

Biosimilars | Regulatory Reforms & a Maturing Patent Framework

A significant uptick in M&A activity in the biosimilars sector is being driven by FDA regulatory reforms, a maturing patent litigation framework and a looming patent cliff — \$200 billion of branded products are 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.

In draft guidance issued in March 2026 (revised Q&As on biosimilar development, Revision 4), FDA proposed moving away from requiring a three-way clinical pharmacokinetic study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, FDA is moving forward with implementing these policies in anticipation of finalization.

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 pre-litigation 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.

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 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 (R&D) costs 15 to 20 times lower than those of the reference drug because safety and efficacy are already established.

Regulatory 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.

Reference:

<https://www.jdsupra.com/legalnews/biosimilars-at-an-inflection-point-how-2526035/>