Case Study 7.

The Commercial Development of *Hoodia*[1]

1. Introduction and Background

The complexities of partnerships, and the difficulties of regulating and implementing access and benefit sharing are vividly demonstrated in the case of *Hoodia* species, succulent plants indigenous to southern Africa and long used to stave off hunger and thirst by the indigenous San peoples, the oldest human inhabitants in Africa (White and Sloane, 1937).

This knowledge was published by colonial botanists and led to the inclusion of *Hoodia* in a 1963 project on edible wild plants of the region undertaken by the South African-based Council for Scientific and Industrial Research (CSIR), one of the largest research organisations in Africa[2]. In 1995, after a lengthy period of development, the CSIR patented use of the active constituents of the plant responsible for suppressing appetite, without the consent of the San[3]. CSIR proceeded in 1998 to grant a license for the further development and commercialization of the patent to the U.K.-based company Phytopharm.

Through a programme dubbed "P57" Phytopharm developed the lead to a more advanced stage, leading to a license and royalty agreement with Pfizer, the US-based based pharmaceutical giant. However, the closure of Pfizer's Natureceuticals group led to the later withdrawal of Pfizer from the agreement. In 2004 a joint development agreement was negotiated between Phytopharm and the consumer giant Unilever. Unilever intends to develop extracts from the active ingredients of the plant and incorporate these into a functional weight-loss food for the mass market. Developments are at an advanced stage and have included clinical safety trials, manufacturing and the cultivation of some 300 ha of *Hoodia* in South Africa and Namibia. Recently, Phytopharm announced the initiation of Stage 3 activities, including supply chain expansion and the inclusion of consumer studies. Much is at stake: the global value of functional foods, meaning "any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contain" (American Dietetic Association, 1995) or, more popularly, "better for you" applications, is estimated at US$65 billion (Phytopharm, 2007). The market value for the dietary control of obesity is over US$3 billion per annum in the United States alone (Phytopharm, 2003).

A parallel *Hoodia* market, has also emerged in the past 3-4 years, based on trade in raw material. The publicity generated by the CSIR-Phytopharm-Unilever agreements, the marketing opportunities of San use of the plant, and the patent awarded to the CSIR led

[1] This case study draws substantially from Wynberg (2004) and Wynberg and Chennells (2008).
[2] See www.csir.co.za
[3] South African Patent No. 983170. This was followed by the granting of international patents in 1998, GB2338235 and WO9846243: Pharmaceutical compositions having an appetite-suppressant activity.

to a frenzied interest in *Hoodia* amongst plant traders. By 2004 concerns about the threats posed to natural populations through unregulated collection led to the inclusion of *Hoodia* spp. in Appendix II of the Convention on International Trade in Endangered Species of Wild Flora and Flora (CITES) (CITES, 2004). By 2006 trade had escalated exponentially—in many cases illegally—from just a few tons to more than 600 tons of wet, harvested material per year, sold as ground powder for incorporation into non-patented dietary supplements. In North America in particular, dozens of *Hoodia* products were sold as diet bars, pills, drinks, and juice, traded by a myriad of companies "free-riding" on the publicity and clinical trials of Phytopharm and Unilever. The CSIR patent was focused on the *Hoodia* extract, and nothing prevented other companies from simply selling the raw material for incorporation into herbal supplements. Most products were of dubious authenticity, contained unsubstantiated quantities of Hoodia, made unfounded claims, and in many cases implied association with the San, who received no benefits. Concerns led to closer analysis of products by the Food and Drug Administration (FDA), which revealed many to have little or no *Hoodia*, and to lack adequate evidence of safety (FDA, 2004). The US Federal Trade Commission (FTC) also brought action against spammers sending e-mail messages about *Hoodia* weight-loss products, alleging that the claims made for the products were false and unsubstantiated (FTC, 2007). In South Africa and Namibia, illegal trade and harvesting of *Hoodia* resulted in a number of prosecutions and arrests; the high prices commanded for the dry product of up to US$200 per kilogram had led to the incorporation of the plant into a global underground network of diamonds, drugs and abalone.

Increasingly, however concerns about the quality and safety of material sold as *Hoodia*, joined with over-harvesting concerns and recognition of the need to ensure the sustainability of *Hoodia* supply have led to a more regulated industry based on cultivated material. Greater vigilance on the part of the FDA and FTC as well as the American Herbal Products Association is rapidly reducing the number of illegitimate products on the US market, and regulators in South Africa, Namibia and Botswana have introduced permitting procedures which prohibit wild harvesting of *Hoodia*, require its transparent cultivation, and set in place mechanisms to track trade across borders.

2. The Types of Resources Utilised: Diverse Approaches to Commercialisation

As described above, the commercial development of *Hoodia* is based on two approaches: (1) a patented *Hoodia* extract, under development by Phytopharm and Unilever as a functional food; and (2) commercialisation of *Hoodia* as a raw, ground up material through incorporation into herbal supplements.

The industry sectors that develop and commercialise *Hoodia* material are thus very different, the former representing the food industry, represented by the largest consumer company in the world; and the latter the herbal supplements market, which is characterised by a large number of relatively small players with extremely divergent policies and ethics.

The economics between these sectors are also vastly different. For Unilever, the focus is on safety and efficacy and the company places emphasis on having sufficient active

material to achieve effective weight loss. This is estimated by Unilever to be orders of magnitude greater the amounts currently sold in herbal supplements (K. Povey, Unilever, pers. comm., 2007). Thus Unilever requires vast amounts of material, and has already planted several hundred hectares of *Hoodia* material, with plans to significantly expand these volumes. Far less material is used for the herbal supplement market, and this combined with the fact that it comprises a much larger group of smaller growers and traders, means that the *Hoodia* industry operates using different economies of scale. This could lead to the emergence of two price structures for consumers, as has emerged for plant sterols: (1) a higher price for supplements, based on low volumes; and (2) a lower price for food, based on high volumes (K. Povey, Unilever, pers comm., 2007). For *Hoodia*, much will depend on how much active ingredient is needed for efficacy, and consumer demand for the product.

