THE LAST WORD

Brazil's Stake in Biotechnology

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B razil has long been viewed by the world's pharmaceutical and biotechnology industries as having vast natural resources that could potentially provide new cures for diseases that continue to plague the globe. However, due to Brazil's restrictive patent laws, neither multinational nor local pharmaceutical companies have had any incentive to fund research and development (R&D) in Brazil, either on their own or in joint ventures.

If pharmaceuticals become patentable, as mandated by the General Agreement on Tariffs and Trade, which Brazil has signed, there is a fundamental question to which the Brazilian government, politicians, scientists, and industrialists are all trying to find an answer. Forget about theory, they say. Just answer the question: What's in it for *Brazil*? To that, I will try to give an equally straight answer: Finding a *national* place in *global* science and technology. That is not easy. No one believes that it will be. One thing is certain: Without patent protection, there is little hope of emerging from today's effortless copying culture into the tougher world of innovative research and development in pharmaceutical chemistry and biotechnology.

It remains, of course, a matter of choice. Perhaps Brazil prefers to opt out, as many developing countries have done and are doing. If so, nothing is simpler than passing a *pro forma* patent law that is as protective of pharmaceuticals and biotechnology as a sieve with holes in it. An urge to opt out is not, however, the impression that was given to me during my interviews with over 20 important members of the pharmaceutical industry and independent experts in Brazil. Far from it. Very few respondents said that they prefer copying to innovation. The majority felt that innovation is desirable, but wondered whether it will be possible. In other words, *difficulty* is the heart of the matter.

Patent protection does not guarantee success. The majority of patented inventions are never industrialized. Patents are there to underwrite innovative effort by ensuring that the results of R&D can be rewarded and are not simply taken home by noninnovators. During my interviews on the subject of Brazil's infrastructure, I was given a virtually unanimous view that Brazil is well placed, scientifically, in biotechnology; more so, perhaps, than in pharmaceutical chemistry. The problem is not lack of scientific skills or originality, but a need to improve the link between universities and industry. That, I suggest, is not an incurable disease, but one that will respond to treatment.

Profitability in the pharmaceutical industry in Brazil has improved significantly since the liberalization of drug price control and the establishment of constructive dialogue on prices between government and industry. Companies that were consistently making losses have come back into profits since 1993. Most of this improvement has occurred in the 85% of the drug market which is free of patent cover. This provides national industry with an important clue to the task of adapting to a future under patents: bridging the gulf that currently exists between the producers of pharmaceutical chemicals and drug formulators.

Brazil possesses the necessary skills for chemical process development—the key to productive investments in this area. Today, patent-expired generic drugs are rapidly emerging as a world market in which any country with low-cost quality production of pharmaceutically active substance can compete successfully.

Strong patent protection would not, in my personal opinion, aggravate hostilities between national and multinational drug companies, but would help to heal the wounds of the past. That is not a paradox, but a logical consequence of the process of adaptation that patent protection would galvanize throughout industry. Research-based multinational drug companies need strong patent protection in order to continue investing in innovative R&D with its high risk of project failure. They cannot and, I am convinced, will not compromise on this issue.

With proper patent cover, the door to international collaboration will open, first on the scientific front The signs are clearly pointing toward a substantial increase in research and training contracts between multinationals and Brazilian universities, once patent protection for pharmaceuticals and biotech is a fact and not an obstacle. This, in turn, would help to strengthen infrastructure and release creative energy that until now has been held captive. A second area of collaboration that would open up is contractual comarketing of new patented drugs by multinational and national companies.

Strong patent protection will also induce or accelerate adaptation by national producers of pharmaceutical chemicals and formulators. There are opportunities to invest productively in the unpatentable and patentexpired segments of the drug market. Given suitable government incentives, strategic objectives could be redefined, focusing on the world market for patent-free drugs as the ultimate target. That, in turn, would help gradually to turn Brazil's chronic trade deficit in "medicinal and pharmaceutical products" into a surplus. In all of this, the role of government is of critical importance. The creation of the right economic and business climate will stimulate constructive endeavor and investment in science, technology, and industry. Strategically, for pharmaceuticals and biotechnology, one of the vital elements in providing a climate of encouragement will be strong patent protection. ///