

BY ROSS DEVOL AND LORNA WALLACE

In today's global economy, governments strongly influence business competitiveness in a host of ways, ranging from education to regulation to fiscal policy. By the same token, it is plain the interaction between the private and public sectors has much to do with the genesis and diffusion of new technology. But it is hard to draw a clear line between too little and too much interaction.

As a variety of failed initiatives suggest – think of the protection of the American steel industry or the aborted efforts to produce synthetic fuels in the 1970s – aggressive intervention may undermine more market-driven progress. Well-researched strategies, stakeholder agreement and commitment, and sound execution are all essential to cost-effective intervention.

Here, we offer some observations on government-private sector interaction in one key technology-driven sector: biopharmaceuticals. Think stem cells (public vs. private funding), intellectual property (Viagra in China), drug reimportation (price controls), student visas (Chinese students in Germany), academic-government-industry relationships (stock options held by NIH staff) and translational research (what's a patent?).

INTELLECTUAL PROPERTY RIGHTS

The lack of global consensus on the definition of intellectual property and the terms under which it is legally protected creates un-

certainty and limits opportunities for technological advancement. The consequences are most striking, perhaps, in the area of biotechnology. Inadequate protection of innovation, as well as inadequate protection of trade secrets, such as test data, undermine prospects for profits in pharmaceuticals and thus undermine incentives to invest in R&D.

Consider the large and rapidly growing market for therapeutics in China. Beijing is notorious for its lax enforcement of foreign IP rights and deference to domestic interests, which has led many multinationals to be cautious about establishing major operations there. Last year, for example, China's State Intellectual Property Office withdrew Pfizer's domestic patent for Viagra after it was challenged by 13 Chinese pharmaceutical companies. It seems that the patent failed to meet "technical standards," because Pfizer discovered the drug's true value by accident.

Many believe that the Viagra case is a litmus test of whether China is serious about adhering to international standards on intellectual property protection. As the head of Pfizer's China-based operations noted, "any major change in the IP rights environment threatens not only our company, [but] any

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research and development company, whether you're investing in pharmaceuticals or electronics." It should also be of concern to prescription drug consumers in the United States; if IP rights aren't upheld in major export markets, foreign sales of therapeutics will decrease and prices in the U.S. will rise as firms are forced to cover more of their R&D investment costs in the American market.

The lure of China remains strong, however. One of the prime reasons is the increasing attractiveness of its educated workforce. China has 17 million university and advanced vocational students (up more than threefold in five years), the majority of whom are in science and engineering. China will produce 325,000 engineers this year – five times as many as in the United States, where the number of graduates has been declining since the early 1980s.

Although the research gap between China and the United States remains vast, foreign companies are quickly moving to integrate Chinese facilities into their global research operations. For along with the prospect of solid returns on R&D investments, establishing a technological presence in China can pay off in terms of favored market access. While the World Trade Organization forbids formal bargains that demand technology transfers, it cannot monitor informal winks and nods.

A Department of Justice task force report calls for greater global cooperation on piracy issues; the report estimates that counterfeiting of pharmaceuticals worldwide represents 8 to 10 percent of sales. But concerns regarding IP rights go well beyond the issue of piracy.

Public-health groups around the world are urging wider use of generic versions of drugs,

even at the expense of property rights considerations, in order to lower the cost of treating diseases in poor countries. Because the United States is the world leader in R&D, U.S. trade negotiators have sought to strengthen protections on brand-name drugs. Even when they succeed, patent holders pay a penalty in terms of private litigation costs.



The broader lesson here is that globalization often brings friction. Harmonization in regulation, with the U.S. playing a key role, has to be a high priority.

RESTRICTIONS ON AVENUES OF RESEARCH

Stem-cell research holds enormous promise for curing disease. Yet current policies on federal grants curtail use of stem cells from embryos. One consequence: the United States may lose its competitive edge in a critical sector of biotechnology.

The private sector is still free to fund embryonic stem-cell research (or to ask the taxpayers of California for a helping hand). But as a practical matter, the research is in too early a stage to attract venture capital. As great as the promise of finding cures to

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Parkinson's, Alzheimer's and other life threatening ailments may be, the outcome is too uncertain and too distant to lure investors who typically have a maximum time horizon of five years.

The world's top research scientists are, as a practical matter, highly mobile. Thus, scientists, interested in pursuing their career interests in restricted research areas, may leave the United States for countries with more open policies. Indeed, several top researchers in stem cells have already left the United States for Britain.

Some 187,000 patents were granted in the United States in 2003. And while some were frivolous or purely defensive in nature (see the book excerpt in this issue on page 59), economists stress the significance of intellectual capital accumulation – of which patents are a major component – in explaining differential rates of economic growth. To the extent that inventors stay offshore due to this country's restrictive research policies, fewer patent discoveries related to stem-cell research are likely to originate in the United States – and thus fewer positive spinoffs are likely to be realized here. The newly re-elected administration, which won't face another national campaign, should re-examine the federal government's stem-cell research funding policy.

As noted above, the federal government's stem-cell policy is being usurped at an individual state level. One may question the soundness of state funding for such basic research, but California's strategy does represent a positive step toward keeping the world's sixth largest economy competitive in a critical technology. Other states apparently plan to follow suit.

