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Foreign Investments In US Biotech Now Covered by CFIUS

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The expansion of CFIUS's jurisdiction to cover the biotechnology sector presents an additional regulatory hurdle for foreign investors that requires careful advance planning.

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The Committee on Foreign Investment in the United States (CFIUS) is a United States federal interagency committee chaired by the US Treasury Department. CFIUS is charged with reviewing and addressing any adverse implications for US national security posed by foreign investment in US businesses.

The enactment of the Foreign Investment Risk Review Modernization Act (FIRRMA) in 2018 strengthened CFIUS' mandate and broadened its jurisdiction over a range of foreign investment transactions involving various US industries, including the US biotech industry. Prior to the enactment of FIRRMA, US biotechnology companies were largely unconcerned with CFIUS in relation to transactional matters. These companies generally focus on research and development, mainly the discovery of therapeutics and diagnostics for diseases, which are activities of little or no concern for US national security outside the limited areas of bioterrorism and toxins.

The enactment of FIRRMA in late 2018, and Treasury's implementation of FIRRMA via interim rules establishing a temporary Pilot Program, abruptly put the US biotech sector in CFIUS' cross-hairs. The interim rules specify 27 industries for focused scrutiny, including nanotechnology (NAICS Code: 541713) and biotechnology (NAICS Code: 541714). All 27 specified industries can be found in Annex A to the interim regulations.

Prior to the enactment of FIRRMA, CFIUS only reviewed transactions that could result in direct control of a US business by a foreign person. FIRRMA and the interim rules expanded the scope of CFIUS reviews to include certain foreign investments in US businesses, even in cases where the investment does not result in a controlling interest.

As a result of FIRRMA, mandatory, not voluntary, filings with CFIUS will be required for controlling and non-controlling investments that fall within the definition of "Pilot Program Covered Transactions," and violations of the new rules could result in substantial penalties.

Applications Of The New Rules To Investments In Us Biotech

Direct Inbound Investments

A direct inbound investment in a US biotech company would constitute a "Pilot Program Covered Transaction" if it meets either one of the following criteria: 1. Any non-controlling (e.g., 5% equity interest) direct or indirect investment by a foreign person in an unaffiliated US business that produces, designs, tests, manufactures, fabricates, or develops one or more "critical technologies" either used in connection with, or designed specifically for use in, the biotechnology and/or nanobiotechnology industries that affords the foreign person one of the following:

• Access to any material nonpublic technical information in the possession of the target US business

• Membership or observer rights on the board of directors or equivalent governing body of the US business, or the right to nominate an individual to a position on the board of directors or equivalent governing body of the US business

• Any involvement, other than through voting of shares, in substantive decision-making of the US business regarding the use, development, acquisition, or release of critical technology

2. Any transaction by or with any foreign person that could result in foreign control of a US business as described in point 1, including such a transaction carried out through a joint venture. As it relates to the biotech industry, the term "critical technologies" under the Pilot Program may include

• Civilian/military dual-use technologies subject to the Export Administration Regulations (EAR), administered by the US Department of Commerce's Bureau of Industry and Security (BIS), that relate to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology, excluding EAR99 items, which are items not covered by a specific Export Classification Control Number in the EAR).

• Select agents and toxins.

• "Emerging and foundational technologies" controlled under section 1758 of the Export Control Reform Act of 2018. As of February 2019, the definition of emerging and foundational technologies has not been finalised.

BIS announced in November 2018 an Advance Notice of Proposed Rulemaking (ANPR) inviting public comments on the scope of "emerging technologies." This ANPR specifically listed nanobiology, synthetic biology, genomic and genetic engineering, and neurotech as the representative categories of biotechnology for which BIS sought to determine whether or not they are essential to US national security. BIS received over 200 comments, and while the Bureau has not indicated a particular timeline, it will probably be at least late spring 2019 before it issues new regulations or otherwise clarifies whether or how it will establish newly controlled classifications for "emerging technologies," biotech-related or otherwise.

Prior to BIS releasing its next round of rulemaking or further clarification, some foreign investors in the biotech industry are taking a wait-and-see approach and some are taking a conservative approach in treating a broad range of biotechnology, particularly the four categories named in the ANPR, as potentially within the scope of CFIUS and US export controls.

BIS plans to issue a separate ANPR for "foundational technologies."

Indirect Investments by Foreign Persons via US Investment Funds

The interim rules establish an exemption from the mandatory declaration requirement for certain passive investments in US businesses made through investment funds that meet several conditions. One of the key conditions is that the investment fund must be managed exclusively by a general partner, managing partner, or equivalent, who is not a foreign person.

Outbound Licensing of US Technologies

Outbound licensing of intellectual property or technology only by a US business to a foreign person does not by itself fall within CFIUS' jurisdiction, unless it constitutes or accompanies an acquisition of, or investment in, a US business.

It is important to note that technology involved in such outbound licensing may itself be subject to US export controls requirements, depending on the classification of the technology under the EAR. US businesses must carefully determine the export classification of any technology before transferring or releasing, e.g., under a licensing agreement, such technology to any foreign person. The pending announcement by BIS of what constitutes "emerging" and "foundational" technologies has added complexity and uncertainty in this area.

The New Mandatory Declaration Procedure

Parties to a Pilot Program Covered Transaction must submit to CFIUS either an abbreviated declaration or a long-form notice. CFIUS has released a five-page declaration form for parties. The filing must be made at least 45 days prior to the expected completion date of the transaction to ensure that CFIUS has an opportunity to review it. The fine for failing to file can be up to the entire amount of the investment.

After CFIUS receives a declaration, the CFIUS staff chair will initially assess its completeness and decide whether

or not to accept it as complete.

After it has been accepted, CFIUS must take one of the following actions within 30 days:

- Request that the parties file a full written notice.
- Inform the parties that CFIUS cannot conclude action on the basis of the declaration, and that the parties may file a full written notice.
- Initiate a unilateral review of the transaction.
- Notify the parties that CFIUS has concluded, i.e., approved, the transaction.

Takeaways

Parties to cross-border transactions involving US biotech businesses, whether simple licensing arrangements or full M&A transactions, should carefully consider all US regulatory implications, including application of the new CFIUS rules and US export controls. This will enable the parties to develop optimal strategies for effectively and efficiently addressing these regulatory requirements while also achieving their business objectives.
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