

AMPLE MARKET OPPORTUNITIES

OBSTACLES TO CANADIAN BIOTECH

NEW YORK—Immigration policies that stop talented managers at the border. Huge patent backlogs and limited intellectual property protection. Faltering financing. Inadequate research spending. Hazy regulations. These are some of the obstacles currently hindering the development of biotechnology in Canada, according to "National Biotechnology Business Strategy: Capturing Competitive Advantage for Canada," a report issued by the National Biotechnology Advisory Committee (NBAC), a private group serving Industry, Science and Technology Canada (ISTC, Ottawa, Ont.), a government department.

Failure to introduce new technologies would harm Canada's biotech companies and its entire natural-resource-based economy.

Although long on criticism, the report sees ample market opportunities within Canada, particularly in forestry, agriculture, and waste management, and for exports as well. Failure to introduce new technologies would harm not only the nation's biotech companies, but its entire natural resource-based economy, NBAC warns.

Canada is home to some 350 biotechnology companies. But only a small number have made public stock offerings, among them Allelix (Mississauga, Ont.), Biomira (Edmonton, Alta.), Cangene (Mississauga, Ont.), IAF Biochem (Montreal, Que.), and Quadra Logic Technologies (Vancouver, B.C.). Canada's biggest conglomerates, for their part, have been too slow to recognize the need for biotech research, says NBAC.

In the regulatory area, NBAC notes that inadequate staffing at two federal departments—Health and Welfare Canada and Agriculture Canada—have worsened delays in the approval process for biotech products. Not surprisingly, NBAC recommends adding staff committed to assessing such products. That's under discussion within government circles now, says Terry Walker, ISTC adviser on biotechnology regulations. The various arms of government, he says, "are aware of the problems, and they're trying to fix them."

The regulatory process could be further streamlined, NBAC argues, by accepting clinical or other data submitted in the U.S. or Europe. Right now, the report says, "a major barrier to the commercialization of biotechnology

products is that new products are regulated on a case-by-case basis" so that "for each new product a new protocol is required."

Patent system needs harmonizing

Canada's patent system also needs harmonization with those of other nations, according to NBAC. Canadian patent law does not allow the deposit of multicellular organisms, which means, in effect, that no one can patent such organisms. The Cabinet has agreed to put forward a bill that would enable Canada to sign the Budapest Treaty, an international agreement recognizing the validity of such depositions in support of patent applications. That would bring Canada into harmony with Europe and the U.S. in this regard.

Although it is not spelled out in the report, NBAC member Brian Gray, an attorney with Blake, Cassels & Graydon (Toronto, Ont.), says that NBAC also wants to see the elimination of Canada's compulsory-licensing law. Under this law, a company that holds a patent for a drug but is not performing additional research or commercializing the product is required to license it to another company that will develop it.

Canada also suffers from a huge patent backlog, in part because of a government hiring freeze. This staff shortage continues even though the patent office actually generates a profit through application fees.

The Canadian government has just made the patent office an independent entity. But it's not yet clear that the patent unit will have the authority to hire the staff it needs to get caught up. "We don't know what the extent of the patent office's autonomy will be, especially its fiscal autonomy," says Gray, adding: "The Canadian government is not as open as the U.S. government."

Bolstering research infrastructure

To bolster Canada's research infrastructure, NBAC wants to see the federal and provincial governments take over indirect costs of university research. Canada also needs a fermentation facility that meets good manufacturing practice (GMP) requirements, NBAC says. Companies can now produce trial lots of biotech drugs at the facilities of the National Research Council's (NRC) Biotechnology Research Institute (Montreal, Que.). But NRC's facilities do not have GMP certification from either the Canadian or U.S. government, and several companies anticipate needing a GMP facility within the next year or so. NBAC estimates such a facility would cost C\$5-20 million.

NBAC's preferred solution would be

for a consortium of private companies—with federal and provincial government aid—to establish such a facility. "We're up and running on that already," says Rob Quinn, president of the Industrial Biotechnology Association of Canada (IBAC, Ottawa, Ont.). He adds that an industry group met late last year to organize a needs study for such a plant.

Developing ag and forestry

NBAC also wants to see the Canadian government take a more active role in encouraging the development of biotech products in forestry, waste treatment, and agriculture, as well as pharmaceuti-

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icals. Because much of the Canadian economy's strength lies in its natural-resource-based industries, a larger proportion of Canada's biotech activity lies in mining, forestry, fishing, agriculture, and environmental industries than in the U.S., the U.K., or Japan.

In particular, NBAC says that Forestry Canada, a federal department, should work with provincial governments to spur the adoption of genetically improved trees for forest regeneration. NBAC also urges Forestry Canada to promote commercialization of biocontrols for forest pests. Negotiations are underway now to relocate a U.S. company specializing in such products to Sault Ste. Marie, Ont., where it can collaborate with a local Forestry Canada research lab.

NBAC also recommends that Environment Canada, another federal department, work with provincial governments to develop biological methods for wastewater treatment. The Wastewater Treatment Centre (Burlington, Ont.) should serve as the focal point for national research, NBAC says. And Agriculture Canada, says NBAC, should assess university agricultural and food-processing research programs to eliminate duplication.

For its part, IBAC is "very positive" about NBAC's recommendations. A stronger government commitment to promoting biotechnology can only strengthen investors' willingness to put money into the industry, says IBAC's Quinn, adding: "The time has come."

—Mimi Bluestone