Biotech in the crosshairs of global politics - the draft US Biosecure Act

Less than two years after the Inflation Reduction Act, another piece of US legislation with global impact is on the minds of the pharma and biotech industries. The Biosecure Act, if passed, would designate specific Chinese companies - including WuXi AppTec - as "*biotechnology companies of concern*" due to national and bio-security concerns over the companies' alleged links with Chinese state entities and the military. The Act would prevent US executive agencies from spending funds on products developed or produced with the aid of these "*companies of concern*" but also from working with companies that use their equipment or services, which is expected to have a major impact on global supply chains. This blog post considers the key aspects of the bill, the global impacts should this legislation pass in its current form, and the main implications for pharma and biotech companies in terms of minimising commercial disruption and exiting existing contractual arrangements.

1. Background to the draft bill – supply chain tension and increasing use of CROs and CDMOs

The draft legislation comes at a time when many countries vie to become hubs for the global biotech industry's capital investment and talent. It also reflects the US government's reaction to rising economic tensions by trying to decouple its economy from China to secure supply chains for critical industries ranging from biotech to semi-conductors.

In the past decades, WuXi AppTec and other Chinese Contract Research (CROs) and Contract Development and Manufacturing Organisations (CDMOs) have become an integral part of the global pharma and biotech supply chain, providing clinical research, drug discovery, development and manufacturing services for many of the world's biggest players, while enabling growing biotechnology innovators by providing access to sophisticated manufacturing facilities at short notice.

According to public reports in *The New York Times*, WuXi AppTec and WuXi Biologics are responsible for developing up to 25% of drugs currently used in the United States. The extent of the reliance or dependency on Chinese contractors is highlighted in regulatory disclosures. For example, Eli Lilly reported to the SEC that "*We, and the pharmaceutical industry generally, depend on China-based partners for integral chemical synthesis, reagents, starting materials, and ingredients. Finding alternative suppliers if and as necessary due to geopolitical developments or otherwise may not be feasible or could take a significant amount of time and involve significant expense due to the nature of our products and the need to obtain regulatory approvals which would cause disruptions to patients and detrimentally impact our business*". Merck similarly reported that it "*has significant research and manufacturing operations in China, including working with Chinese entities such as Wuxi Apptech Co., Ltd*" and that "*disruption could result in a material adverse effect on the Company's product development, sales, business, cash flow, results of operations, financial condition and prospects*".

2. The key aspects of the draft bill(s) in detail

The United States has a bicameral legislature in which two versions of draft legislation often proceed in parallel in the House of Representatives and the Senate. If passed by each chamber, the bills are then sent to the Conference Committee to implement changes to reconcile any differences, which must then be approved by each chamber. At present, the House of Representatives and Senate are each considering a proposed version of the Biosecure Act (H.R. 8333, S. 3558). The draft bills are consistent on the two core prohibitions at the heart of the Biosecure Act:

- *First*, US government agencies are prohibited from (i) "*procur*[ing] *or obtain*[ing] *and biotechnology equipment or service produced or provided by a biotechnology company of concern*"; or (ii) "*enter*[ing] *into a contract or extend*[ing] *or renew*[ing] *a contract with any entity that*" either (a) "*uses biotechnology equipment or services produced or provided by a biotechnology company of concern . . . in performance of the contract with the executive agency*" that are acquired after the effective date; or (b) "*enters into any contract the performance of which such entity knows or has reason to believe will require, in performance of the contract with the executive agency, the use of biotechnology equipment or services produced or provided by a biotechnology company of concern*" that are acquired after the effective date.
- *Second*, US government agencies are prohibited from "*obligat*[ing] *or expend*[ing] *loan or grant funds*," and any "*loan or grant recipient may not use loan or grant funds*," to either (a) "*procure or obtain any biotechnology equipment or services produced or provided by a biotechnology company of concern*"; or (b) "*enter into a contract or extend or renew a contract with*" such entities.

See H.R. 8333 § 2(a), (b); S. 3558 § 2(a), (b).

Based upon the second prohibition (which applies to any US federal loans or grants), the "*loan or grant recipient*" is bound by the same prohibitions as US federal agencies. Given that the US federal government provides large amounts of funding for US state-run hospitals and US state medical spending generally, and that programs such as Medicaid are joint-federal and state programs, the scope of the second prohibition has the potential to reach a significant portion

of medical spending in the United States. In this connection, we note that the House bill defines the term "*contract*" as "*any contract subject to the Federal Acquisition Regulation*" (which governs procurement for the US federal government), except as the term is used subsections (b)(2) and (c)(3) of the Biosecure Act. H.R. 8333 § 2(k)(3). It is not clear what the intended effect of this definition (or the limited carve-out from the definition) is intended to have. Moreover, since the Senate bill does not define the term "*contract*," this provision will likely have to be clarified before the bill is enacted into law.

