

# Green Idea!

**Brazil backs private IP efforts to harvest the wealth of its rain forests.**

**By Michael P. Ryan**

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hen a man in Brazil injured his knee playing soccer, a local healer urged him to apply the leaf alcohol of the maria milagrosa plant to relieve the swelling. It worked. The soccer player, who was also a founder of the French-Brazilian drug maker Aché, was impressed with the market potential for such a remedy in a country full of soccer players. He recruited a University of Sao Paulo scientist to isolate the active compound.

But that was the easy part. Who would pay to develop the best formulation of a new anti-inflammatory drug? Who would pay for the toxicology studies? Who would pay for the laboratory tests, the animal trials, and the

human trials? If all these investments were made, how could competitors be prevented from analyzing the chemical composition of the final product and selling it under their own brand names?

This story took place in Brazil in the early 1980s, so competitors couldn't be stopped: Two decades ago Brazilian law did not permit the patenting of pharmaceuticals. And that meant the answers to all the "who would pay" questions were just as negative: not Aché and, indeed, no one.

The failure to capitalize on Brazil's rich biodiverse resources to create a medically successful, commercially

profitable drug symbolizes all that was wrong with Brazilian innovation. Government scientists may have seen the myriad possibilities. But lack of financial investment in the private sector severely constricted the pipeline from laboratory to marketplace.

Flash forward to 2006: New appreciation for intellectual property rights and private enterprise is finally making Brazil-based commercialization possible. The country is sustainably tapping a great natural resource. And one of the first beneficiaries of the changed climate is none other than Aché, with its cure for sore knees.

### **GOING FOR THE GREEN**

Brazil has long recognized that the vast jungles traversed by the Amazon River hold tremendous wealth. But traditionally efforts to exploit these resources have focused on drilling for oil and natural gas, mining for minerals, cutting trees, and planting agricultural crops. The fact that Amazonia possesses the world's greatest biodiversity—extraordinary flora and fauna seen nowhere else—was ignored, commercially speaking.

The opportunities for advanced biomedical research were simply not a priority for Brazilians. Companies were reluctant to invest in the long process of research and development. And the public and private sectors did not work together.

Until recently. The change began in 1996. After several years of acrimonious bilateral diplomacy—including threats of trade sanctions—with the United States and a year after the World Trade Organization's Trade-Related Intellectual Property Rights Agreement (TRIPS) went into effect, the Brazilian government undertook a major reform of its patent law. The new patent regime permitted patents on pharmaceutical products and processes, provided a 20-year term of exclusive rights, and barred parallel imports of patented products. Suddenly drug inventions could be protected in Brazil.

### **FRESH INTEREST**

That same year Aché's founding families decided to hire a team of executives with experience in global pharmaceutical management. The new president articulated a new business strategy—to partner with multinational companies to market drugs previously unavailable in the Brazilian marketplace, and to push Aché itself into the innovation business.

The new R&D director heard the story of the anti-inflammatory remedy that had never been developed and saw real market potential. Because Aché lacked its own internal R&D capabilities, it sought partnerships with universities and hospitals to establish a program of toxicology research, animal testing, and human trials. Aché paid for this initiative by, among other things, winning a government grant.

Seven years of study, testing, and trials demonstrated the *maria milagrosa* compound to be both effective and safe. The Brazilian counterpart to the U.S. Food and Drug Administration approved the compound for sale in November 2004. Aché also filed for patent protection in Brazil, the United States, and Europe. The anti-inflammatory cream Achéflan went on the market in the summer of 2005.

Achéflan is apparently the first patent-protected biomedical product to be developed by Brazilians from a natural resource. And it was an instant hit with professional soccer players, weekend athletes, and doctors.

Buoyed by its medical and financial success, Aché has gone on to establish more R&D partnerships with universities. Together, Aché and its partners are seeking to develop therapeutic treatments in such areas as anxiety, diabetes, high blood pressure, liver disease, and sleep disorders. It's likely that none of this investment would have seemed like a reasonable risk without the 1996 patent law changes.

