Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant

By Rachel Wynberg[1]

Published in The Journal of World Intellectual Property

November, 2004, Vol 7, no. 6, pages 851-876.

Citation: Wynberg, R. 2004. Rhetoric, Realism and Benefit Sharing: Use of Traditional Knowledge of *Hoodia* Species in the Development of an Appetite Suppressant. Journal of World Intellectual Property, 7(6): 851-876.

I. Introduction

> This is the real ghaap of the natives, who use it as a substitute for food and water. The sweet sap remindsone of licorice and, when on one occasion thirst compelled me to follow the example of my Hottentot guide, it saved further suffering andremoved the pangs of hunger so efficiently that I could not eat anything for aday after having reached the camp.
>
> **Marloth (1855-1931)**

One of the first agreements ever to give holders of traditional knowledge a share of royalties from drug and product sales was recently concluded between the CSIR, a South African state research institute and the San, indigenous peoples of southern Africa. The case concerns the development of an appetite suppressant derived from species of *Hoodia,* succulent plants indigenous to southern Africa and long used by the San, indigenous peoples of the region, to stave off hunger and thirst[2]. Use of active constituents of the plant responsible for suppressing appetite has been patented by the CSIR, which represents one of the largest research organizations in Africa, accounting for about 10% of the entire African research and development budget[3]. The appetite suppressant is likely to be commercialised into a food supplement and/or prescription medicine, with considerable financial potential. The current market potential for the dietary control of obesity is over $3 billion per annum in the United States alone [4]. Up until 2001, the San remained oblivious to the fact that their knowledge of *Hoodia* had commercial application, and that this knowledge had led to research, scientific validation, and the filing of international patents by the CSIR. They were, moreover, excluded from lucrative deals being struck to develop the drug. In 2003, however, following intense negotiations, an agreement was reached between the CSIR and the San, to give the San a share of royalties from potential drug sales.

Issues raised by the Agreement on Trade-Related Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) and the Convention on Biological Diversity (CBD) are central to the case. Under TRIPS, a global regime has been created for intellectual property rights (IPRs) over biological resources. This has significant implications for member states, which are now obliged to implement minimum IPR standards, and to allow patents and other forms of IPRs to enter the realm of agriculture, food production and healthcare. The interface between IPRs and biological resources is also addressed by the CBD, which recognises the sovereign right of countries over their biological resources and their right to determine access to these resources[5]. The CBD notes that access to genetic resources should be on the basis of prior informed consent from providers of resources and knowledge, and on mutually agreed terms that provide fair and equitable sharing of the results of research and development and the benefits of commercialisation and use. It also calls for the fair and equitable sharing of benefits derived from the use of traditional knowledge.

These principles are encapsulated in the *Bonn Guidelines on Access to Genetic Resources*[6], adopted by parties to the CBD, and are likely to form the basis of the international 'access and benefit-sharing' (ABS) regime to be negotiated under the auspices of the CBD as mandated by the World Summit on Sustainable Development (WSSD)[7]. In contrast, TRIPS contains no provisions requiring prior informed consent and benefit-sharing. <

Intellectual property rights are often considered incompatible with traditional knowledge systems because they are privately held and monopolistic by nature, and are based on 'innovations' or 'discoveries', while traditional knowledge is typically collective and based on prior use[8]. Intellectual property rights have also often worked against effective and equitable benefit-sharing with local communities for their traditional knowledge, and have provided poor protection of community resource rights. For example, the U.S. Patent and Trademark Office granted a patent to a U.S. researcher on the South American vine ayahuasca, *Banisteriopsis caapi*, which is used widely in traditional religious and healing ceremonies in South America[9]. The Co-ordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Centre for International Environmental Law (CIEL) have worked for many years to annul the patent[10]. Patents have also been granted, and successfully challenged for their lack of novelty, based on traditional knowledge of *Azadirachta indica*, the neem tree[11]. Patents can also impact negatively on communities that traditionally use certain species and varieties. For example, the granting of a patent by the U.S. Patent and Trademark Office to Colorado University based on the food crop quinoa, lapsed after it was revealed that the Bolivian origins of the biological material were not disclosed and enabled the scope of the patent to be so broad as potentially to intrude on the exportation to the United States of traditional quinoa varieties and quinoa products exported from Bolivia and its neighbouring countries[12]. Numerous other examples exist of the illegitimate use of traditional knowledge in the granting of patents, without the consent of holders of such knowledge, or their involvement in any benefits derived from the patent[13].

