

Case Study: Hoodia Plant¹

January 2008

Executive Summary

This concerns a dispute and subsequent partnership between the San people in South Africa and pharmaceutical companies in developed countries over the ownership and the right to commercially exploit as well as benefit sharing of the use of Hoodia plant which contains traditional medicinal knowledge and patentable active components. An appetite-suppressant drug developed by pharmaceutical companies are faced with counterfeiting drugs. The case involves several players in different countries and poses a number of questions on IP management, transfer of technology and knowledge between the North and the South and mutually beneficial and sustainable partnerships of all the parties.

I. Descriptive Part

1. Title: Hoodia Patent
2. Country: South Africa, United States of America, and United Kingdom
3. Key Words: Hoodia, plant, food, drug, medicines, milestone payments, patent, license, benefit sharing, traditional knowledge, indigenous people, counterfeiting, PCT.
4. Facts:

The San people have lived in the Kalahari Desert in South Africa for thousands of years. The San have used the bitter flesh of the Hoodia plant (*Hoodia gordonia*) for centuries to block feelings of hunger and give them energy when hunting or on long trips across their inhospitable land. This practice was brought to the attention of the South African Council for Scientific and Industrial Research (CSIR), based in Pretoria, which began to take an interest in the properties of the Hoodia in the 1960's. The innovative environment in which the CSIR functions allows it to carry out much important research and development (R&D). The work resulted in this case in certain properties of the Hoodia (called "P57") and of their potential as an appetite-suppressant and anti-obesity drug.

¹ This case study was prepared by WIPO Academy on the basis of WIPO Magazine articles and other public information for the purpose of IP education and training.

Initially, the CSIR was criticized for exploiting the San's knowledge without appropriate recognition of the San's knowledge and benefit sharing with them. After a controversial process involving some legal negotiation, the role of San, its traditional knowledge and innovative activity in the initial discovery and development of the properties of the Hoodia were recognized, explicitly acknowledged by the CSIR, and set out in a memorandum of understanding (MoU) between the CSIR and the San.

The CSIR filed an international patent application through the Patent Cooperation Treaty (PCT) (WO98/46243 (publication number), filed on April 15, 1998, covering more than 100 countries) on the basis of its national application (national application number 97/3201, filed on April 15, 1997). In some countries, including the United States of America, it was patented (US6376657). It covers pharmaceutical compositions which were extracted from Hoodia plants and identified as chemical products having appetite suppressant activity.

The market potential of a new drug containing such pharmaceutical compositions is considerable, particularly as it is derived from a natural product and, seemingly, does not have the side effects of many such treatments. However, the CSIR, a semi-public research institute, has realized that its capability to further develop and market a new drug was limited.

Then the CSIR decided to license its patent to Phytopharm, a UK-based company, for the necessary investment needed to further test, develop and commercialize this new patent product. The MoU was followed by a benefit-sharing agreement, providing for the San to obtain eight percent of all milestone payments received from the licensee by CSIR as well as six percent of any royalties CSIR receives on sales of the final product. Reports estimate that the milestone payments will amount to some US\$1 to \$1.5million, while royalty payments could bring additional millions to the economically poor San. The milestone payments will be paid during the clinical development stage on the successful completion of certain technical performance targets. It is reported that Phytopharm invested more than \$18 million in researching active fractions of the Hoodia plant that are said to suppress appetite, including a human clinical trial.

The development of this Hoodia-derived product has had several important consequences for the San. It has resulted in the 100,000-strong San population organizing and setting up the San Hoodia Benefit Sharing Trust, which will ensure that the monies received are used for "the general development and training of the San community." The trust is composed of three representatives appointed by the San Council, a CSIR representative, a non-voting observer from the South African Department of Science and Technology, three representatives appointed by the Working Group for Indigenous Minorities in Southern Africa (WIMSA), a member of WIMSA, and a professional appointed by the San Council. Immediate plans include buying land, building clinics and investing in education and development projects. The lawyer representing the San in the Hoodia case, Roger Chennells, says the ground-breaking, benefit-sharing agreement "represents enormous potential for future bio-prospecting successes based on the San's extensive knowledge of the traditional uses of indigenous plants of the area. We are optimistic that this case will serve as a sound foundation for future collaboration, not only for the San but also for other holders of traditional knowledge."

By the time the CSIR concluded the above-mentioned MoU in 2002, the CSIR's first potential partner in P57's development and sales, an American pharmaceutical company Pfizer, had pulled out. The CSIR then signed up another company Phytopharm, as licensee. Phytopharm is a UK company focusing on plant extracts as functional foods and veterinary products. It proceeded to clinical trials and at the same time started plantations to grow sustainable quantities of Hoodia gordonii. A new drug is expected to be marketed in 2008.

However, by 2003, Hoodia preparations in capsule and liquid form were pouring into the market place, sold by farmers to legitimate nutritional diet supplement companies. The CSIR's patent is on the molecule, P57, and not on the plant itself.

In December 2004, Phytopharm licensed P57 to Unilever for use in a new range of weight loss products and chose to work with it as its marketing partner.

Phytopharm and Unilever are aware of companies that are selling products over the internet and in stores claiming to contain Hoodia and causing weight loss. Phytopharm and Unilever are in discussion with the authorities concerning this development.

Trouble is, the patented product is not yet on the market. The necessary clinical trials and other studies to ensure the safety of the extract will take a few years before a product will be available, probably in 2008. Meantime, all of the Hoodia products that are on sale seek to bypass the patent. Isolation of the molecule requires complex processes that do not apply to the raw plant extract.

II. References

1. "Intellectual Property as a Lever for economic growth, The African Experience, Part II," WIPO Magazine November/December 2003, pages 6 and 7;
2. "Struggle over Hoodia patent continues" Business Day, Johannesburg: Jul 12, 2006, page 6;
3. "Hoodia: Business Opportunity or Dangerous Business?"
4. Nutraceuticals World, September 2005, at www.nutraceuticalsworld.com
5. "Hoodia's uncertain future in Europe", May 18, 2005, foodnavigator.com