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SD Biosensor-SJL Partners/Meridian: Covid-19 Test Concerns Could Spark Lengthy CFIUS Review, Experts Say

The national security review of South Korean-based SD Biosensor's (KRX: 137310) and SJL Partners' proposed $1.53 billion acquisition of U.S. Covid-19 test maker Meridian Bioscience (VIVO) could be exhaustive because of the target's important role in fighting the pandemic, according to experts.

National security experts who aren't involved in the deal said that the Committee on Foreign Investment in the United States (CFIUS) has launched in-depth reviews of previous proposed U.S. bioscience company acquisitions. As with those earlier reviews, CFIUS likely will probe whether the Meridian deal could weaken the country's response to the pandemic, giving a foreign entity power to sabotage disease-fighting technology such as the Covid tests or withhold supply.

While the U.S. doesn't consider South Korea an adversary, SD Biosensor is likely to draw CFIUS's close attention because some of the company's own testing kits that weren't authorized by the Food and Drug Administration were illegally distributed in the U.S., the experts said, prompting the FDA to demand a recall.

"Compliance with U.S. laws and regulations is one of the core requirements that could be crucial in determining whether a CFIUS approval can be granted," said Giovanna Cinelli, who leads the international trade and national security practice at Morgan Lewis.

The committee probably also will pore over contracts that Meridian, which makes tests to detect multiple illnesses, has with the Defense Department and other government agencies, and consider if some of the company's work is too sensitive to entrust to the proposed buyers, the experts said.

Although these issues may take CFIUS time to investigate, the panel isn't averse to foreigners buying U.S. Covid test makers. After examining several issues with Italian diagnostics company DiaSorin's (BIT: DIA) proposed $1.8 billion purchase of Luminex, a U.S. Covid testing kit manufacturer, the committee waved through the transaction last year.

SD Bionsensor and SJL Partners, a Seoul-based private equity firm, are preparing for CFIUS's scrutiny. Based on provisions in their merger agreement, the companies are likely to file a joint notice with the committee in mid-August, triggering the national security review.

The investigation could be co-led by the Health and Human Services Department, which isn't a member of CFIUS, because of the agency's expertise in the sectors where the companies conduct business, the experts said. The department's involvement would underline how the U.S.

government increasingly is looking at the national security risks in medical products' supply chains, they said.

In its review, CFIUS is unlikely dwell much on DOJ's ongoing grand jury investigation into Meridian's wholly-owned subsidiary, Magellan, the experts said. The Food and Drug Administration has required Magellan to recall some of its lead tests because they gave falsely low results; the recall has occurred amid accusations of test tampering and other potential violations of federal law. Although the allegations are serious, CFIUS typically focuses not on such matters but on whether a U.S. asset being purchased is vulnerable to security breaches that a foreign entity could exploit, the experts said.

CFIUS doesn't comment on ongoing reviews. SDB, SJL Partners, and Meridian didn't respond to requests for comment.

The deal is expected to close by the year's end, with SDB controlling 60% of Meridian and SJL holding the remaining 40%.

Test distribution questions. CFIUS will probably be drawn to how the pink-and-white boxes containing SDB's Standard Q Covid-19 Ag Home Test ended up in the U.S. The FDA has approved some SDB Covid tests for the U.S., but not these, spurring the agency in March to warn against using the tests and ordering a recall.

The company has said that their testing kits were illegally imported into the U.S. and that it was conducting a thorough investigation into the incident. The company also pledged to crack down on illegal imports and strengthen the enforcement of its contracts with distributors.

SDB is now facing a class action lawsuit in New York state in which the plaintiffs allege the company violated numerous state and federal laws in relation to the tests' distribution, including misleading advertising, false statements and fraud.

CFIUS "may likely engage in heightened scrutiny in a transaction involving a party with a less-than-stellar compliance record," said Andrew Astuno, an associate at Stroock & Stroock & Lavan who advises companies on national security matters. The committee coordinates with other agencies on compliance matters and the effect the company's record could have on national security, he said.

Government contracts. CFIUS will likely want to determine if the deal could present a national security risk for Meridian's ongoing and future government contracts, the experts said.

"During the review, the committee will assess whether the acquisition of Meridian could adversely affect the delivery of research and services it provides under government contracts," said Shannon Reaves, a partner at Stroock with national security expertise.

U.S. government acquisition data shows that both DOD and HHS have awarded Meridian contracts. For example, in January 2021, Meridian received $5.5 million from HHS to support research and development and increased production of the company's Revogene tests, which detect illnesses such as Covid, strep and C. difficile. HHS also awarded the company $2.5 million to boost its Covid research efforts.

In May 2017, DOD, a frequent purchaser of Meridian products, awarded the company a $384,250 contract to supply equipment for diagnosing respiratory diseases.

"Even if grant dollars are small, they have an outsized impact on the reviews because they reflect where the future research can go," Morgan Lewis' Cinelli said. CFIUS would be concerned about foreign entities buying companies that participate in research for the U.S. government and work on novel technologies that one day could be critical, Cinelli said.

Meridian develops tests for Ebola, monkeypox, influenza and Legionnaires' Disease.

CFIUS could conclude that some of the company's work would be too sensitive to share with SDB.

Meridian stores dangerous viruses in its facilities and is subject to a number of regulatory restrictions. In reviews involving companies with similar responsibilities, CFIUS has consulted with the Agriculture Department's Animal Plant and Health Inspection Agency, which helps oversee transfers of pathogens and viruses.

HHS role. CFIUS's review of the deal could provide an opportunity for HHS's expanding influence of the committee's decisions.

"HHS's role has grown significantly. Any transaction that involves health data or businesses involved in medical supply chains would warrant HHS input," said Stroock's Astuno, who also served as a policy adviser on the panel. "In such cases, CFIUS will often ask HHS to co-lead the review."

When helping to review proposed mergers, HHS relies on its Office of National Security (ONS) to conduct an intelligence analysis.

Headed by Captain Michael Schmoyer, ONS is entrusted with protecting U.S. citizens' health care data and sensitive information related to U.S. policies on global health, medical countermeasures, research and acquisitions, public health threats, pandemics and containment laboratories, where dangerous viruses are stored.

The experts said ONS usually advises the committee during the initial review period, which lasts 45 days. That consultation takes up 20 to 30 days of that initial period, when the Office of the Director of National Intelligence (ODNI) is conducting an assessment of the deal.

During the ODNI assessment, ONS will gauge the impact an acquisition would have on the supply of Covid tests, sensitive health care information, and research and development.

HHS input has become so important on some reviews that members of Congress have proposed giving the department a permanent spot on the committee. In October 2021, a bipartisan group of lawmakers introduced a bill that would expand CFIUS from its current nine members to 11, adding HHS and the USDA.

The Luminex case. CFIUS will probably look at the Meridian deal closely, but that doesn't mean the committee is prepared to recommend that it be blocked. The U.S. has allowed such acquisitions before.

Prior to approving DiaSorin's purchase of Luminex, CFIUS expressed concern about a joint venture established between DiaSorin and two Chinese regional governments, Fuyuan City and Baoshan, a suburban district of Shanghai, said one of the experts. The committee feared that post merger some health care data and technology from Luminex could end up in China.

The committee also reviewed the merger's impact on the supply of testing kits, experts said.

Still, CFIUS finished its investigation within the initial period of 45 days and cleared the deal on July 8, 2021.