

Key Lessons From a Recent Export Enforcement Case Against a U.S. Pharmaceutical and Medical Supply Company

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Recently, a U.S. pharmaceutical and medical supply company was fined over \$16 Million for illegal sales, exports and reexports to Iran, Sudan, and Syria—countries that are currently subject to U.S. embargoes and economic sanctions programs. Alcon Laboratories, Inc., located in Fort Worth, Texas, as well as its Swiss affiliates (Alcon Pharmaceuticals, Ltd. and Alcon Management SA), recently settled with the U.S. Treasury Department’s Office of Foreign Assets Control (“OFAC”) and the U.S. Commerce Department’s Bureau of Industry and Security (“BIS”) for exporting surgical and pharmaceutical products from the United States to its affiliates in Switzerland, and then reexporting the items to distributors in Iran, Sudan, and Syria to fulfill orders in those countries. The company was charged with:

- 452 unlicensed sales and exports to Sudan;
- 104 unlicensed sales and exports to Iran;
- 45 unlicensed reexports to Syria; and,
- 100 charges of acting with knowledge that a violation of the EAR would occur.

The BIS imposed a civil penalty of \$8.1 million for the EAR violations, and OFAC imposed \$7.6 million in civil penalties for violations of the sanctions on Iran, Sudan and Syria.

An interesting point in this case is the fact that the company could have applied for and obtained the required authorizations for the shipments to all three countries under the Trade Sanctions Reform Act (“TSRA”). Peculiarly, the company had previously obtained TSRA authorizations for exports of similar products to sanctioned countries.

OFAC concluded that there was little harm to the sanctions programs in this case because the sales and shipments in question were licensable and could have been authorized. Alcon also had no prior history of export and sanctions violations, and took remedial actions by stopping future shipments to these countries and implementing a formal export compliance program that consisted of documented policies and procedures and trade compliance training for personnel.

However, OFAC considered the fact that Alcon had no formal export policies and procedures in place, despite its substantial international trade activities, as one of several aggravating factors in the case. Alcon also failed to take appropriate steps to stop its activities. In addition, the BIS concluded that the company had reason to know that a violation of the EAR was about to occur, a violation of the EAR in and of itself, because: (1) one of its freight forwarders refused to ship the goods to Iran on behalf of the company; and, (2) the company had previously obtained export authorizations to export similar items to Iran.

There are several key take-away's from this enforcement case from which U.S. companies can learn. First, it is critical for U.S. companies to implement formal trade compliance programs—the lack of such policies and procedures can be treated as an aggravating factor in export enforcement action by the U.S. government. U.S. companies should also have formal compliance training processes and issue escalation processes to enable personnel to take swift action and make the necessary internal inquiries when “red flag” information is received—such processes here would have enabled Alcon to ask questions, escalate the company's freight forwarder's refusal to ship goods to Iran, Sudan, and Syria, and perform additional due diligence about the overall legality and licensing requirements for its proposed shipments. In addition, one can only assume that the company failed to obtain the required TSRA authorizations for these shipments because of a lack of adequate personnel training and documented policies and procedures—such processes are critical especially in situations where personnel turnover could lead to knowledge gaps and inadvertent violations. Finally, when export violations are discovered, companies can receive significant mitigating treatment from the U.S. government agencies where they promptly cease the violative conduct, take appropriate remedial actions, and cooperate fully in the export investigation.

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National Law Review, Volume VI, Number 242

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