The Hoodia case described in this paper tells a similar story but is unique in that the holders of the patent (the CSIR) and holders of traditional knowledge (the San) have reached a mutually acceptable agreement to share benefits. On face value, the case presents a good argument both for the utility of patents in benefiting holders of traditional knowledge, and for the potential benefits that holders of traditional knowledge can glean from bioprospecting. But what does this development really mean for the San and holders of traditional knowledge worldwide: business as usual with a politically correct face, or a fundamentally new way of introducing equity into the marketplace? Through the lens of the Hoodia case three distinct but related questions are asked in an attempt to enhance understanding of these intractable issues.

First, what can we learn from the negotiating process to develop a benefit-sharing agreement that can usefully be applied in similar situations? Second, is the benefit-sharing agreement one that secures fair and equitable benefits for holders of traditional knowledge, and for countries of origin, and if not, which aspects require further attention? Third, the role played by IPRs as a tool to promote benefit-sharing is explored, and both the legitimacy of the patent and alternative options for protecting indigenous knowledge, including co-ownership of the patent, *sui generis* systems of protection, and compulsory disclosure of the source of genetic resources and traditional knowledge in patent applications are discussed. These questions are explored sequentially below, after providing an overview of the ecology and use of *Hoodia* species (Section II), and a history of commercial development (Section III). In Section IV, I analyse the process by which the CSIR and the San negotiated a benefit-sharing agreement, and describe the content of the agreement. In Section V, I provide a critical review of the benefit-sharing agreement developed between the CSIR and the San, and in Section VI I analyse intellectual property considerations arising from the case. The final section of the paper draws these issues together with some concluding remarks.

II. The Ecology and Use of *Hoodia* spp.

Species of the genera *Hoodia* and *Trichocaulon* have long been used as thirst quenchers and appetite suppressants[14]. Both genera are succulent perennials, and members of the Apocynaceae family, adept at storing moisture during long dry spells in their native habitats[15]. More than twenty species have been recorded from southern Africa, although the species of most interest for their appetite suppressing properties are *Hoodia gordonii, Hoodia currorii, Hoodia flava, Hoodia lugardii (*now *Hoodia currori* subsp. *lugardi*), *Trichocaulon piliferum* (now *Hoodia piliferum*), and *Trichocaulon officinale* (now *Hoodia officinale*)[16]. Vernacular names for the plants include ghaap, and !khobab, |goa.-|, |khowa.b, |goai-|, |khoba, |khoba.b|s, |khowab, |goab, otjinove, !nawa#kharab, sekopane, seboka[17], [18], [19], [20], [21], [22].

Increasing interest in the commercial application of *Hoodia* species, and concomitant concerns about the

threats posed to plant populations through unregulated collection, have led to the (del recent) tabling – and recent adoption, in October 2004 - of a proposal to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) to include *Hoodia* species in Appendix II of CITES[23]. The proposal from range states is to establish Aa standardised international trading framework and monitoring regime for *Hoodia* will now be established, *to* ensuring that range states are able to properly regulate that trade in the species is properly regulated, and that states within the plants' range whilst capturing the economic benefits that accrue from its commercialisation.

The first recorded use of *Hoodia* was in all likelihood by the botanist Francis Masson (1741-1805), who visited the Cape in South Africa (1772-1774 & 1786-1795), recorded finding '*Stapelia gordoni*'[24] and wrote that the stems of *Trichocaulon piliferum* were eaten by the 'Hottentots'. It was this knowledge, recorded in the literature[25] and combined with field studies, that provided the motivation for the CSIR to include *Trichocaulon* spp. in a research programme aimed at determining the nutritional and possible toxic properties of 'foods from the veld'.

Who are 'the Hottentots' and what claim do they presently have to knowledge about properties of the plant? Strictly speaking, the 'Hottentots', or Khoe peoples, were herders who arose from the San, but this distinction is not recognised in the colonial botanical accounts, which cluster all groups as 'Hottentots', including the San. We do however know that the San are the oldest human inhabitants in southern Africa, who lived in small nomadic groups as hunters and gatherers for thousands of years and were the sole occupants of the region[26]. Use of *Hoodia* by these groups was likely for millennia, although the ways in which the plant was used are open to interpretation. A popular but perhaps simplistic version alludes to the San's use of the plant for hunting purposes to give 'strength', and anecdotal accounts even suggest that hunters may have been given *Hoodia* to prevent their eating of the kill. But San informants suggest that this would have been insulting to the hunter, whose skills and integrity would have negated the need for any external appetite suppressants. What is undisputed, however, is use by the San of *Hoodia* and related species as a food and, especially, as a drink substitute and appetite suppressant, as well as for a variety of other purposes[27].

