

reatment systems, is already looking ahead to develop new systems aimed at other toxic chemicals on EPA's priority-pollutant list. For the time being, Celgene is likely to stick close to chlorinated solvents in liquid waste streams, probably chloroform, perchloroethylene, and trichloroethylene. Eventually the company plans to branch out into vapor-stream treatment systems.

Lewis, in addition to his duties at Celgene, chairs the Pollution Prevention Subcommittee of the EPA's fledgling Biotechnology Action Committee (BAC). He is frankly concerned about the continued flow of government-generated information about industrial emissions—and information about effective methods for reducing them at the source. If pollution prevention is to become a real

national priority, Lewis believes, a body of case studies must be generated to support the development of effective biological technologies capable of reducing toxic emissions economically. Small and mid-sized companies, he points out, may have an even greater need for information to help them assess and solve their own problems, if only because of the greater potential impact of environmental liabilities on their bottom lines.

BAC is trying to develop just such a data bank of case studies, but so far has run into trouble with companies that are reluctant to share relevant technical information for proprietary reasons. In the past few years, TRI has jump-started the information revolution. Since 1989, the number of total filings to TRI has grown more than 20

percent (to 82,000 in the 1991 report), and there is considerable pressure to expand both the number of chemicals and facilities reported. But unless industry and government can find cooperative mechanisms for sharing information about new bioremediation technologies, biotech firms interested in finding innovative, economical ways to prevent industrial pollution are likely to have a tough time competing against more conventional technologies.

And those 287 silent megapolluters will have even less reason to RSVP the next time around.

—Russ Hoyle

Russ Hoyle, former senior environment editor at Time, is currently editor of ECO, a new magazine on business and the environment due out next year.

SEND MONEY, TOO

HARMONIZE GLOBAL PATENTS, SAYS OTA

WASHINGTON, D.C.—Notwithstanding that “biotechnology is not an industry,” its U.S. chapter is well-populated by “dedicated biotechnology companies,” according to “Biotechnology in a Global Economy,” which is the latest in a series of full-scale reports on the topic from the Congressional Office of Technology Assessment (OTA) here. Harmonization of international patent law “looms as perhaps the greatest challenge for commercializing biotechnology-related processes and products,” the report concludes. Running a close second is the ability to secure needed capital.

Although U.S. companies continue to “lead the world” in the commercial development of biotechnology, unsettled regulatory policies, shortages of capital, and a slower-than-promised realization of commercial goals could soon threaten the survival of many companies. To address these concerns, the OTA report outlines a series of options for Congress to consider. The options fall into categories ranging from federal funding and regulatory matters to patenting and tax policies.

Most small, dedicated U.S. biotechnology companies are trying to maintain an intensely innovative pace, particularly in the pharmaceutical area where the technology's impact will likely continue to grow very rapidly. Because these efforts are so ferociously capital intensive, most such dedicated companies already consistently lose money. However, as increasing numbers of them turn to-

ward clinical trials—an even more costly phase of product development—bottlenecks may impede progress and threaten their survival, warns the OTA report.

Before the 1987 stock market crash, U.S. biotechnology companies had little trouble securing capital. Since then, venture capital and other sources of investments have generally been tighter. Even the unexpected investment boom of 1991 should be viewed as “short term,” unless a spate of products or an unanticipated surge in markets occurs, according to the OTA report, whose views are considerably more pessimistic than those outlined in a recent report on the industry by Ernst & Young (*Bio/Technology* 9:1032, Nov. '91). However, OTA says, despite fears that capital shortages invite foreign takeovers, there is “insufficient evidence” to conclude that such acquisitions “threaten U.S. commercial interests.”

In the same vein, the OTA report plays down widespread fears that U.S. biotechnology will soon bow to foreign competitors. For example, it notes, “Japan suffers from the lack of a strong research base, which has led firms to seek access to research and training abroad. Japan also suffers some weaknesses in the industrial sectors to which biotechnology is most applicable.” Weak areas include pharmaceutical products and agriculture, whereas Japanese strengths include fermentation for the production of amino acids and industrial enzymes.

Competition between the U.S. and Europe over biotechnology is differ-

ent, largely because of strengths there in the pharmaceutical industry and in agriculture, the report notes. “The picture is clouded, however, by several factors: the fragmentation of research efforts, adverse public opinion, and uncertain effects of European Community directives on field testing.”

The OTA report points to national and international patent issues as critical. Although current U.S. laws are the “broadest and most inventor generous” in the world, the backlog of applications and concerns about “patent piracy” are creating disincentives and difficulties in planning business strategies. Meanwhile, the ability to understand and meet requirements of various patent offices may “be the issue of most importance” to inventors of biotechnology products and processes.

Representative James Scheuer (D-NY), who chairs the Environment Subcommittee of the House of Representatives' Science, Space, and Technology Committee, interprets the report to indicate a “disturbing lack” of biotechnology activity in the critical fields of agriculture and the environment. Thus, he plans to “explore means to promote vital research” in those areas. His colleague Tom McMillen (D-MD), a co-chair of the recently formed Biotechnology Caucus (*Bio/Technology* 9:797, Sep. '91), promises to probe how Congress can help ensure the availability of “ample venture capital to maintain a steady stream of innovation.”

—Jeffrey L. Fox