

National Security and Scientific Research

Tips on How to Avoid Violating Export Control Regulations

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Suppose that Genetic Transduction, a fledgling biotechnology company, has been using foreign graduate students to help develop gene transduction techniques, although the company does not yet have a product to sell. Further suppose that the company's president receives a letter from the Bureau of Industry and Security (BIS) of the Department of Commerce requesting certain documents and advising him that the company may have violated the Export Administration Regulations (EAR), the most commonly encountered regulations popularly referred to as "export control regulations".

The question is, since the company is not selling anything at this stage, either within or outside the U.S., how could it have violated export regulations?

The EAR were adopted "for reasons of national security and protection of trade" to regulate transfers of certain information, products, and technologies to certain specified persons. As the word "export" implies, the regulations prohibit transfers of these items out of the U.S. to anyone, including U.S. citizens, without a proper license.

However, in addition to covering actual cross-border exports of technology, the EAR also address what are referred to as "deemed exports"—the release of technology or software to a nonresident foreign national even if the transfer takes place totally within the U.S.

This means that a license is required for the delivery of restricted technology to foreign nationals on U.S. soil. So if Genetic Transduction uses graduate microbiology students who are not U.S. residents or citizens for various assignments, disclosure of sensitive technology to some of those graduate students could result in a violation of the EAR.

Access to sensitive scientific information by hostile or potentially hostile countries has troubled the national security establishment since at least the Cold War. However,

as technological savvy has spread to more and more countries, the concern that enemies of the U.S. might successfully develop bioweapons and other weapons of mass destruction has gone up significantly.

At the same time, the mapping of the human genome, advances in microbiology, and the perception of the potential for new knowledge to generate blockbuster drugs, have all resulted in substantial increases in the amount of public and private funds invested in generating these innovative technologies. Unfortunately, from the point of view of the defense establishment, every advance in the understanding of biological processes also represents a potential insight into how to create a biological weapon.

As an example, a company looking for ways to combat the avian flu virus might discover a biochemical process in the virus that, if tweaked in a particular way, could reduce the likelihood of transmission to humans. However, another use of this insight might be to make the virus more, rather than less, likely to infect humans.

The EAR is intended to permit the government to control the circumstances in which details of such dual-use technology (having both commercial and potential military applications) could be released outside the U.S.

Regulatory Categories

The specific classes of technology restricted under the EAR are described in the Commerce Control List (CCL) set forth at 22 CFR Part 774. The category most likely relevant to biotech businesses would be Category 1—Materials, Chemicals, Microorganisms, and Toxins. With respect to Genetic Transduction's business, under this category, the regulations address materials constituting "Genetic elements and genetically modified organisms."

However, the regulations only extend to information identified in this category that involves genetic sequences related to the

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pathogenicity or toxicity of an organism. If Genetic Transduction's research might generate this type of information, its technology might well be considered sensitive. However, if confusion exists as to whether the EAR classifies materials or information as sensitive, the BIS will provide an advisory opinion.

If the relevant technology is covered by the regulations, access by most foreign nationals is restricted. This includes tourists, students, businesspeople, scholars, researchers, technical experts, sailors, airline personnel, salespeople, military personnel, and diplomats, among others.

Disclosure of the technology to any such person (even by giving a demonstration or oral briefing) constitutes the export of the technology to the country where the foreign national is a citizen or a permanent resident.

However, it is important to note that the hiring of foreign nationals is not prohibited nor regulated by the EAR. If an individual is properly documented for work in the U.S., a company may employ him or her. But where the technology is sensitive, its disclosure to restricted persons is only permitted if the company developing the technology has obtained an appropriate license from the BIS under its rules governing that individual's home country.

To get such a license, the company would have to submit a letter of explanation, including basic personal information about the foreign national; a detailed job description; proposed employment; a description of the technology intended for release to the employee; the commodity to be produced with the controlled technology; and an explanation of how the company will benefit by employing the foreign national.

Even if a student is already conducting cutting-edge (and potentially sensitive) research at his or her academic institution, it should not be assumed that the institution's existing license will cover the work that the student will be doing for the pri-

vate company. A university may have a general license permitting properly documented foreign nationals enrolling in an academic program to engage in particular programs of "fundamental research".

Under National Security Decision Directive 189 (NSDD 189), which was issued in 1985 and confirmed in 2006, fundamental research is defined as being "basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community." In other words, if there are no conditions placed on the academic research, and it is the intent of the research team to publish its findings in scientific literature, then it is considered fundamental research, and the foreign student can participate under the university's general license.

However, NSDD 189 distinguishes fundamental research from proprietary research on the basis that the publication of results of proprietary research ordinarily are restricted for commercial reasons. Therefore, if a contract between a commercial biotech company and an academic institution requires that the private corporation review the findings of the research team with the intent of controlling what results are to be released in open literature, then the research is considered proprietary, and either the university or the research sponsor may need to obtain an additional or different license.

It should be clear that companies involved in biological research should take care to comply with the regulations pertaining to deemed exports. The good news is that the Department of Commerce views its role as working in partnership with private industry.

In short, the Bureau does not perceive its job as denying licenses but rather as obtaining information about sensitive research and the ways in which companies may be making that research available to others. **GEN**