Some of these uses can undoubtedly be attributed exclusively and originally to the San, but the wide distribution of certain *Hoodia* species suggests extensive use by a range of peoples in the region, including the Nama, Damara, and Topnaar, both as a medicinal remedy and as a food and water substitute. These Khoi-speaking peoples emerged in Southern Africa many millennia after the San, occupying similar geographical regions and no doubt acquiring San knowledge of plants and their uses and evolving others[28],[29],[30].

Contemporary San, of course, are quite different to the rather romantic picture painted by the media, which depicts the San persisting as hunters and gatherers, living in harmony with nature

in and around the Kalahari Desert and subsisting on wild food. While in the past, groups moved about the landscape, aggregating and dispersing according to season and resource-availability, today the reality is very different and many, if not most, San live in small settlements in the more remote regions of southern Africa, earning their living through a combination of agriculture, livestock raising, small-scale industries, veld (or non-timber forest) product harvesting, and wage labour[31]. A long history of dispossession and relocation has accompanied the San, commencing with their persecution and displacement upon colonisation of the region in 1652, their discrimination along with other people of colour during South Africa's apartheid regime, their invidious use by the South African Defence Force in Namibia and Angola for counter-insurgency operations, and continuing today through evictions and continued political marginalization[32],. [33] ·Many San live below the poverty datum line and face extreme hardship in terms of access to social services, employment, and income-generating opportunities. Presently, the San number between 85,000 and 90,000 in southern Africa, the overwhelming majority of whom live in the Kalahari Desert and its surrounding regions in Namibia, Botswana, and to a lesser extent, in South Africa[34].

III. The Commercial Development of *Hoodia Spp.*

The documented use of *Hoodia* as a food and water substitute in colonial botanical accounts is significant because it led directly to the CSIR including the plant for further investigation in a 1963 project on edible wild plants of the region[35], which aimed to inform the South African Defence Force about the toxic and nutritional properties of wild foods, and so ascertain their suitability for the army. Existing literature, combined with laboratory tests on mice which were fed *Hoodia*, led scientists to identify the potential of *Hoodia* as a non-toxic appetite suppressant, although insufficient evidence existed to file for a patent. The lack of technology to isolate and identify active ingredients halted progress of the research, which commenced again in the early 1980s.

In 1986, acquisition by the CSIR of high-field nuclear magnetic resonance spectroscopy made it possible to elucidate relevant molecular structures of *Hoodia*[36], and in 1995, following nine years of confidential development, a patent application was filed in South Africa by the CSIR for use of active components of the plant responsible for suppressing appetite[37]. In 1998 the CSIR signed a licensing agreement with Phytopharm[38], a small British company, specialising in the development of phytomedicines[39], and this was followed in the same year by the granting of international patents in some countries[40]. The agreement granted Phytopharm an exclusive world-wide license to manufacture and market *Hoodia*-related products and to exploit any other part of CSIR's IPRs relating to *Hoodia.* Through a programme dubbed 'P57', Phytopharm progressed this drug lead to a more advanced stage, leading to a License and Royalty agreement

in 1998 with Pfizer, the U.S.-based pharmaceutical giant, for further development and commercialisation.

In December 2001, Phase IIa / third stage 'proof of principle' clinical trials were reported to be successfully completed[41], and in July 2002, Phytopharm announced a future development programme for P57, whereby Pfizer would take responsibility for development of the programme. During July 2003, Pfizer merged with Pharmacia and closed its Natureceuticals group, responsible for the development of P57. The company announced it was to discontinue clinical development of the drug and was returning the licensing rights to Phytopharm, leaving Phytopharm free to license P57 to other parties[42]. Some critics saw this as the death knell for the development of *Hoodia* as a block-buster drug, but Phytopharm and the CSIR remained confident of the possibility of finding other partners to take forward the project. Currently, Phytopharm is seeking partners to manufacture P57 as a food supplement and recent developments include its raising of £6.5 million through a new share placement in preparation for the future licensing of *Hoodia* formulations to manufacturers of meal replacements[43]. However, the possibility of another partner taking P57 along a pharmaceutical route still remains[44]. Table I sets out the chronology of the development of Hoodia.

