nature biotechnology

Open secrets

The world's richest nations dominate biotechnology. They are the major innovators, funders and consumers of biotechnology's products. They are the ones that have benefited in terms of jobs, productivity, wealth and health. Developing countries hardly get a look. Why would they? Biotechnology is difficult enough when markets are lucrative, R&D spending is high and economies are stable. Yet developing countries are often cast as those in most need of biotechnology's products. Too little information is shared about the ability of poorer nations to harness biotechnology for their own needs—how they can use recombinant technology to build their own wealth and improve the well-being of their own people. This supplement seeks to address these issues.

Health Biotechnology Innovation in Developing Countries presents findings from a three-year study of the biotechnology sectors of seven countries (Brazil, China, Cuba, Egypt, India, South Africa and South Korea); it is the brainchild of a group of researchers at the Canadian Program on Genomic and Global Health at the University of Toronto Joint Centre for Bioethics. For each country, data and information were gathered from interviews with local experts, background documents, the scientific literature and patent databases. The study sought to highlight biotechnology successes in these countries and the means by which these successes were achieved, with a view to reproducing them more widely in other parts of the developing world.

One of the most important lessons to emerge is that biotechnology is a long hard slog. Governments that see it as a means of growing their economy and augmenting the health of their populations must commit to funding for many years, often with little hope of return. It takes time to build all the elements—an advanced education system, a requisite level of scientific excellence, a business-friendly set of intellectual property laws and an adequate regulatory infrastructure and healthcare system—needed to promote venture creation and the commercialization of products.

Even if all these elements are in place, there are still no guarantees. Biotechnology is a leap of faith for investors in industrialized countries; imagine how hard it is in countries where R&D expenditures may be only a fraction (usually less than a quarter of that in industrialized nations) of gross national product, skilled and educated labor is at a premium, intellectual turf wars stifle collaboration, economic difficulties and inflation are rampant, venture capital investors are an unknown species, intellectual property protection is murky and political turmoil is a frequent backdrop.

Under such conditions, one might argue that trying to establish a biotechnology presence would be folly. But sometimes fools who persist in folly become wise. And as this supplement shows, developing nations that have persisted in promoting biotechnology have found several ways to succeed.

One approach has been to exploit lax local intellectual property laws to enable the creation of ventures that can copy from industrialized nations brand products that address local unmet medical needs. By producing these products internally at cheaper prices, developing countries can reduce dependence on expensive imports of Western brand drugs, generate income for their own economies and, by improving the health and wellness of their populations, indirectly reduce healthcare spending and increase economic productivity.

This expertise in producing recombinant products to good manufacturing practice standards is likely to prove increasingly attractive to foreign investors and Western biotechnology companies seeking to cut costs by outsourcing protein manufacture. It seems likely therefore that manufacturing operations will increasingly migrate from the West to generic companies in developing countries with manufacturing expertise. There is also the possibility that markets in rich nations may open to generics companies from poorer nations as first-generation recombinant proteins lose patent protection and the possibility of biogeneric approvals comes closer. At the same time, the profitability of the generics business should enable reinvestment in R&D and more innovative products. This may become a necessity as developing nations implement the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and are forced to adopt more stringent patent protection law. Whatever the case, developing countries like India will need to tailor their intellectual property law to ensure that they create an environment that encourages innovative enterprises, yet does not stifle existing generic businesses.

Vaccine production is another opportunity for developing nations. Because the technology is relatively simple and overheads are low, companies and institutes in developing countries have a chance to compete with existing vaccine manufacturers, a sector currently in decline in industrialized nations because of poor profit margins, problems with litigation and regulatory changes. Thus far, most success has been in producing generic versions of existing recombinant vaccines, but innovative products, such as Cuba's meningitis B vaccine, have also been created. Here again, the potential for cheaper generic vaccines may extend from home markets to those of other developing nations, and if manufactured under the appropriate standards, innovative vaccines might also be sold in the markets of rich nations.

All that being said, it is necessary to reemphasize the obvious: biotechnology is clearly no panacea for the health problems of developing nations, and as an endeavor for producing wealth it can take decades. Innovative enterprises require huge amounts of investment before they produce products and profits; generic companies require less and reap rewards faster. But if governments in developing nations are prepared to stay the course, the benefits could be substantial. As the United Nations Development Program has noted: "Biotechnology innovation and globalization is a means of helping the poor of the world live fuller, richer and more secure lives." Thus far, few have seen those benefits. But on the basis of evidence in this supplement, this may be changing: biotechnology for the few may soon become biotechnology for the many.

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