Every U.S. Life Sciences Company Needs an Export Control Compliance Program (No, Really….)

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Two recent settlements by the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) confirm that every U.S. life sciences company engaging in exports should have an effective U.S. export control compliance program:

- In July, Alcon Laboratories, Inc. and certain of its affiliates settled, for $7,617,150, potential civil liability for apparent violations of each of the Iranian Transactions and Sanctions Regulations (ITSR) and the Sudanese Sanctions Regulations (SSR). The alleged violations involved the unlicensed sale to Iran and Sudan of certain medical end-use surgical and pharmaceutical products.

- In early September, World Class Technology Corporation paid $43,200 to settle potential civil liability for alleged violations of the ITSR related to the sale of orthodontic devices to Iran; the alleged transactions had an aggregate value of $59,886.

In each case, the absence of an effective export compliance program was determined by OFAC to be an aggravating factor in calculating financial penalties. During OFAC's investigation, Alcon produced information indicating that from August 2008 to December 2011, it violated the ITSR on 452 occasions and the SSR on 61 occasions by selling and exporting, without prior OFAC authorization, medical end-use surgical and pharmaceutical products to distributors located in Iran and Sudan, respectively. Before determining the final penalty, OFAC determined that the statutory maximum civil monetary penalty amount for Alcon's alleged violations was $138,982,584 and the base penalty amount was $16,927,000.

World Class Technology Corporation produced information indicating that it violated the ITSR on seven occasions between April 2008 and July 2010 by exporting U.S. origin medical devices to Germany, Lebanon and/or the United Arab Emirates with knowledge, or a reason to know, that such shipments were intended specifically for supply, transshipment, or re-exportation to Iran. OFAC determined that the maximum statutory civil penalty amount for World Class Technology's alleged violations was $1,750,000, and the base penalty amount was $80,000.

Prior to assessing a penalty or otherwise entering into any settlement, OFAC considers mitigating and aggravating factors to reduce, or increase, the final penalty amount.[1] OFAC's discussion of mitigating and aggravating factors is valuable reading for U.S. exporters, as it illuminates OFAC's expectations as to export compliance.

In the Alcon and World Class Technologies cases, OFAC found the following aggravating factors:

- Alcon was determined to have extensive experience in international trade, and therefore demonstrated reckless disregard for U.S. sanctions requirements by (i) having virtually no compliance program at the time of the alleged violations; and (ii) failing to take adequate steps to investigate a third-party freight forwarder's cessation of shipments to Iran.

- Although OFAC determined that World Class Technologies "lacked commercial

1 These factors are listed at *General Factors under OFAC's Economic Sanctions Enforcement Guidelines*, 31 C.F.R. part 501, app. A.

sophistication in conducting international sales at the time of the alleged violations," the company did not have an effective U.S. export compliance program prior to June 2008.

- Each company's senior management knew, or had reason to know, about the alleged violations, and the alleged violations were 'willful.'
- Neither company voluntarily self-disclosed the alleged violations.

In the Alcon and World Class Technologies cases, OFAC found the following mitigating factors:

- Neither company's alleged violations were determined to be 'egregious.'
- Neither company's alleged violations harmed U.S. sanctions programs because the exports in question involved medical end-use products that were licensable for sale/export/shipment to Iran and Sudan pursuant to the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA). The TSRA licensing mechanism, limited to defined medical end-use products and other specific items, is an exception to the general prohibition on U.S. businesses transacting with Iran or Sudan. In fact. Alcon had used the TSRA mechanism to obtain licenses for other similar exports to Iran and Sudan both before and after the time period in which the alleged violations took place.
- Neither company had a prior OFAC sanctions history; neither had received a Penalty Notice or Finding of Violation from OFAC in the five years preceding the date of the earliest transaction giving rise to the alleged violations. Each of Alcon and World Class Technology was eligible for "first violation" mitigation of up to 25 percent.
- Each company substantially cooperated with OFAC's investigation by, among other actions, agreeing to toll the statute of limitations during the pendency of such investigation.
- Each company instituted or upgraded to robust compliance program that included: (i) updated or newly-created corporate export and trade sanctions compliance documents; (ii) enhanced trade compliance training; and (iii) enhanced compliance procedures for requesting OFAC licenses.

AGG Observations:

U.S. life sciences companies engaging in exports should take away the following practice points from these settlements:

- OFAC has made a clear statement that each exporter, including those that may lack commercial sophistication as to international transactions, must have a robust export compliance policy and program.
- The transactions cited in the World Class Technology Corporation settlement were valued at $59,886. The maximum statutory civil penalty amount for the alleged violations was $1,750,000, the base penalty amount was $80,000, and the settlement amount was $43,200. OFAC has consistently told exporters that potential penalties are not calculated based solely on the value of the underlying transaction(s).World Class Technology could have been penalized between 134% and 2922% of the value of the underlying transaction, and that's a powerful argument for investing in an export compliance program.
- OFAC considers tolling agreements a key indicator of 'cooperation' from those companies being investigated. A tolling agreement eliminates the usual five-year statute of limitations, and expands the potential scope of transactions OFAC may review and could potentially penalize in a given investigation.
- OFAC places significant mitigation value on voluntary self-disclosures. If you've determined that your company has violated (or there is a high probability that it has violated) U.S. export controls, a voluntary self-disclosure is the recommended course of action. If OFAC discovers a potential violation before a self-disclosure is filed and/or

if the self-disclosure is filed more than thirty days after you have become aware of a potential violation, you lose all of the mitigating benefits that otherwise attach to the self-disclosure.

- Just as a pro-compliance ‘tone from the top’ is important for an effective export compliance program, situations where senior management knows, or has reason to know, about potential export compliance violations but does not act will be a significant aggravating factor in OFAC’s analysis.

If your company does not have an export compliance program, or if you have not reviewed or updated your program in the last year, now is the time to make the compliance investment.

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