### **LET'S MAKE A DEAL**

Other Brazilian drug makers are also stirring the creative juices. Two companies, BioLab and Biosintetica, have formed an R&D strategic alliance because, in the words of one manager, "innovation is fundamental to survival." Their first-of-its-kind initiative in Brazil was five years in the making. Its goal was to develop new drugs from Brazil's many snake and insect species.

The partners, whose independent R&D efforts have resulted in some three dozen international patents between them, saw in each other complementary business capabilities. But they realized that they also needed to connect with university researchers. Not surprisingly, BioLab and Bio-sintetica managers report that their collaborative agreements with academia were difficult to negotiate. (Aché tells a similar story about its research arrangements with universities and hospitals.)

In general, universities in Brazil did not have experience with these kinds of collaborative relationships. Academic researchers did not trust the private sector as partners. They also lacked both know-how and capabilities with respect to intellectual property management. And they brought to the table some unrealistic expectations regarding risks, rewards, and royalties.

But over time, the BioLab and Biosintetica negotiators built up a level of mutual trust. Eventually, they figured out how to protect everyone's interests to everyone's satisfaction. To date, the R&D partnership has yielded 11 international patents, although it has not yet brought any innovative new products to market.

### **SELECTIVE SCIENCE**

The successes of BioLab, Biosintetica, and Aché, while

heartening, just begin to point the way to more public-private pairings.

For many years, the Brazilian government has made significant investment in the country's public research universities and national laboratories. This investment has been most pronounced in the State of Sao Paulo, which dominates the Brazilian economy. For 50 years, the State of Sao Paulo Research Foundation—commonly known as FAPESP (Fundação de Amparo à Pesquisa do Estado de São Paulo)—has funded basic scientific research and graduate education at the University of Sao Paulo, the University of Campinas, and Paulista State University.

The biomedical research base in Brazil also includes two important publicly supported research institutes, the Instituto Butantan and the Oswaldo Cruz Foundation. As operations of the Ministry of Health, both institutes seem to have been organized to create biomedical development and production capability for government-owned pharmaceutical facilities, which in Brazil produce some 200 different drugs and vaccines. But the institutes have not traditionally served to encourage much innovation or to push the commercialization of technology through public-private partnerships.

The problem for Brazil has been that all the public investments in basic science and technology have not yielded many marketable products. And the private sector in general still invests too little in R&D. FAPESP data show that two-thirds of R&D spending comes from the government; only one-third is invested by the private sector. Seventy-five percent of scientists and technologists work in the universities; only 18 percent work in private business.

Most R&D carried out in the Brazilian private sector occurs in the agriculture, aircraft, and energy industries. Until very recently, private-sector biomedical R&D was close to nil. Few companies run their own research laboratories. There are not many private-sector jobs for biomedical graduates and thus modest incentives to pursue higher education in the biomedical sciences.

Clearly, something needed to be done to jump-start the engine of private innovation.

### **AMAZON PARTNERS**

In December 2004, the Brazilian government promul-

gated another major legal reform, the Technology Innovation Law. The purpose of the legislation is to encourage more public-private cooperation by making it easier for public and private enterprises to share resources, raise capital, and clarify intellectual property rights.

Eight provisions are key:

- Public research institutes are permitted to share their laboratory facilities with private-sector enterprises.
- Public research institutes and private-sector enterprises are permitted to enter into capital relationships for the purpose of R&D.
- Public and private partners may specify the ownership of any future intellectual property rights by contract.
- Public research institutes and their employees must protect trade secrets associated with their research.
- Public research institutes may license their technologies to private enterprises.
- Individual public researchers may share in the economic returns associated with the successful commercialization of a new product.
- Public researchers may take leave from their public positions in order to work for a private enterprise.
- Government development agencies should provide financial and human-resource assistance in support of private-sector R&D.

Last summer the government released more specific details as to how the law would be implemented.

Other developing countries, especially those with similarly underexploited biodiverse resources, should be taking notes. By substantially reforming its patent law and removing major institutional barriers to technological development, Brazil has made certain that innovation will not end with Achéflan. The stage has been set for the next fruitful act in Brazil's quiet biomedical revolution.

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