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Preparing For Disruptions To Life Sciences Supply Chains

By **Kane Wishart, Brianne Kucerik and Chris Chapman** (March 14, 2025, 12:57 PM EDT)


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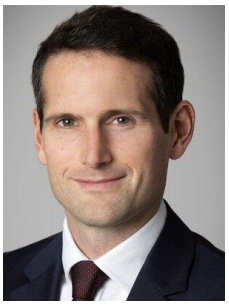
Chris Chapman

Life science companies are especially vulnerable to international supply chain disruptions. Like many trade-exposed industries, keeping supply chains operating during the COVID-19 pandemic was a constantly evolving challenge.

2025 presents a similarly disruptive challenge, with the Trump administration upending long-established norms of global trade and announcing significant tariffs across a range of product categories and source countries.

At the same time, the U.S. continues to ratchet up technology transfer restrictions on China in a bid to curtail its alleged misappropriation of intellectual property and data.

Accepted wisdom as to the highest quality, least-cost and least-risk jurisdictions for sourcing key components or locating manufacturing hubs may no longer prove reliable, and assuming a business-as-usual approach may not be sustainable.

That said, any restructuring of supply chains involves significant costs, risk and legal complexity, including potential antitrust scrutiny. Given the lead times inherit in any such restructuring, now is the time to determine the best strategy for maintaining reliable, least-cost supply of products to patients.

Significant tariffs appear likely.

The Trump administration is seeking to impose significant new import restrictions. On March 4, new 25% tariffs on all imports from Canada and Mexico went live, as did an additional 10% tariff — now cumulatively a 20% tax — on all Chinese imports.[1]

On March 6, however, the U.S. announced a pause on tariffs for many Canadian and Mexican products until April 2, pending further discussions.[2]

Relevantly, the U.S has signaled that it is considering a 25% flat tariff on all pharmaceutical imports,[3] as well as a 25% tariff on imports from the EU.[4] China, Canada and Mexico have each responded with a mix of retaliatory measures targeting U.S. goods, although Canada and Mexico have paused such measures until April 2, commensurate with the U.S. pause.

Uncertainty is likely to persist as these new tariffs and responsive retaliatory measures continue to be

negotiated and implemented. In the interim, companies may need to revisit prior assumptions as to where high-quality, least-cost components and manufacturing capacity can be accessed.

Of course, it will not only be the direct effects that are relevant to such an assessment. The macro effects of these measures over time may serve to weaken certain economies, alter the distribution of local industries and capacities, and redeploy skilled workers to different geographies.

These effects will need to be assessed over time to better understand how they may affect existing supply chains. Several players are already looking to expand U.S. production, and Pfizer's CEO noted in a recent speech that they may reshore certain manufacturing activities to the U.S. if the announced tariffs are implemented.[5]

These measures are not being implemented in a vacuum. The Trump administration's targeting of China can be understood as an — albeit more aggressive — continuation of the measures imposed by prior administrations.

In May 2024, the U.S. Trade Representative released a report reviewing the outcome and impacts of measures taken under Section 301 focused on curtailing alleged IP misappropriation by China in key industries, including biopharmaceuticals and high-performance medical devices.[6]

The report concluded that the suite of restrictions previously imposed had been modestly effective at curbing such alleged practices, but that there remained a "persistent and increasingly aggressive campaign to steal U.S. technology, IP, trade secrets, and confidential business information" and that further efforts should be made to cooperate with the private sector in moving supply chains out of China.

Additional life sciences export controls are possible.

The history of U.S. measures targeting China may prove instructive in assessing not only future tariff measures, but also the use of export controls, which may be used to limit the development of China's domestic life science and technology industries.

China's biotech sector is growing rapidly, with Bloomberg reporting this month that the Chinese share of molecules licensed to Big Pharma reached 31% in 2024, from a baseline of 0% in 2019.[7] The U.S. is likely to continue to evaluate options in limiting this growth.

