opportunity for pharmaceutical companies looking

to diversify their pipelines by diving into the highly attractive biosimilars market.

The Evolution of the Biosimilar Market

When biosimilars were first created in 2010 as part of the Affordable Care Act, adoption fell short of expectations.

As of July 2026, there were 88 FDA-approved biosimilars that corresponded to 21 different branded biologics, according to the Association for Accessible Medicines, the trade association for manufacturers of generics and biosimilars.

More than one-third of the biosimilars were approved between January 2024 and January 2026, even though the pathway was created more than a decade earlier.

Yet biosimilars accounted for only about 23% of the biologics market where they competed, and only about 10% of branded biologics losing protection over the next decade have biosimilars in development.

As discussed below, new FDA reforms directly attack the two primary barriers — high development cost and complex market-entry pathways.

Biosimilars typically launch about 40% below the price of the reference biologic and exert downward price pressure similar to generic drugs; they have generated more than \$56 billion in health care savings since 2015 (\$20.2 billion in 2024 alone).

By reducing clinical trial burdens and encouraging pharmacy substitutions, regulators are moving biosimilars closer to the generic model in terms of regulatory accessibility and cost predictability.

The trend is not U.S.-only. For example, the European Medicines Agency adopted a reflection paper in March 2026 supporting reduced reliance on clinical endpoint studies for biosimilars.[1] Meanwhile leading regulators in the U.K. and Canada have pursued streamlining that effectively removes the need for Phase III trials.

The consistent message: Analytical work is increasingly viewed as more effective than Phase III trials at detecting meaningful differences between biosimilars and branded biologics, which, in turn, makes biosimilars less expensive to develop and expedites the path to market.

Regulatory Tailwinds: Streamlining the Biosimilar Pathway

Biologics account for the majority of drug spending. In 2024, spending on biologics exceeded 50% of total drug spending in the U.S.

Biosimilars offer comparable safety and effectiveness at significantly lower cost. And, in recent years their path to market has been streamlined.

First, in October 2025 the FDA published draft guidance recommending a streamlined approach in which a comparative analytical assessment, pharmacokinetic similarity data and an immunogenicity assessment may be sufficient to demonstrate biosimilarity, as a substitute for a comparative efficacy study, which is expensive, typically enrolling hundreds of patients for tens of millions of dollars.

Because the average biosimilar takes roughly five to eight years and \$100 million to \$300 million to develop — much of it attributable to a comparative efficacy study — this reform could save developers two to four years and up to \$150 million.

Second, in draft guidance issued in March 2026, revised Q&As on biosimilar development, Revision 4, the FDA proposed moving away from requiring a three-way clinical pharmacokinetic study — studying what the drug does in the body.

These studies average about \$40 million and make up nearly 30% of total development costs, so this proposal could cut study costs by up to 50%.

While these guidances are in draft stages and the timeline for finalizing guidance is unpredictable, the FDA is moving forward with implementing these policies in anticipation of finalization.

Patent Litigation Landscape: The "Patent Dance" and Biologic IP Strategy

Now, the majority of biosimilar-related patent disputes resolve through negotiated settlements that provide market-entry certainty rather than through final judgments. But, as part of the biosimilar pathway, there is a prelitigation information-exchange process known as the patent dance.

The patent dance is a structured sequence of disclosures and patent-list exchanges between the biosimilar applicant and the reference product sponsor in the lead-up to litigation.

It is a more complex litigation structure than the Hatch-Waxman Act counterpart for traditional generics, and since enactment, fewer than two dozen biosimilars have been litigated after the dance.

The U.S. Supreme Court's 2017 decision in the seminal biosimilars case *Sandoz Inc. v. Amgen Inc.* made the patent dance optional — an applicant may dance fully or partially, or decline entirely — shifting the opening strategic move to the applicant, but there are some caveats worth flagging.

A biosimilar applicant that skips steps of the patent dance exposes itself to an immediate declaratory judgment action by the reference product sponsor while also forfeiting the protections that come with timely compliance, so skipping the dance is not a straightforward decision.

Courts have also indicated that an applicant's lack of good faith participation in the process can factor into a court's injunctive relief analysis, including whether to grant a preliminary injunction against marketing the biosimilar. Together, these consequences shift procedural and litigation leverage toward the reference product sponsor and increase the applicant's exposure to earlier, less predictable and potentially more damaging litigation.

Reference sponsors continue to build larger patent portfolios and innovative formulations to protect their investment; patent-driven delays have historically created gaps of 2.3 years (in applicant wins) to 16.5 years (in losses) between reference-patent expiration and biosimilar launch.

These are being navigated more effectively today through sophisticated freedom-to-operate and patent-landscape analysis, and we anticipate that this area will continue to evolve as biosimilar manufacturers use more sophisticated patent litigation strategies.

The M&A Opportunity: Where Regulation and Patents Converge

Cheaper, faster development plus more manageable, more predictable patent litigation make biosimilars more competitively priceable and commercially viable. Industry leaders describe the past year as a "turning point" and an "inflection point," noting that reduced regulatory requirements and lower litigation risk have given investors the confidence to place large bets. The single largest component of biosimilar investment — expensive clinical trials — is being reduced.

The Patent Cliff

Biologics worth more than \$200 billion in annual revenue face patent expiration by 2030. Over the next decade (2025 to 2034), 118 biologics are expected to lose patent protection, presenting a \$232 billion market for biosimilars — a biosimilar opportunity estimated at around \$70 billion.

The global biosimilar market is projected to grow from about \$34.8 billion in 2024 to an estimated \$93.1 billion by 2030. Smaller manufacturers can develop biosimilars at research and development, or R&D, costs 15 to 20 times lower than those of the reference drug because safety and efficacy are already established.

The cliff has drawn many entrants — a number of them smaller, R&D-focused developers that make attractive acquisition targets. Acquirers value the ability to access late-stage or approved programs with shorter time to market while de-risking regulatory and development risk; the primary M&A rationale is access to products, followed by R&D/manufacturing capabilities and commercial reach.

Generics Diversification Into Biologics

Generics manufacturers — traditionally focused on small molecules — are increasingly using biosimilars to diversify, leveraging life cycle management experience. Acquiring a biosimilar company can serve as a strategic entry into the higher-growth biologics space and a shortcut to scale versus the six to eight years typically required to build a platform organically.

Strategic Implications for Clients

The above three trends intersect as streamlining lowers development costs and time; a maturing, settlement-oriented patent framework reduces litigation cost and uncertainty; and the looming patent cliff supplies an enormous, time-bound commercial opportunity. Together, they compress the risk-adjusted path to market and have re-rated the value of biosimilar assets and platforms.

In the biosimilar deal history and trajectory, deal activity has been continuous since 2015 and peaked in 2021-2022. Critically, generics companies' roles have surged: They accounted for about 67% of biosimilar acquisitions in 2023-2024 and roughly 50% of licensing deals since 2023.

Licensing remains the most common, lower-commitment structure up front and milestone payments that de-risk smaller research licensors focused on R&D, while M&A is used to secure products, manufacturing capabilities for R&D, and commercial reach. Industry leaders expect further consolidation, viewing the market as unsustainable for the large number of players seen in traditional generics.

The convergence of regulatory reform, a more navigable patent framework and a historic patent cliff has transformed biosimilars from a slow-moving, high-friction business into one of the most active arenas for life sciences dealmaking. Clients that move deliberately — aligning regulatory, IP and transactional strategy — will be best positioned to capture the opportunity before the window narrows.

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[1] https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf-0?utm_source=chatgpt.com.