The original House version of the bill (H.R. 7085) was amended by a 40-1 vote of the House Committee on Oversight and Accountability on 15 May 2024. The amended version of the House bill (H.R. 8333) includes certain elements that appear to have been calculated to address concerns voiced by industry groups. For example, H.R. 8333 "*grandfathers*" any contracts that are entered into with biotechnology companies of concern prior to the effective date of the Biosecure Act and until January 1, 2032. See H.R. 8333 § 2(c)(3)(A). This is generally consistent with the Senate bill (S. 3558), as amended on 6 March 2024, although the Senate bill does not impose any end date on grandfathered contracts, ie a grandfathered contract remains outside the scope of the prohibition indefinitely. See S. 3558 § 2(c)(3)(A). Relatedly, the revised version of the House bill now limits the scope of the prohibition to biotechnology equipment or services that are used (or that there is reason to believe will be required) in the performance of a contract with the US government agency, which has the effect of narrowing the prohibition and is consistent with the Senate version. See H.R. 8333 § 2(a)(2); S. 3558 § 2(a)(2).

On the other hand, the amended House bill expressly includes WuXi Biologics as a biotechnology company of concern, which was not specifically included in the original House bill or in the current Senate bill (although WuXi Biologics is likely covered by the broad language referencing all subsidiaries in both the House and Senate bills). Compare H.R. 8333 § 2(f)(2)(A) (listing BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics as "*biotechnology companies of concern*") with S. 3558 § 2(f)(2)(A) (listing BGI, MGI, Complete Genomics, WuXi AppTec, "*and any subsidiary, parent affiliate, or successor of such entities*"). It is unclear whether designated entities may seek to challenge the legislation (if enacted) as an unlawful bill of attainder (ie Article I, Section 9 of the US Constitution prohibits Congress from engaging bills of attainder, which are defined as laws that impose punishment on specific individuals without the protections of a trial). Moreover, unlike designations on the Entity List under US export controls, which apply only to the specific entities named on the Entity List, or to US economic sanctions designations, which generally apply to any entities owned, fifty percent or more, directly or indirectly, by a designated person, each of the House and Senate versions of the Biosecure Act will apply far more broadly to entities both up and down the corporate ownership chain. Specifically, the Biosecure Act would apply to each "*subsidiary*" and each "*parent*" of any designated "*biotechnology company of concern*," as well as to all "*affiliates*" of such entities, a term which is undefined in the draft legislation.

Further amendments may be made before either bill becomes law. The draft legislation is the target of significant lobbying from individual companies and trade groups such as the Biotechnology Innovation Organization (BIO). BIO had initially opposed the bill before changing its position and pushing for more comprehensive grandfathering provisions after reportedly cutting ties with WuXi AppTec. In a recent survey conducted by BIO of members from 124 biopharma companies, 52% of members reportedly estimated that it would take as long as two to eight years to replace designated Chinese partners for production of marketed drugs, whereas 85% of members estimated that it would take between six months and six years to switch to non-designated vendors for their preclinical and clinical projects.

The draft bills contemplate an inter-agency process for adding to the list of "*biotechnology companies of concern*." Specifically, the draft bills require a list of proposed additional "*biotechnology companies of concern*" to be prepared by the Director of the Office of Management and Budget based upon, or in consultation with, the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, and the Secretary of State. See H.R. 8333 § 2(f)(1); S. 3558 § 2(f)(1). The House bill also requires coordination with the National Cyber Director. Each bill sets a different deadline for the above US federal departments and agencies to publish additions to the list (365 days after enactment of the Biosecure Act in the House version; 120 days in the Senate version). See id. The US federal departments and agencies may designate an entity as a "*biotechnology company of concern*" if the following three criteria are met:

- The entity is "*subject to the administrative governance structure, direction, control, or operates on behalf of the government of a foreign adversary*" in the House version (or the entity is "*subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary*" in the Senate version);
- The entity is "*to any extent involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service*"; and
- The entity "*poses a risk to the national security of the United States based on*" one of three criteria, ie (a) "*engaging in joint research with, being supported by, or being affiliated with a foreign adversary's military, internal security forces, or intelligence agencies*"; (b) "*providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary*"; or (c) "*obtaining human multiomic data via the biotechnology equipment or services without express and informed consent*."

H.R. 8333 § 2(f)(2)(B); S. 3558 § 2(f)(2)(B).

Both bills define the term "*control*" as used in the above provisions expansively by incorporating the definition of "*control*" used in the US foreign direct investment regime administered by the Committee on Foreign Investment in the United States, or CFIUS. See 31 C.F.R. § 800.208.

