CFIUS Reform's Impact on Biopharma

What the new rules mean for Chinese-related investments and acquisitions in the US

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One of the prominent topics in the last few years has been the rise of the Chinese Biopharma industry. One aspect of that rise has been the investments and acquisitions made in the U.S. by Chinese biopharma companies and investors. That activity has been heavily impacted by the recent changes in the rules and laws affecting the activities and scope of the Committee on Foreign Investment in the United States, particularly with regard to the criteria for acquisitions and investments in U.S. companies that are in "sensitive" sectors.

CFIUS was created in 1988 by the Exon-Florio Amendment to the Defense Production Act of 1950. CFIUS' authorizing statute was amended by the Foreign Investment and National Security Act of 2007 (FINSA). This statutory framework authorizes the President of the United States (through CFIUS) to review "any merger, acquisition, or takeover ... by or with any foreign person which could result in foreign control of any person engaged in interstate commerce in the United States." The Committee on Foreign Investment in the United States, therefore, has been in existence for decades and was originally established to review foreign investments and acquisitions of entities that related to national security. The definition of national security had some nuances, but CFIUS did not typically target biotechnology. In addition, the regulations focused primarily on control acquisitions of companies, not minority shareholdings.

Although the new rules supposedly cover any foreign company or investor, it is clear that the concerns of the U.S. government are focused on Chinese, Russian and related countries.

The recent changes are perceived to have been prompted by the very aggressive investment and acquisition activities of the Chinese in the last couple of years and the designation of a number of industries by the Chinese government as industries that they planned to achieve leadership positions by 2025. This policy was widely known as "Made in China 2025". Interestingly, biotechnology was one of the industries specifically on the list of industries in "Made in China 2025".

What has actually changed with the new rules? There are a number of changes, but the rules now allow the U.S. government to block acquisitions of minority investments, not just control stakes. In addition, they have expanded the definition of foreign interest to include not only the location and nature of the general partners or investing entity, but also may also include who the limited partners are. So, for example, if a Chinese company or venture firm makes an investment in a U.S. biotech company that would result in a 10% ownership stake on a pro forma basis that could be a prohibited investment. In addition, if a U.S. venture firm has a Chinese limited partner who has invested in the

U.S. venture firm (or any foreign limited partner), the U.S. venture firm could potentially be treated as if they were a foreign investor.

The regulations require a filing with regard to an investment or acquisition in "critical technologies", otherwise if it voluntary. However, the government has the right to investigate the investment or acquisition even if you do not file. In addition, there is no defined deadline when a ruling is owed by the government to the filer. In the end if there is a CFIUS ruling is against the transaction, the transaction can be disallowed and a penalty up to the value of the investment or acquisition can be imposed.

The filing itself, which carries a filing fee cost, is not a major obstacle. There is an onerous scenario, however, where the U.S. government may not rule in any reasonable timeframe and the transaction can be disallowed after a long period of time has passed.

The new rules have resulting in a major cooling of investments in and acquisitions of U.S. biotech/biopharma companies by Chinese entities and some non-Chinese foreign entities. The perceived risks are too high for both the company selling or seeking equity funds and for the Chinese entity.

How, then, have the Chinese biopharma companies and Chinese related private equity and venture firms adjusted? In most cases, they have focused their energies elsewhere, including by investing more in China and other countries. In addition, they have placed a heavy emphasis on in-licensing of products and drug candidates from the U.S. biopharma companies as a way of at least getting new products for the rapidly growing Chinese domestic market and other non-U.S. markets.

However, there has been another interesting shift by the Chinese biopharma companies. Many are increasing their hiring of R&D people from U.S. biopharma companies and bringing them into the Chinese companies. Although this does not necessarily give them direct access to the U.S. company intellectual property, it does give them the R&D skills and training of the individuals who they have hired.

What impact has it had on the U.S. biopharma companies? Prior to the recent rule changes, there was a flood of cash from China at very attractive valuations. The valuations were high in part because valuations in China, both private and public, were much higher than in the U.S. However, they were also high because of the strategic importance to the investors and acquirers. All that has changed such that the "cheaper" money from China has disappeared.

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