Table I. Chronology of the commercial development of *Hoodia*

Date	***Event***
Circa 25 000 BP - Present	**Use of wild plants by the San in a hunting and gathering economy**
1796	**Use of *Hoodia* species by 'the Hottentots' is first recorded by the botanist Francis Masson**
1936	**First recorded use of *Hoodia* species for suppressing appetite, based on San knowledge**
1963	**CSIR includes *Hoodia* species in a project on edible wild plants, based on ethnobotany of the San**
1968	**Death of leading scientist on the project and technical problems leads to its mothballing**
1983 – 1986	**Acquisition of high-field nuclear magnetic resonance spectroscopy allows for the relevant molecular structures of *Hoodia* to be elucidated.**
1986 – 1995	**Confidential work continues on the development of *Hoodia* species.**
1995	**A patent application is filed in South Africa by the CSIR**

	for use of active components of *Hoodia* species responsible for suppressing appetite.
August 1998	**A license agreement is signed between CSIR and Phytopharm for further development and commercialisation of "P57".**
1998	**International patents are granted to the CSIR in some territories. Phytopharm sub-licenses Pfizer to complete clinical development, obtain regulatory approval, and commercialise. CSIR publishes its Bioprospecting Policy, declaring its commitment to sharing benefits with holders of traditional knowledge. However, in practice, this commitment is not implemented in the P57 project until 2003.**
1999	**CSIR signs a Memorandum of Understanding with a group of South African traditional healers and begins implementing a system to document the use of traditional knowledge based on biodiversity.**
2001	**Phase IIa / third stage 'proof of principle' clinical trials for P57 reported to be successfully completed.**
June 2001	***The Observer*** reports commercial development of *Hoodia* without involvement of the San. The San establish that a patent has been registered based on *Hoodia* use, and that the CSIR has granted Phytopharm a license to exploit the patent. Negotiations between the CSIR and the San commence in the same month.
1 February 2002	**Memorandum of Understanding signed between the CSIR and the South African San Council, recognising the San as originators of knowledge about *Hoodia* and including a commitment to benefit-sharing.**
February 2002 – March 2003	**Negotiations continue between the CSIR and the South African San Council.**
March 2003	**CSIR and the South African San Council sign a benefit-sharing agreement.**
July 2003	**Pfizer withdraws from commercial development of P57**
2001 – 2004	**In parallel to the CSIR/Phtopharm initiative, a growing**

	herbal market develops for *Hoodia,* using knowledge of the San to promote products. Some products are later revealed to be fakes, with no *Hoodia* content.
2004	**Phytopharm announces its intention to develop P57 as a food supplement.**
May 2004	**Proposal is tabled to list *Hoodia* as a CITES Appendix II plant, to allow for controlled commercial trade**
June 2004	**Namibia announces its intentions to commercialise *Hoodia***
August 2004	**San apply for registration of the San *Hoodia* Benefit-Sharing Trust.**
September 2004	**Biodiversity Act 10 of 2004 is enacted in South Africa, requiring a benefit-sharing agreement to be developed with holders of traditional knowledge where their knowledge is used for bioprospecting.**
October 2004	**Proposal to list Hoodia as a CITES Appendix II plant is adopted by the 13th Conference of the the Parties to CITES. The CSIR announces the initiation of a broader bioprospecting project with the San.**

IV. Negotiating a Benefit-Sharing Agreement

A. Initiating talks

What did these developments mean for the San, the original holders of knowledge about the properties of *Hoodia*? Up until 2001, agreements for the further development and commercialisation of the *Hoodia* drug lead had proceeded apace without acknowledgement of the contribution of the San, let alone their prior informed consent. Indeed, a newspaper report quotes the CSIR having told their international collaborators that the 90,000-strong San 'no longer existed'[45]. In a defence of its position, the CSIR linked its initial reluctance to engage with the San to a concern that 'expectations would be raised with promises that could not be met'[46], and insisted that the organisational policy on bioprospecting was to eventually share benefits of research based on indigenous knowledge. But clearly, the realities of implementing this policy were complex and difficult. How, it was argued by the CSIR and Phytopharm, could the real owners of traditional knowledge be identified, and what if one group had historically stolen the knowledge from another group? The potential complexities and scenarios seemed endless.