An earlier draft of the House bill (H.R. 7035) contained certain "*findings*" making it clear that the focus of the bill was indeed specifically on China, stating that the PRC government "*seeks to dominate biotechnology as an industry of the future*" and has "*pursued a strategy known as "military-civil fusion" that merges public and private industries to enable the military modernization of the People's Liberation Army (PLA)*". While these points are absent in the latest bills, statements from the bills' co-sponsors indicate that the purpose of the legislation is to limit Chinese government access to US health data and drug patents. In an open letter, WuXi AppTec denied that it poses a national security risk, and highlighted the important role it played in global supply chains over the past decades.

3. US legislation - global impact

While the ban prevents US "*executive agencies*" from dealing with the CROs "*of concern*", the impact of the legislation will not be restricted to the US market. Early indications suggest that the impact instead will be felt by pharmaceutical and biotechnology companies across the globe. Both established pharma businesses and biotech start-ups might pivot away from using the services of the designated CDMOs and CROs, to avoid losing access to US government contracts.

The passing of the Biosecure Act could also signal to companies that further economic tensions with China are to follow - in the form of similar legislation in other countries or US import/export controls on

the Chinese CROs. To mitigate that risk, companies may look at alternative suppliers. While a number of the industry's main players have said little in public to date (aside from regulatory disclosures highlighting the risk associated with the Biosecure Act), it seems that at least some companies are already preparing to find alternative partners, moving away from WuXi AppTec and other Chinese CROs. In that sense, the lawmakers may achieve their main goal before the Biosecure Act comes into force - or even if it never becomes law at all.

4. What's next for pharma and biotech companies?

Regulatory requirements: Public and listed companies will need to consider whether the Biosecure Act will impact their operations in a way that requires a disclosure to the market. Given the draft legislation's broad application to any subsidiary, parent, or affiliate of any designated entity, enhanced due diligence regarding corporate structure may be required. Disclosures by public companies such as Eli Lilly, Amicus, Iovance Biotherapeutics over the past months have highlighted risks to operations generally, or regarding the development of specific drugs. Companies may also need to carry out enhanced due diligence on their supply chains to ensure that subcontractors comply with the Biosecure Act. In the context of upcoming IPOs or fund-raising rounds, smaller biotech companies with links to the restricted entities may also be required to make disclosures which may impact or delay their growth.

Commercial disruption: The Biosecure Act could become law before the end of 2024. However, this became less likely on 12 June 2024, when the Biosecure Act was not included among the amendments to the National Defense Authoritzation Act for Fiscal Year 2025 – a wider bill on defence spending which is virtually guaranteed to pass. However, and in any case, depending on the grandfathering provisions, businesses will need to consider shifting to new partners, which might lead to delays in the development and production of new and existing drugs, for example if clinical trials need to be repeated by new CROs, production shifted to different CDMOs, and regulatory re-approvals being required following changes to the development and production processes. Eli Lilly commented in a regulatory filing that it relied on Chinese partners and finding alternative CROs and CDMOs "*may not be feasible or could take a significant amount of time*". This could lead to delay on some drugs getting to market, and some therapeutics not making it to market due to increased development costs or revised timelines. It is likely due to these and similar concerns that a transition period until 2032 was included in the latest draft of the Act.

In the medium-term, the market for CRO and CDMO services is likely to become increasingly competitive, with CROs and CDMOs based outside of China facing unprecedented demand as at least some businesses shift away from the designated entities. Resulting inflation for the services of providers based outside of China is one way that even companies and research organisation that are not *directly* affected by the Biosecure Act, may ultimately feel the impact of the legislation. Options for larger pharmaceutical companies include extending internal research and production capacities (in-sourcing), moving supply chains to countries that are geopolitical allies (friend-shoring), or – as AstraZeneca reportedly plans – maintaining two parallel but separate manufacturing networks for supplying different markets. In that sense, the Biosecure Act also opens up new opportunities, not least for other major CROs and CDMOs based in – for example - Korea, Switzerland, Germany or India.

Exiting existing contracts: Many businesses will be considering whether - facing political pressure - they can exit existing agreements and enter new ones with CROs outside of China. However, exiting existing agreements can pose legal challenges. Each contract will need to be analysed separately to assess if and when an exit is possible without penalties or whether there might be an argument of force majeure or frustration. Alternatively, where the CRO is required to obtain all necessary permits or consents to supply services, the CRO could potentially be in breach once the Biosecure Act comes into force. Parties seeking to exit a relationship may also pay closer attention to their counterparty's performance more generally, with an eye on any applicable termination rights or leverage in any commercial discussions to facilitate an exit.

Global trends: The Biosecure Act comes at a time when major economies are actively trying to protect supply chains by moving key suppliers out of high-risk jurisdictions and ideally 'onshore', as well as regulating investment from high-risk jurisdictions into sensitive sectors - for example, the National Security and Investment Act 2021 in the UK gives the government the power to veto foreign investments in key sectors, and the headline-grabbing push in the US to have semi-conductor factories built on US territory. It remains to be seen how a pivotal year of elections will affect this trend.

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