In 2022, the Biden administration imposed export controls on semiconductors chips. In order to comply with these rules, one of the world's leading chip manufacturers, NVIDIA Corp., made changes to its then-leading H100 chip to reduce processing power and interconnect speed, below thresholds established by the export controls, resulting in the H800 chip, which it made available to the Chinese market.

In late January, a Chinese startup, DeepSeek, announced performance results for its new large language model that rivaled results of leading AI models,[8] and claimed that its model was trained using these H800 chips, providing fodder to critics who argue that existing measures are insufficient.[9]

Coincidentally, weeks before the DeepSeek announcement, the U.S. announced a suite of life science export controls targeting China, with export of parameter flow cytometers and mass spectrometry equipment restricted on the basis that such equipment can produce training data for AI systems intended to design biological products.[10]

Media reports in late February suggest that the U.S. is planning further export restrictions targeting Chinese AI efforts, as well as imposing new restrictions on companies providing services into China.[11]

As a result, the U.S. administration may utilize export restrictions more broadly, by adding such measures to the suite of tariffs it is imposing on other products and countries. In IP-intensive industries such as the life science sector, implementation of further export controls could result in not only the loss of important international markets for products, but it could also disrupt important R&D collaborations and partnerships.

Antitrust and foreign direct investment scrutiny is expected to continue.

Any transaction involving an input in the supply chain or a manufacturer in the supply chain may need to be reported to antitrust authorities.

For many years, antitrust authorities did not dedicate significant resources to the review and analysis of transactions involving parties at different points in the supply chain, i.e., vertical transactions. However, in recent years, antitrust authorities have more carefully scrutinized whether supply chain transactions might limit access to a critical ingredient, input, manufacturing process or supplier, as reflected in the repeal of the vertical merger guidelines and issuance of the 2023 merger guidelines in the U.S.

In addition, antitrust authorities have increasingly considered novel theories of harm, including innovation and conglomerate effects in their assessment of life sciences transactions.

The new leaders at the U.S. Federal Trade Commission and U.S. Department of Justice Antitrust Division have expressed support for the 2023 merger guidelines and careful scrutiny of vertical transactions as well as transactions affecting healthcare.

Similarly, antitrust authorities in Europe have emphasized that healthcare remains a high priority for enforcement and that transactions in the sector, including vertical transactions, are actively monitored for potential competition concerns.

Importantly, however, antitrust authorities have had mixed success in bringing challenges to vertical transactions. This includes a split challenge to Illumina Inc./Grail Inc., where the Federal Trade Commission prevailed, but the European Commission did not, and failed challenges to UnitedHealth Group Inc./Change Healthcare Inc. and Tempur Sealy International Inc./Mattress Firm Inc. in the U.S., in part because judges often credit procompetitive benefits that flow from many vertical transactions.

Further, the new leaders at the FTC and DOJ have expressed support for accepting remedies, which are often useful in mitigating the potential for anticompetitive effects in vertical transactions and have previously been accepted by the European Commission in several vertical cases.

Potential for Call-In Investigation

Even if a transaction is not reportable, there is a risk that it may nevertheless be subject to scrutiny. For example, the European Commission's review of Illumina/Grail came despite EU merger control thresholds not being met.

Indeed, Grail did not have any activities or revenues in the EU, following a referral by the French

National Competition Authority under Article 22 of the EU Merger Regulation, reflecting a 2021 European Commission policy to actively encourage National Competition Authority referrals of below-threshold transactions, specifically targeted at sectors such as life sciences.

The European Court of Justice overturned the European Commission's prohibition of Illumina/Grail in September 2024, ruling that the EC's approach of using Article 22 of the EUMR to review otherwise nonreportable transactions is unlawful.

While this removes a layer of uncertainty, the risk that such deals may face scrutiny has not fallen away entirely, with a number of national competition authorities having discretionary call-in powers and other EU member states actively considering introducing them.

Moreover, certain National Competition Authorities have started reviewing nonnotifiable transactions under abuse of dominance rules, a possibility confirmed by the European Court of Justice in its 2023 Towercast judgment.

In the U.S., state attorneys general have been more active in reviewing life sciences transactions and may open an investigation or pursue a remedy if a transaction has a local impact in a particular state.

Expanding FDI Requirements

A separate but related consideration is the potential review of cross-border supply chain transactions under foreign direct investment, or FDI, regimes, which focus on the national security implications of foreign investments.

Such regimes have proliferated globally in recent years, with an expanding notion of national security that has moved beyond defense and critical infrastructure to capture a range of activities including, in many jurisdictions, life sciences, healthcare and broader supply chain resilience.

Notably, FDI regimes may capture transactions that fall outside the remit of merger control, such as through lower notification thresholds and requirements to notify acquisitions of minority shareholdings, or even internal restructurings in certain jurisdictions. Accordingly, FDI analysis is now a key upfront consideration, alongside merger control, at the outset of any supply chain deal in the life sciences sector.

Prepare for evolving supply chain challenges.

Life science companies will need to assess the impact of new and escalating tariffs, together with other restrictions on cross-border activity singling out pharmaceutical products and medical devices, on their supply chains and proactively prepare for the antitrust and FDI regulatory review process.

License and Technology Transfer Rights

Companies should assess the extent to which they need to transfer know-how or proprietary materials across borders as part of any existing partnership, and the impact of any restrictions on such transfer.

Similarly, where critical know-how or other IP is held offshore, companies should consider seeking an express license and transfer of that technology into the U.S., or alternatively seek to set up escrow arrangements so that they may still access such technology in the event of future restrictions, and

careful consider what additional guardrails or exit ramps should be included in any research collaboration or similar agreements with non-U.S. entities.

Supply Chain Diversification

Companies should also assess the international exposure of their supply chains, including higher direct costs, negative neighborhood effects of tariffs on local economies, and the impact of any export controls.

Where significant risks are identified, it may be prudent to diversify existing supply chains, or, if the cost can be justified and domestic capacity can be identified, by onshoring especially sensitive elements of the supply chain or by establishing standby sources in alternative geographies.

Of course, global manufacturing capacity is already scarce, and the costs inherent in setting up a secondary source, together with the logistics and risks involved in transferring sensitive manufacturing processes to new partners, may prove prohibitive.

Additionally, supply chain transactions in the life science sector can involve significant legal complexity, requiring careful management of licensing, trade secret, and technology transfer provisions in agreements, as well as managing potential antitrust scrutiny.

Assess Antitrust and FDI Requirements

Companies should proactively assess global antitrust and FDI filing requirements for any supply chain transactions, as well as the potential for a call-in investigation, and take steps to prepare for the regulatory review process as appropriate.

While it is important to be aware of the antitrust and FDI enforcement environment, given the often procompetitive nature of life sciences supply chain transactions, there is likely a path to clearance with appropriate planning.

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[1] https://apnews.com/article/trump-tariffs-canada-mexico-china-643086a6dc7ff716d876b3c83e3255b0.

[2] https://apnews.com/article/tariffs-trump-economy-mexico-canada-bfed103a11a2a71d8353350f94c78814.

[3] https://www.reuters.com/business/autos-transportation/trump-auto-tariff-rate-will-be-around-25-

2025-02-18/.

[4] https://apnews.com/article/eu-us-trump-trade-war-tariffs-e799b44cbaf81b19c37a57d7fd55ee6d.

[5] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-could-move-outside-manufacturing-us-says-ceo-2025-03-03/.

[6] https://ustr.gov/sites/default/files/05.14.2024%20Four%20Year%20Review%20of%20China%20Tech%20Transfer%20Section%20301%20(Final)_0.pdf.

[7] https://www.bloomberg.com/news/articles/2025-03-10/china-s-biopharma-and-biotech-sector-is-booming.

[8] https://arxiv.org/pdf/2501.12948.

[9] https://arxiv.org/pdf/2412.19437.

[10] https://www.bis.gov/press-release/commerce-implements-new-controls-address-national-security-risks-related.

[11] https://www.bloomberg.com/news/articles/2025-02-25/trump-administration-seeks-more-restrictions-on-china-tech-weighs-nvidia-curbs.