While such concerns were undoubtedly valid and are common in similar cases throughout the world, they were also obfuscatory and to some extent provided a useful defense for CSIR and Phytopharm. In point of fact, such sentiments were also in flagrant disregard of the ILO Convention 169 - an international agreement for the protection of indigenous peoples' rights, the letter and spirit of the Convention on Biological Diversity, the African Union's Model Law on Access and Benefit-Sharing [47], the Bonn Guidelines, as well as numerous indigenous peoples' declarations and statements which explicitly refer to the importance of obtaining prior informed consent from holders of traditional knowledge before commercialisation of this knowledge; and ensuring that benefits derived from commercialisation are equitably shared with original holders of the knowledge[48].

In June 2001, the situation changed dramatically. Ongoing vigilance by a South African-based NGO, Biowatch South Africa, combined with assistance from the international NGO Action Aid, alerted the foreign media to the potentially exploitative nature of the agreement, and a leading story in a British newspaper *The Observer* was published about the case[49]. This was not the first time that news about the patent was made public[50], but action on the case was catalysed by the international news coverage, heightened interest in linkages between patents, traditional knowledge and benefit-sharing, and associated pressures for a rapid response on the part of both the San and the CSIR. Ironically, the negligence of the CSIR to consult with the San in the early stages of the agreement considerably strengthened the bargaining arm and political leverage of the San, who in securing the moral high ground now had a high-profile case being followed keenly throughout the world. In contrasting images of emaciated San and obese Americans, and reinforcing popular notions of 'biopiracy' by large pharmaceutical companies, the media captured the public's imagination, embarrassed the CSIR and Phytopharm, and this in turn led the CSIR to enter into high-level negotiations with the San.

On the part of the San, this was effected largely through three organisations:

– the Working Group of Indigenous Minorities in Southern Africa (WIMSA), established in 1996 at the request of San groups in the region to advocate and lobby for San rights;

– the South African San Council, a voluntary association established by the =Khomani, !Xun and Khwe communities of South Africa; and

– the Cape-Town based San Institute of South Africa (SASI), a non-governmental organisation facilitating access of San-based organisations to funding and expertise.

As a South African state institution, the CSIR was reluctant to negotiate with parties outside the country, and through WIMSA, the South African San Council was formally mandated to represent San groups in Namibia and Botswana as well as South Africa in all benefit-sharing negotiations about *Hoodia*. With this arrangement in place, recognition was given to the fact that knowledge about the plant crossed

country borders, and that the details of sharing benefits between San in different countries needed further consideration. WIMSA and SASI instructed their lawyer to negotiate with the CSIR on behalf of the San, and discussions between the two parties began in earnest.

B. Reaching a Memorandum of Understanding

Three months later, in February 2002, a Memorandum of Understanding (MOU) was reached between the CSIR and the South African San Council. Key aspects of this agreement included recognition by the CSIR of the San as originators of the body of traditional knowledge associated with human uses of the *Hoodia* succulent[51]; an acknowledgement by the San of the 'context' in which CSIR first registered the P57 patent, without having first engaged the San in negotiations; and a commitment, on the part of both the CSIR and the San, to a process of negotiating with one another in good faith, in order to arrive at a comprehensive benefit-sharing agreement[52].

An additional understanding considered the San and the CSIR to be the primary parties with regard to benefit-sharing[53]. This latter point is especially significant because it effectively excluded other groups – genuine or opportunists – from claiming benefits through prior knowledge about *Hoodia*. While this helped to address earlier concerns expressed by CSIR and Phytopharm of the need to identify genuine holders of traditional knowledge about the plant, it also raised new concerns about excluding non-San groups, such as the Nama, Damara, and Topnaar, who had historically occupied and still occupy areas where *Hoodia* grows, and had undoubtedly used the plant as a medicinal remedy and as a food and water substitute. How were these groups to benefit from use of their knowledge?

C. Developing Positions and Identifying Key Issues of Concern

While the MOU represented an important first step, negotiation of a concrete benefit-sharing agreement was still some way off. At a series of CSIR-funded workshops and meetings, representatives of the San, CSIR, and in some cases certain government departments and NGOs, were brought together to further articulate concerns and positions[54]. Key issues arising from these discussions focused on three main themes: