Gastrointestinal Medicines from African Aloe: Baylabs (Pty) Ltd.

The plant species *Aloe ferox*, indigenous to the eastern and southeastern Cape regions of South Africa, has sustained an aloe tapping industry for more than 250 years. However, the industry has failed to substantially improve the economic conditions of communities in the region. Between 1,600 and 3,000 aloe tappers earn, on average, $150 per month.

In 1998, a method for producing a novel fiber in powder form from the discarded leaves of the plant was patented by South Cape Aloe (SCA). A virtual startup company with a strong emphasis on technology and intellectual property (IP) was subsequently formed in South Africa to develop a product to treat irritable bowel syndrome (IBS) and AIDS-related diarrhea (ARD).

The company, Baylabs, aims to form local partnerships to develop, manufacture, and distribute the product to both developed and developing countries. Baylabs' strategy is to focus on R&D to generate and protect intellectual property and products, while outsourcing noncore functions such as manufacturing, sales, and distribution.

SCA granted the manufacturer African Aloe exclusive rights to make the powder and gained a share hold in Baylabs in exchange for exclusive, royalty-free, worldwide rights to exploit the powder. Baylabs filed a Patent Cooperation Treaty application for the novel powder formulation, with national filings in 13 European countries and prosecutions in the United States, Japan, Australia, and China.

Baylabs has developed four over-the-counter natural remedies from *A. ferox* that are distributed to pharmacies. The revenue generated is used to file patents and obtain scientific evidence of efficacy for gastrointestinal (GI) problems. The products will continue to be marketed and regulated as a dietary supplement while scientific evidence is being gathered and until the product is registered as a medicine.

The company's value has grown through its intellectual property and clinical trials of IBS and infantile diarrhea disease (IDD). Discussions are underway with international strategic partners regarding exclusive license agreements; efforts to secure government or venture capital funding are in progress. Baylabs plans to build preprocessing field plants and a facility to manufacture the powder, with the aloe tapper community as an equity partner, which could lead to increased salaries (almost double) for aloe tappers.

There is no traditional knowledge (TK) involved in using the waste leaf but TK exists in using the *A. ferox*. A key feature of this case study is the potential for other treatments; the formulation can be used for IBS in developed countries and ARD in developing countries. Once clinical trials have been completed, Baylabs plans to register the product as a medicine. However, the advantages of registering the product as a drug rather than as a food supplement have been questioned. Such registration would require, among other things, strict manufacturing quality standards and could be fraught with regulatory difficulties. Many intended herbal remedies, if subjected to full clinical trials and toxicity (as required by regulation), would not meet these standards.

In natural products a key issue is long-term planning and supply. If the product were to become a blockbuster, arrangements would have to be made for the community to benefit, such as through a trust fund. It is important to recognize traditional harvesters and

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Editors' Note: An earlier version of this case study was presented at the MIHR conference Using Intellectual Property for Improved Health in Developing Countries: An Evidence-Based Approach to Good Practice, Bellagio, Italy, June 14–18, 2004.

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traditional plant users and their stake in bioprospecting. Baylabs is set to give the aloe tapping community a stake in the project.

The Baylabs example illustrates how the development of a technology can have positive commercial and positive moral outcomes. Through the creation of strategic alliances and partnerships, there can arise opportunities for securing and developing intellectual property for the benefit of underserved communities in both developed and developing countries.

TYPES OF AGREEMENTS

As part of the GI medicines from African aloe project, Baylabs has entered into the following types of agreements:

- exclusive patent license agreement
- exclusive supply agreement

IP RIGHTS DECISIONS AND IP MANAGEMENT

Baylabs has faced key areas of IP rights decision making and strategic IP management issues including:

- securing a strong IP portfolio through international filings, scientific proof-of-concept, and rigorous clinical trials
- securing ownership of intellectual property and outsourcing noncore functions

POLICY IMPLEMENTATION

The SA Medicines Control Council (MCC) is presently formulating policy on traditional and herbal medicines. Companies are therefore able to place over-the-counter products in the market without clinical trials. These may not make any medicinal claims. This enabled Baylabs to place four elementary products (aloe gel, a high fiber tablet, a laxative tablet, and an antiarthritic tablet containing aloin as the active ingredient) on the market and to secure income from their sale. These products had to be submitted to the traditional medicines registry at the MCC to enable continued manufacturing and sales.

EXTERNAL FACTORS THAT AFFECTED DECISION MAKING

A number of considerations influenced Baylabs' strategies and decision making. These include:

- burden of disease from ARD in developing countries
- burden of disease from IBS in developed countries
- commercial opportunity from IBS
- indigenous occurrence of *Aloe ferox*
- opportunity to exploit a by-product of the aloe tapping industry
- regulatory issues relating to aloe mixture
- opportunity to alleviate IDD

KEY LESSONS LEARNED

The following items represent key lessons from the Baylabs GI Medicines/Aloe project, which may be applicable to other companies that aim to utilize intellectual property:

- have a moral as well as a commercial reason for existence (improve living standards of aloe tappers and alleviation of ARD, IBS, and IDD)
- have a global commercial opportunity, which big pharma has been unable to effectively address (IBS—a US$15 billion annual industry)
- create and protect intellectual property (registers serious intent)
- create alliances and partnerships
- a startup can be successful operating as a virtual company and securing IP ownership
- choose partners with a shared value system
- have a good IP attorney (preferably in-house)—there are always issues! ■

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