THE LAST WORD

by Lisa J. Raines

INS AND OUTS OF THE NEW DRUG EXPORT LAW: INTERMEDIATES AND TROPICAL DISEASES

The drug export bill signed by President Reagan in December creates a number of opportunities for biotechnology companies to increase their export earnings. Getting the most out of these opportunities, however, requires strategic planning.

Although the new law contains some ambiguities—no doubt because its final provisions were drafted during a frenzied horse-trading session on the night before the 99th Congress was expected to expire—it has remedied the inequities imposed for most of this century upon U.S. pharmaceutical manufacturers. The law now permits the export of new drug and biological products intended for human or animal use to any of 21 developed countries once the Food and Drug Administration (FDA) has approved an export application. (See *Bio/Technology* **5**:46, Jan. '87 for background and analysis of the Drug Export Amendments Act of 1986.) The statute also relaxes restrictions on exporting partially processed biological products. In fact, one of the most important decisions that biotechnology company executives need to make is whether to export finished or partially processed products. Another significant issue is what strategy to pursue if the company wants to export to an unlisted country.

Some companies have assumed that they should always prefer to export finished products—which can be applied directly to prevent or treat disease—over partially processed biologicals—also known as biological intermediates. Finished products generally have greater value added and are therefore more profitable. But consider the following:

- No Investigational New Drug (IND) exemption is needed prior to exporting a biological intermediate, although it is required prior to exporting a finished biological product.
- A company may only export a finished biological if it is actively pursuing U.S. approval, as demonstrated by its annual progress reports to FDA. But the exporter of a partially processed biological product need not be actively pursuing a license to market the finished product in the U.S.
- The exporter of a finished biological may ship only those quantities of the product that may reasonably be sold in the importing country. The biological intermediate exporter is not required to limit the quantities shipped.
- A company may export finished biologicals only after the foreign country has approved marketing. The finished product into which the intermediate will be converted, however, need not be approved in the importing country as long as approval of the final product is being sought in that country.
- A company may only export a finished biological to an importer who is willing to certify to FDA that he will not export the product to an unapproved country, that he will notify the exporter if he discovers the product is being diverted to such a country, and that he will maintain records of the distributors to which the product is sold. Importers of biological intermediates need not take these responsibilities; in fact, they need not even be identified to FDA. Indeed, some importers may be willing to handle partially processed biologicals but not finished products.

Thus, there are circumstances when a company may be eligible to export an intermediate but not the final product, as well as circumstances when a company is eligible to export either but should prefer to export the intermediate. But what strategy should a company pursue if it wants to ship to an *unlisted* country?

The obvious strategies predate the drug export law: vigorously pursue FDA approval of the product for marketing in the U.S., produce the product abroad, or license the technology to a foreign producer. But there is now another option for some products: seek approval to export under the tropical disease provisions of the new law.

A drug or biological product that is to be used in the prevention or treatment of a tropical disease may be exported on more liberal terms than other unapproved products—and exports are not limited to the 21 countries specified in the law. These products may be exported to any country in which FDA finds that the product would be safe and effective in the prevention or treatment of a tropical disease. Furthermore, a company need not be pursuing U.S. marketing approval to export a tropical-disease product, though active pursuit of domestic approval is required for other products. Because tropical diseases are not defined in the law, FDA has considerable latitude in determining product eligibility.

One option that is *not* available is petitioning FDA to add the desired country to the approved list. Contrary to popular belief, FDA is not empowered to expand the list beyond the 21 countries to which export of unapproved products is now permitted. Although it is true that the drug export law contains criteria for expanding and contracting the list of countries, it does not actually authorize FDA to modify the list in accordance with these criteria. While the drug export bill that passed the Senate in May 1986 granted FDA this authority—and Senate negotiators attempted to preserve this power—House negotiators did not want to vest this authority in the agency and succeeded in getting the authorizing language deleted. In the absence of authorizing language, only Congress itself may modify the list; the statutory criteria merely serve the marginal purpose of advising future congresses. My own experience in lobbying for this legislation leads me to predict that donkeys will grow wings before Congress adds to the approved list. (Then again, in the era of biotechnology, anything is possible.)

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