DRUG IMPORTATION

Under current U.S. regulations, the FDA pro-

hibits importation (or reimportation) of pharmaceuticals – regulation that is nominally based upon safety concerns. Several state and local governments have authorized importation from Canada, in direct violation of FDA rules. And while President Bush will no doubt be under pressure to reconsider the ban, the long-term costs in drug innovation would surely outweigh the short-term benefits.

Few “Canadian” drugs are actually produced in Canada – most are imported from the United States or third countries. But Canadians pay less than American retail customers because the Canadian government regulates maximum wholesale drug prices. Now, someone has to cover the spectacular costs of R&D in the biopharmaceutical industry. And if Americans, in effect, reduce drug makers' capacity to price discriminate by importing Canada's drug price regulation, the private sector will have less incentive to innovate.

Research shows that biopharmaceutical R&D is positively correlated with profits. To the extent that reimportation leads to reduced firm profits, enabling reimportation will lead to less R&D in the United States; fewer drugs will be brought to the market and U.S. competitiveness will suffer. More important, if the incentives for innovation (profits) are diluted, an important discovery in treating or finding a cure to prostate or other types of cancer may be eluded or postponed.

As Dr. John Lechleiter of Lilly and Company recently argued, “under price controls, we probably would have to resort to tweaking existing drugs rather than taking expensive risks on new molecules.... The drug and biotech industries would almost certainly undergo consolidation, eliminating jobs.”

The ideal solution is greater international burden-sharing in prescription drugs. But the



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only way to get from here to there is through international negotiation.

STUDENT VISA REGULATORY APPROVAL PROCESS

Since 9/11, the U.S. State Department, has, understandably, taken a more cautious approach to entry by foreigners. However, the ramifications go beyond the intended benefits to national security. Student visa restrictions and processing delays have created backlogs that are proving to be a disincentive to foreign study in the United States. And one consequence is to reduce both the size and vitality of the biopharmaceutical research establishment.

These student visa problems not only affect the American economy's long-term pros-

pects for innovation, but harm it in the near term as well. U.S. exports of education services contribute over \$12 billion to GDP. But the number of international students at U.S. colleges and universities hit a plateau about two years ago and began to decline last year. Meanwhile, graduate school applications by foreigners in the 2003-2004 academic year fell by 32 percent – with some of the largest declines in applications from India, China and Taiwan, the new foreign centers of engineering and science.

As international applications at U.S. academic graduate programs decline, European institutions are witnessing a surge in enrollment. In the past three years, international enrollment at German institutions rose by an average of 20 percent annually. U.K. colleges

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and universities have witnessed large gains as well, and Japanese institutions are attracting more students from other Asian nations.

Advanced research institutions in the United States are now spending more time and resources to guide students through the visa application and interview process. But the U.S. government must play a role here, eliminating impediments to entry by foreign students that do not compromise the country's security.

The Milken Institute's research on the biopharmaceutical industry reveals that the states that lead in patents issued are also home to the leading research universities. Government policies that undermine the competitiveness of American universities may thus also undermine economic development.

ACADEMIC-INDUSTRY-GOVERNMENT RELATIONSHIPS

R&D is becoming increasingly collaborative, making it necessary to better define the rights and obligations of the parties involved. Government agencies, including the Public Health Service and the National Science Foundation, established regulations in 1995 regarding individual financial conflicts of interest. Three years later, the FDA adopted its own set of rules for disclosing and managing financial conflicts of interest. Meanwhile, the Department of Health and Human Services has been working on guidelines to protect human subjects. For their part, professional organizations – notably the Association of American Medical Colleges – have assumed a leadership role in setting policies for academic/government/industry relationships in clinical trails and data confidentiality.

But as the issues grow more complex, more must be done to promote fruitful relationships between government, nonprofit

research institutions and private enterprise. “Translational research,” or the immediate sharing of research findings on the Web, is the latest step in scientific research collaboration. Yet for reasons of profit or professional competitiveness, access to biopharmaceutical research is typically restricted.

Some funding organizations, including the National Institutes of Health, the Christopher Reeve Paralysis Foundation and the Michael J. Fox Foundation for Parkinson's Research, now mandate translational research for at least some of their grant monies. It would make sense to revise government regulations to encourage translational research while protecting the property rights of contributors.

Note that biopharmaceuticals represent a huge source of income to this country as well as a font of life-extending technology. In 2003, the sector directly employed 406,700 workers in the United States; when the full multiplicative impact is figured in, it was responsible for some 2.7 million jobs. That same year, the average annual salary in the industry was a remarkable \$72,600.

Note, too, that the U.S. biopharmaceutical industry was directly responsible for \$63.9 billion in real output in 2003. And it remains a bright spot in the mixed American experience in international trade. The value of pharmaceutical exports increased from \$3.7 billion in 1989 to \$16.2 billion in 2002.

The United States is the global center of this dynamic, knowledge-based industry. But this is no time to rest on our laurels. The failure to protect intellectual property rights, to fund basic research in controversial areas, to do what is necessary to attract bright foreign students in the field, or to facilitate rapid diffusion of scientific knowledge could cost America its leadership role. For better and worse, the whole world is watching. **M**