3. Navigating Prior Informed Consent and the Access and Transfer of Genetic Resources

Obtaining PIC from government

Although access arrangements vary between these two approaches to commercialisation, there are similarities. Both approaches, at least initially, required access to wild *Hoodia* material, and thus the permission of government departments. The first accessions by the CSIR of *Hoodia* material would have taken place in the 1960s, however, long before any CBD requirements and involved a local research institution (the CSIR) partly funded by government. Later acquisitions of wild material would also have been done by the CSIR, collecting directly from private or public lands for research purposes in South Africa and Namibia, requiring collection permits. The involvement of Phytopharm as a license holder occurred only after the lodging of a patent by the CSIR, and thus the CSIR took primary responsibility both for collecting and negotiating consent with landowners and government at the research stage, prior to the development of a licensing agreement. In South Africa this was done initially at provincial level through request to the Northern Cape Directorate of Nature Conservation to collect *Hoodia* species for their intended commercialisation. In this case, a conventional permitting process led to the CSIR being granted permits for the collection of *Hoodia gordonii*, subject to resource assessments being undertaken and various environmental conditions being met (E. Powell, Northern Cape Nature Conservation, pers. comm., 2002).[4]

At the commencement of the contract between CSIR and Phytopharm for the commercial development of *Hoodia* in 1998, requests were made to the Department of

[4] As the Hoodia industry has evolved and matured, a more sophisticated permitting system has developed for the harvesting and cultivation of Hoodia, and in parallel, government departments in provider countries have engaged more actively in ensuring compliance with ABS requirements. Phytopharm, Unilever and Hoodia growers have also taken a more active role in overseeing permits and working directly with the South African, and more recently, Namibian governments.

Environmental Affairs and Tourism (DEAT) –the South Africa 'national focal point' for bioprospecting – for permission to develop a bioprospecting agreement. According to the CSIR, the response from DEAT was to acknowledge the lack of legislation in place to govern bioprospecting, but to suggest that the intended commercial collaboration be pursued through law of contract, so as to have case studies from which to learn for future policy development (M. Horak, CSIR, pers. comm., 2002).

Obtaining PIC from traditional knowledge holders

While certain administrative procedures were followed by the CSIR to obtain the consent of government bodies responsible for regulating bioprospecting and the collection of biological material, the CSIR was clearly remiss in following similar procedures with the San, holders of traditional knowledge about the appetite suppressing properties of Hoodia. In fact, until 2001, agreements for the further development and commercialisation of the *Hoodia* drug had proceeded apace without acknowledgement of the contribution of the San, let alone their prior informed consent. Indeed, a newspaper report quotes Phytopharm having been told by the CSIR that the 100 000-strong San "no longer existed" (Barnett, 2001). In defence of its position, the CSIR linked its initial reluctance in engaging with the San to a concern that "expectations would be raised with promises that could not be met" (Barnett, 2001) and insisted that the organisational policy on bioprospecting was to eventually share benefits of research based on traditional knowledge. 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 they were clearly also in flagrant disregard of the International Labour Organisation (ILO) Convention 169 – an international agreement for the protection of indigenous peoples' rights, the letter and spirit of the CBD, the African Union's Model Law on Access and Benefit Sharing (Ekpere, 2001), and the Bonn Guidelines, a voluntary guide to assist governments to develop an access and benefit-sharing strategy, as well as necessary legal, administrative or policy measures (CBD, 2002). Although not overtly stated by the San, who to a large degree remain on the fringes of international indigenous peoples' movements, they also ignored 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 (see Dutfield, 2002 for a review of such statements).

But in 2001, ongoing vigilance by a South Africa-based NGO Biowatch, combined with assistance from the international NGO Action Aid, alerted the foreign media to the potentially exploitative nature of the CSIR/Phytopharm agreement and a leading story was published in a British newspaper. This catalysed a flurry of media interest, which pressurised the CSIR to enter into negotiations with the San, who had 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.

On the part of the San, the following three organisations played – and continue to play - significant roles throughout the case:

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

– the South African San Council, a voluntary association established as part of WIMSA by the three San communities of South Africa (the =Khomani, !Xun and Khwe) in November 2001; and

– the Cape Town-based South African San Institute (SASI), a San service NGO 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 the San 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 national 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.

4. Negotiating a benefit-sharing agreement with the CSIR

Negotiating a Memorandum of Understanding

Early on in the negotiations, the San were faced with a difficult choice. Should they oppose or even challenge the patent, based on ethical considerations and lack of novelty, or should they adopt a more practical approach and become active partners in negotiating a share of royalties from the patent? This was a critical moral dilemma. In communities such as the San, the sharing of knowledge is a culture-defining attribute and is basic to their way of life. Traditional knowledge of plants is viewed as a collective and the idea of 'owning' life abhorrent. The patenting of active compounds of *Hoodia* by the CSIR ran counter to this belief, yet brought with it lucrative opportunities for financial benefits. Ultimately, however, the principle of 'no patents on life' was considered 'too expensive' (Chennells, 2003) and the poverty-stricken San opted to obtain a share of royalties. Writing to the CSIR President in 2001, the CSIR was informed by San lawyers that a legal challenge of any nature did 'not form part of our clients' plans', but emphasised that the San looked on their traditional knowledge regarding *Hoodia,* as well as other plant uses, as being collective San intellectual

property that should not morally be able to be owned by any individual or entity (Chennells, 2001)[5].

Three months after formal commencement of negotiations, 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:

- an acknowledgement by the CSIR that the San are the 'custodians of an ancient body of traditional knowledge and cultural values, related *inter alia* to human uses of the *Hoodia* plant', and recognition that such knowledge pre-dated scientific knowledge developed by Western civilization over the past century;
- a commitment by the CSIR to (1) recognise the role of indigenous peoples as custodians of their own knowledge, innovations and practices; and (2) provide for fair and equitable benefit sharing;
- an acknowledgement and acceptance by the San of the explanation of the CSIR, which provided the 'context' in which the CSIR first registered the P57 patent, without having first engaged the San in negotiations with respect to material transfer, information transfer and associated benefit sharing;
- recognition by the CSIR of the San as originators of the body of traditional knowledge associated with human uses of *Hoodia*;
- a specification that any intellectual property arising from the traditional use of Hoodia and related to the CSIR patents for P57 remains vested exclusively with the CSIR. The San Council has no right to claim any co-ownership of the patents or products derived from the patents; 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.

It was also agreed that both parties would provide each other with full disclosure of any 'matters of significance' relating to the agreement, and that all relevant disclosable information held by the CSIR relating to the P57 patent and subsequent licensing agreements would be made available to the San.

An additional understanding considered the San and the CSIR to be the primary parties with regard to benefit sharing. This latter point is especially significant because it effectively excluded other groups – genuine or opportunist – from claiming benefits through prior knowledge about *Hoodia.* While this helped to address earlier concerns expressed by the CSIR and Phytopharm of the need to identify genuine holders of traditional knowledge about the plant, it also raised new concerns from some commentators about excluding non-San groups, such as the Nama, Damara, and

[5] Of interest, is the subsequent appeal against the patent by the European Patent Office, on the basis of it lacking novelty and being based on prior art. The appeal was subsequently overturned, however.

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.

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, the CSIR, and in some cases certain government departments and NGOs, were brought together to further articulate concerns and positions (e.g. Spies, 2002). Key issues arising from these discussions focused on three main themes:

1) building trust between the parties;
2) identifying genuine holders of traditional knowledge about *Hoodia* and potential beneficiaries; and
3) ensuring the broader protection and promotion of San cultures and knowledge.

Building trust

The development of trust between the CSIR and the San emerged initially as a major concern (e.g. Spies, 2002), more especially given the CSIR's history as an institution shaped by the *apartheid* regime, and serving the interests of a repressive government for nearly 40 years. While transformation of this state institution is now well underway, its initial inertia in drawing the San into the project created mistrust and negative impressions amongst the San. Questions raised during this process focused on how the San could be assured that they would receive appropriate royalties and other benefits, and how they could trust that they would have access to all the necessary information. At an early stage in the negotiations the South African San Council alluded in writing to the CSIR's alleged collusion with the *apartheid* regime, as a potential problem in their building of trust. This was met with an outraged response from the CSIR Board, but the frank exchanges that ensued enabled the parties to clear the air and thereafter develop a more trusting relationship as they moved towards a final agreement (Private notes, R. Chennells).

Identifying holders of traditional knowledge and beneficiaries

The San immediately commenced a process amongst communities represented by WIMSA to establish the extent to which *Hoodia* was known and used. Responses from far flung communities in South Africa, Namibia and Botswana confirmed published records that *Hoodia*, known as *!Xhoba* to the San, was still well known and used for a number of purposes, and chiefly as a sustaining *veld*[6] food that also reduced hunger and thirst (Private notes, R. Chennells). Some informants cautioned about the danger of feeding the plant to small children for sustained periods, but otherwise it was confirmed to have a safe and ancient history. This bolstered the belief of the San, as the first peoples on the subcontinent, that their traditional knowledge of *Hoodia* had predated that of pastoralists who had subsequently entered and settled in Southern Africa. The

[6] An Afrikaans word meaning uncultivated lands or grassland.

San view was that they had shared knowledge with all subsequent migratory groups, and were thus the primary holders of traditional knowledge relating to *Hoodia*.

Despite this opinion, parties were anxious of the potential conflict that could arise between the San and other groups such as the Nama and Damara. Because both the plant and traditional knowledge about its use extend across Namibia, South Africa and Botswana, this matter was potentially especially complex and fraught. How could a system be created that ensured fairness and equity across the three countries, and within the relatively new organisational structures set up by different San groups in different countries? The restricted distribution of *Hoodia* suggested that not all groups of the San had utilised the plant within living memory. But identifying those groups that did have a clear record of historical use was near impossible, given the San's history of resettlement and dislocation over millennia, and also the manner in which the San have historically moved about the landscape, aggregating and dispersing according to season and resource availability (Hitchcock & Biesele, 2001). Moreover, thousands of people in southern Africa currently claim San descent, and are able to claim a recent history of use of *Hoodia.* Knowledge about the appetite-suppressant properties of *Hoodia* is shared among a broad spectrum of communities in the region, including the Nama, Damara, and other Khoe speaking peoples, who share the same linguistic roots with the San and have during the past centuries suffered a similar history of persecution and marginalisation.

Resolving these uncertainties presented difficult challenges but there was agreement amongst the San that a nit-picking exercise to link benefit sharing to specific communities using *Hoodia* would be futile and potentially divisive. WIMSA had taken a binding decision at an annual general meeting in 2001, after years of discussions, to the effect that heritage is indivisible, and that benefits resulting from shared heritage, such as *Hoodia*, must thus be shared equally amongst all San peoples. This decision led to a shared formula, decided collectively by the San during the negotiation process, for the equal division of financial benefits between the countries that WIMSA represents.

Protecting San culture and knowledge

More generally, the San sought further clarity about how they could more effectively protect their cultural heritage, including their world-renowned rock art, as well as their rich ethnobotanical and environmental knowledge. In the years preceding the benefit-sharing agreement, the San-affiliated non-governmental organisation the South African San Institute (SASI) had begun to assist WIMSA to establish a code of conduct for research and researchers, and to ensure the control and protection of all San intellectual property (WIMSA, 2001; WIMSA, 2003). There was growing sensitisation and awareness amongst the San about the past appropriation of their knowledge over centuries, without acknowledgement or compensation. How, it was asked, had the CSIR obtained local knowledge of *Hoodia* without the San knowing, and how could such knowledge be protected from future exploitation? Although legislation to protect and promote indigenous knowledge systems was under development in South Africa at the time of the negotiations (and had been for at least five years), there had been no consultation with the San about its content and scope. The absence of legislation to protect holders of traditional and/or indigenous knowledge presented a major stumbling block, requiring the San to negotiate in the absence of any legal requirement for benefit-sharing

agreements to be developed with owners of knowledge and/or biological resources. This gap in the South African legislature was subsequently filled by the introduction of the Biodiversity Act (10 of 2004) (Republic of South Africa, 2004) for which the supplementary regulations are still awaited. A similar situation pertained in other countries of origin, such as Namibia and Botswana, where no law was yet in place requiring benefit-sharing agreements.

On the part of the CSIR and government, the absence of legislation created uncertainties as to who should be party to the benefit-sharing agreement, and exactly how traditional or indigenous knowledge should be obtained or used. The CSIR stepped gingerly, unsure (and undoubtedly reluctant) about 'shedding their white coats' and entering into protracted negotiations, but politically obliged to do so. A primary concern for the CSIR was to ensure that the San leadership they engaged with was genuine and representative, and that their agreement with the San would not lead to a flurry of claims to the knowledge from third parties.

Represented by Petrus Vaalbooi, chair of the South African San Council, and one of the authors (Roger Chennells), acting as legal representative, a series of meetings ensued between the San and the CSIR. In March 2003, less than two years after commencing discussions, negotiations concluded on the specifics of a mutually acceptable benefit-sharing agreement. Announcing the deal, Ben Ngubane, then South African Minister of Arts, Culture, Science and Technology, referred to its historical significance in 'symbolising the restoration of the dignity of indigenous societies', and in unleashing benefits by joining together owners of traditional knowledge and local scientists to add value to the biodiversity and indigenous knowledge systems of southern Africa. It was the 'right thing' to do, he said (Ngubane, 2003).

5. Benefit sharing

The CSIR-San benefit-sharing agreement

The parties negotiated at arm's length for eighteen months, the San initially claiming ten percent of the royalties, in response to the CSIR's early offer of three percent. Both parties argued strongly in favour of their positions, each listening to the other's position, reconsidering implications, moving steadily to ensure progress, and finally, reluctantly, settling on an agreed amount. In terms of the agreement[7], the San would receive six percent of all royalties received by the CSIR from Phytopharm as a result of the successful exploitation of products (Figure 1). This would be for the duration of the royalty period or for as long as the CSIR received financial benefits from commercial sales of the products (Provisions 1.5 and 2). The San would also receive eight percent of the milestone income received by the CSIR from Phytopharm when certain performance targets were reached during the product development period. In the event of successful commercialisation, these monies would be payable into a trust set up jointly by the CSIR and the South African San Council to raise the standard of living and well-being of the

[7] Benefit-sharing Agreement between the CSIR and the South African San Council, March 2003.

San peoples of southern Africa[8] (Figure 1). Monies received by the San would be extracted from royalty and milestone payments obtained by the CSIR, whereas profits received by Phytopharm and Pfizer would remain unchanged. Overall, therefore, the San would receive less than 0.03% of net sales of the product (Wynberg, 2004) although if successful this would still translate into millions of dollars.

Clear and transparent accounting procedures were required to be in place on the part of both the CSIR and the San Trust with regard to financial benefits paid by the CSIR and used by the San Trust. The Trust would include representatives of the CSIR, the =Khomani, !Xun and Khwe, other San stakeholders in southern Africa, WIMSA, a South African lawyer nominated by the South African San Council, and the Department of Science and Technology, with strict rules determining the distribution of funds to beneficiaries. Payments would not be made to individuals and would need to be used to attain the aims and objectives of the Trust. No distribution of funds would be made to a beneficiary community or institution unless a request, approved formally by the Trust, set out a detailed budget and coherent plan, identified a bank account opened by elected representatives, with a proper constitution, and indicated the capacity to account fully for the proper expenditure of funds.

It is noteworthy that the CSIR-San benefit-sharing agreement is confined almost exclusively to monetary benefits, which hinge on product sales and successful commercialisation, although there are general provisions relating to non-monetary benefits. These include a commitment by parties to conserve biodiversity and to undertake best-practice procedures for plant collection (Provision 3.6), required the CSIR to grant the San access to existing study bursaries (Provision 3.7), and, significantly, laid the ground for further collaboration in bioprospecting (Provision 3.8).

In addition to spelling out the details with respect to benefit sharing and administrative aspects such as accounting, the agreement also broadly covered intellectual property issues and, importantly, set out comprehensive measures to protect and indemnify the CSIR. 'Knowledge' was defined as 'the traditional knowledge on the uses of the *Hoodia* plant that occurs in Southern Africa, originally in the hands of the San people'. Provision 4 of the Agreement specified that 'any intellectual property that may be developed or created by the CSIR, including any patent, trade mark or plant breeder's right, as a result of any use of the traditional knowledge, shall be and remain vested in the CSIR'. Moreover, the San Council had no right to claim any co-ownership of the patents or products derived from the patents.

Provision 6, Warranties and Indemnity, included an undertaking and warranty by the San that, *inter alia,* it is the legal custodian of traditional indigenous knowledge on the use of *Hoodia;* that it would not assist or enter into an agreement with any third party for the development, research and exploitation of any competing products or patents; that it would not approach Phytopharm or Pfizer to obtain additional financial benefits; and that it would not contest the enforceability or validity of the CSIR's right, title and interest in the P57 patent and related products.

[8] Deed of Trust of the San *Hoodia* Benefit-Sharing Trust.

A further provision on Third Party Claims (Provision 9) set out various measures to protect the CSIR against claims by any third party for intellectual property infringement and stipulated that a successful third party claim against the CSIR could lead to a review of the agreement to accommodate claimants in the sharing of financial benefits. It also required the San Council to share financial benefits with a third party if the latter were successful in proving a claim.

In February 2005, the San Trust, formally named the San *Hoodia* Benefit-Sharing Trust, was registered. The content of the Trust document was discussed over several meetings, including a consultative conference at Upington, South Africa, in October 2003, during which San delegates from South Africa, Namibia and Botswana debated issues and agreed upon guiding principles relating to benefit sharing. There was unanimous agreement that 75 percent of all Trust income would be equally distributed to the then constituted San Councils of Namibia, Botswana and South Africa; that 10 percent would be retained by the Trust for internal and administration purposes; that 10 percent would be allocated to WIMSA as an emergency reserve fund; and that 5 percent would be allocated to WIMSA to cover administration of the San networks. Priorities within the region, such as education, leadership empowerment, and land security, were agreed upon as non-binding recommendations to the Councils. Principles for benefit sharing that would bind the Trust were unanimously endorsed by the WIMSA Annual General Meeting in December 2003 (WIMSA, 2004). The Trust began its work in earnest, electing a Chair, Secretary and Treasurer, and started engaging with the practical challenges of distributing milestone income received from the CSIR, at that time a total of R560,000.

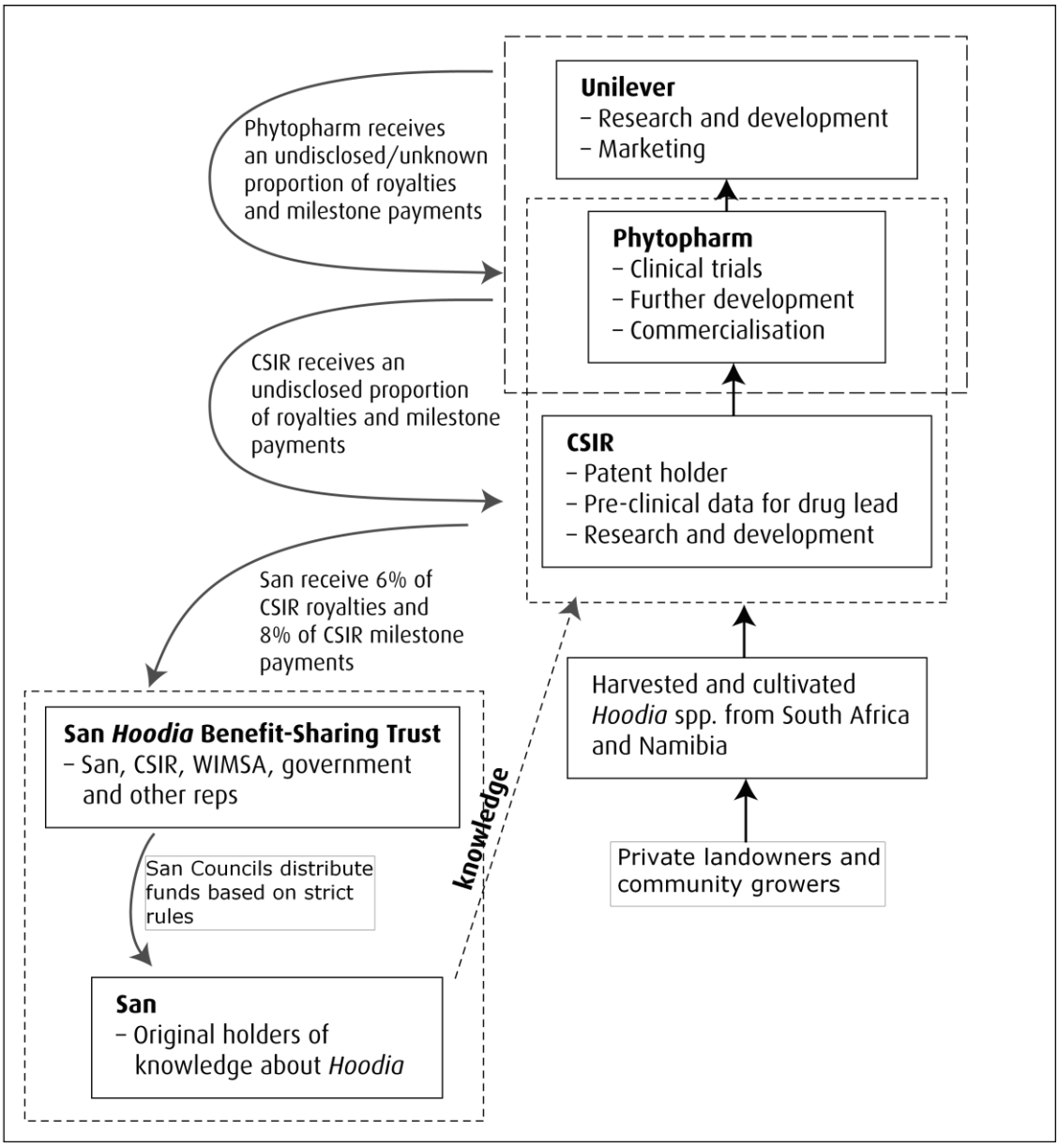

Figure 1. Benefit-sharing and value-adding under the San-CSIR-Phytopharm-Unilever agreements. After Wynberg (2006).

CSIR-Phytopharm-Unilever license agreements

What of the benefits for the CSIR? At the national level, these are purportedly substantial, although difficult to specify or verify owing to the confidentiality of the agreement and reluctance on the part of CSIR and Phytopharm to divulge these details. While CSIR and Phytopharm have been reimbursed for their continuing roles in research and development (R&D), these funds have been allocated largely to cover R&D costs and are not considered by the CSIR as income. Through licensing the technology, the CSIR is likely to earn $10-million in milestone payments, linked to success of the drug

during different stages of the clinical trials. The specific royalty percentage has not been divulged publicly but is considered by the CSIR to "be substantial" compared to international norms (M. Horak, CSIR, pers.comm., April 2002). Typically, royalty percentages for pharmaceuticals range from 0.5% to 5% of total sales (Laird and ten Kate, 1999). If successful, commercialisation of P57 is likely to amount to hundreds of millions of Rand *per annum* for the lifetime of the patent. In this regard many consider South Africa to have reached an important turning point in bioprospecting. Patent rights to the active constituents of *Hoodia* responsible for suppressing appetite have been successfully retained by South Africa through the CSIR (although notably, other *Hoodia*-related patents remain foreign-owned), with foreign drug firms attaining licences for the further development and commercialisation of the drug.

In terms of non-monetary benefits, some of the more significant benefits to emanate from the agreement have been the construction of the Food & Drug Administration (FDA) approvable medicinal plant extraction facility at the CSIR for the manufacture of material for use in clinical trials on P57, as well as the establishment of a Botanical Supplies Unit – both the first of their kind in the world. South Africa is also considered a preferential site for cultivation and the production of material, although Phytopharm does have the right to establish plantations outside of South Africa. Already, up to 300ha of *Hoodia* is cultivated in South Africa and Namibia, generating substantial jobs and investment, and a €30 million extraction facility for *Hoodia* is planned for development in the region.

Benefit Sharing and the Southern African Hoodia Growers Association

Benefit streams have also emerged from those involved in growing *Hoodia* for the herbal and dietary supplement market, with South African growers recently negotiating another benefit-sharing agreement with the San, based on a levy on processed *Hoodia*.[9] This process was initiated in late 2005 when the San were approached by a group of South African *Hoodia* growers who were cognisant of their obligations to share benefits with the San under the 2004 Biodiversity Act and its anticipated access and benefit-sharing regulations. The San realised that the new market for *Hoodia* as a food additive or dietary supplement was likely to grow over the years, and that they had a right to share in benefits. Because these products did not relate directly to the P57 patent and the use of *Hoodia* extracts, the San were legally able to sign an additional benefit-sharing agreement with *Hoodia* growers that was not in breach of their prior agreement with the CSIR. Negotiations commenced between the South African San Council (again acting on behalf of WIMSA), and the South African *Hoodia* Growers Pty Ltd (SAHG), which represented the interests of some commercial growers of *Hoodia* in South Africa who had agreed to comply with certain standards of best practice, safety, fair trade and benefit sharing. In March 2006 a preliminary benefit- sharing agreement was concluded with the SAHG. In terms of the agreement 6% of the gross value of *Hoodia* sold would be allocated to WIMSA – 4% into a Trust for the San, and 2% to WIMSA or the South African San Council. No member was permitted to sell to vendors engaged with the production or marketing of illegal *Hoodia* products.

[9] Benefit sharing agreement and joint venture between the Southern African Hoodia Growers Association and the Working Group of Indigenous Minorities in Southern Africa, March 2007. Unpublished signed legal agreement

Royalties of R176,000 trickled in from this agreement, but it was soon replaced with another more comprehensive initiative that included the majority of South African *Hoodia* growers as well as South African provincial environmental government agencies responsible for ensuring sustainable use of *Hoodia* and administering permits. After a year of negotiations, during which the different realities and negotiating positions of the respective parties emerged in an increasingly mature climate of transparency, a benefit-sharing agreement was concluded in March 2007 between the San and the newly formed Southern African *Hoodia* Growers Association (SAHGA). This had been preceded by the signing of a Memorandum of Understanding in January 2007 between the San (represented by WIMSA), *Hoodia* growers, and the Western Cape and Northern Cape environmental departments[10] which captured the intention of the parties as they entered negotiations.

The benefit-sharing agreement, drafted to be compliant with the provisions of the Biodiversity Act, acknowledged the San to be the primary traditional knowledge holders of *Hoodia*, having a legal right to share benefits arising from its harvesting, growing and marketing. It also recognised the urgent need for regulation to minimise impacts on wild populations and to ensure attainment of standards of legality, safety and fair trade. Stated objectives of the non-profit SAHGA were *inter alia* to regulate the legal production and harvesting of *Hoodia* by its members, in compliance with the CBD; to promote a sustainable *Hoodia* industry in southern Africa; to liaise with all roleplayers; to gather and exchange relevant information relating to permits, quality control, sales and compliance; and to promote research. Two San representatives were elected to be members of the Board of Directors, and an additional two San representatives were designated as observers. WIMSA in turn was to ensure the proper administration of financial benefits, and to further the objectives of SAHGA and help with effective marketing of *Hoodia*. Although the stated intention of the parties was to create an exclusive joint venture and benefit-sharing agreement, WIMSA was entitled, on good cause, to motivate to SAHGA for the signing of another, separate agreement. Parties additionally agreed to promote SAHGA as the only legitimate source of *Hoodia* for the food, food additive, and dietary supplement market, outside of the CSIR/Unilever agreement, and to 'inform the world' that *Hoodia* products outside of the two benefit-sharing agreements were illegal under the CBD. The agreement also, significantly, acknowledged other groups holding traditional knowledge of *Hoodia*, such as the Nama and Damara, and provided an opening for further discussions and possible agreements with such groups.

Financial benefits for the San were formulated based on a ZAR24 levy charged on each kilogram of dry, processed *Hoodia*, paid prior to the issue of CITES export permits and to be revisited on an annual basis. Calculation of the levy was based on a number of factors including the previous SAHG levy of six percent of the sale from the farm, as well as conditions in the world *Hoodia* market - recognising its high levels of fluctuation, the need for the levy to be affordable for growers, and other equity considerations. The agreement also provided for re-evaluation after one year, in recognition of the need for the eventual amount to be fair to both sides. Parties were fully aware that the original

[10] Signed unpublished legal agreement.

figure of six percent had been agreed upon with SAHG without the benefit of adequate knowledge about trade volumes, without extensive calculation of likely implications of percentages for all parties, and without sufficient reliable information to fix an appropriate percentage with surety. Conflict resolution was proposed through mediation or, failing this, through arbitration. The agreement, whilst negotiated in South Africa, was drafted in such a way as to welcome and enable the participation of *Hoodia* growers from neighbouring Namibia and Botswana in due course.

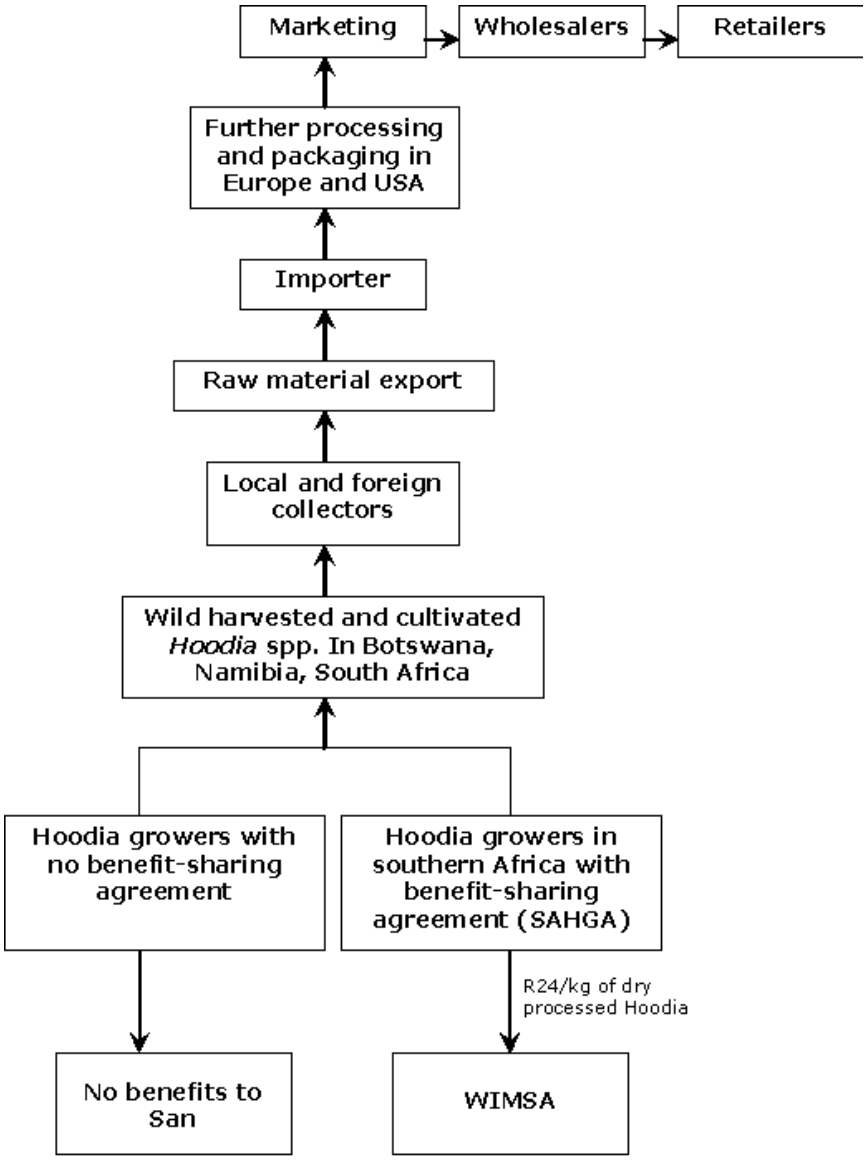

Figure 2. Benefit-sharing through the Southern African *Hoodia* Growers Association, and the *Hoodia* value chain based on trade of raw material

6. Implementation challenges

The conclusion of two benefit-sharing agreements represents a major achievement. Indeed, these agreements characterise some of the most unique examples in the world of where the much-touted benefits from bioprospecting have had practical realisation. Nonetheless, a number of implementation challenges are now faced by the San, by those involved in the *Hoodia* industry, and by regulators and policy-makers.

Decision-making and the distribution of benefits

One of the key challenges concerns the way in which decisions will now be made about the sharing of benefits. The CSIR/San agreement will pay six percent of royalties into the San *Hoodia* Trust, which as described above, has begun the task of preparing the policies and structures necessary to distribute the significant flows of money anticipated within the next two years. The fair and equitable distribution of large sums of money to beneficiaries in three different countries would be an enormous challenge for any organisation. The fact that these beneficiaries are impoverished indigenous peoples, wrestling with problems of organisational cohesion and under-development, introduces a heightened degree of complexity to this challenge. The SAHGA benefit-sharing agreement also promises to deliver millions of Rands within the next few years, this income flow being channelled directly to the San regional organisation WIMSA. This money does not have any prior allocations that have been earmarked, and its wise distribution will similarly present the relatively inexperienced Board with major challenges.

The burden on San individuals on the San *Hoodia* Trust as well as on the WIMSA Board to meet heightened expectations, and to act wisely and transparently in the eyes of the watching world, will be heavy indeed. NGOs entrusted with providing support will be expected to shoulder part of this responsibility. The objective will be to minimise the negative social and economic impacts, and the intra-community conflicts that may arise following the introduction of large sums of money into San communities. Limited international and local experience exists in the administration and implementation of such agreements, and few, if any, cases address the sharing of benefits within communities. As Barrett and Lybbert (2000) point out, thus far benefit-sharing questions have remained issues of distribution between the community in aggregate and outsiders, whilst at a local and intra-community level there has been little practical experience. Early experiences, however, suggest the potentially divisive impact that natural product trade can have in indigenous communities. In India, for example, the commercialisation of Jeevani *(Trychopus Zeylanicus*) a wild plant with anti-fatigue properties, has led to divisions amongst the tribal community, the Kanis, as to how their knowledge should be used (Tobin, 2002; Gupta, 2004). In Peru, a 1996 agreement of the International Cooperative Biodiversity Group also led to conflict between organisations representing local Aguarana communities, as well as at a national level (Tobin, 2002; Greene, 2004).

In the case of the San, intra-community issues are especially complex. The organisations set up to politically represent the San are relatively new and the introduction of Western values and economies into supposedly traditional communities, already fractured and 'hybridised', presents a suite of difficult social and economic problems. Robins (2002) describes the social complexities of contemporary San identity, knowledge and practice, and charts the intra-community divisions and conflict that emerged between self-designated 'traditionalists' and 'western bushmen' when San land claims were lodged in the Northern Cape Province of South Africa. While these claims resulted in significant benefits for the San, they also had unintended consequences in terms of generating conflict. Robins (2002) points out the contradictions between San 'cultural survival' and the promotion of the values of 'civil society' and 'liberal individualism', a conclusion that holds particular resonance for the *Hoodia* case, contextualised as it is within the international discourse of indigenous peoples, a vigilant NGO community alert to biopiracy cases, and a new policy framework that requires fair and equitable benefit sharing for use of traditional knowledge.

The possible compensation of other groups that use *Hoodia* and have traditional knowledge of the plant such as the Nama, Damara and Topnaar also represents a major challenge that will demand resolution, especially once Unilever products emerge, other *Hoodia* markets mature, and significant profits begin to flow. Already, Namibia has articulated a position that supports the inclusion of the Nama and other groups in benefit-sharing arrangements, bolstered by the fact that *Hoodia* wild and cultivated populations occur in areas occupied by Nama communities. However, these communities, even more than the San, lack organisational structures and cohesion and will require substantial support to enable them to get to the point at which they can negotiate their rights, and manage and disburse incoming funds. In the interim, structures have emerged through the Hoodia Growers Association of Namibia, to raise and manage funds for the inclusion of the Nama and other indigenous groups in the Hoodia industry with the intention to build organisational and technical capacity within such groups in the medium to long term.

Regional differences in benefit-sharing policies

One of the more interesting aspects of the case lies in its regional implications. *Hoodia* is a biological resource that is shared across national political boundaries, and knowledge of the plant is similarly shared by communities straddling these boundaries. Thus far, however, South Africa has played a leading role - in lodging the patent, developing commercial partnerships with multinational companies, negotiating benefit-sharing arrangements with the San, and facilitating legal trade in the plant. Botswana and Namibia by comparison, although involved in harvesting and cultivating *Hoodia*, have not yet legalised trade in the plant, nor developed commercial partnerships. Moreover, South Africa has adopted ABS legislation, and is supportive of recognising the San as a community with clear rights to benefit from *Hoodia*, but Namibian and Botswanan policies have been more ambivalent. Neither Namibia nor Botswana have ABS legislation in place and in both countries benefits from *Hoodia* are considered to belong to the state, rather than the San or other traditional knowledge holders. Unsurprisingly, these divergent policy approaches have led to concerns.

A central concern relates to the difficulties of controlling trade. Numerous reports exist of illegal material entering South Africa from Namibia, and being exported from South Africa under permit. The areas in which the plant occurs are typically very remote and illegal harvesting is difficult to monitor and enforce. While steps could be taken to address these concerns, their efficacy would be questionable without a regionally coherent position on *Hoodia* use. Strategic approaches to value adding and the use of marketing tools such as Geographical Indications would also be undermined in the absence of strong regional collaboration – needed at government, industry, farmer and community level.

Although the San-*Hoodia* Trust that is set up to disburse benefits already implements benefit-sharing across regional boundaries, based on an acknowledgment of the shared knowledge of *Hoodia*, there is clearly a need for benefit-sharing strategies to be developed at regional and national levels in cases where genetic resources are shared across boundaries.

Hoodia trade and markets

Without the development of a sustainable and viable industry, no benefits will emerge and a set of complex challenges also confronts those involved in trading and growing *Hoodia.* Like other agricultural commodities, *Hoodia* markets follow the law of supply and demand, which determines the prices, quantities and allocation of resources (Wall, 2001). In line with the classical model described by Homma (1992) *Hoodia* has moved through a rapid expansion phase, followed by a stabilisation phase, where an equilibrium has been reached between the supply and demand of the product, supposedly close to the maximum capacity of extraction. Prices have consequently risen because of the inability to meet a growth in demand, which have lead to the adoption of policies to protect the sector or stimulate sustainable production of the resource. Shrinkage of the resource, restrictive policies on wild harvesting, and incentives to cultivate have stimulated a substantial increase in cultivated *Hoodia* with the challenge now to secure markets for this material. Similarly, although Unilever markets are secure, there remain questions as to whether a product can be developed that is safe and efficacious and desirable to consumers.

Further challenges lie in the monitoring of compliance to the benefit-sharing agreements. While this is relatively straightforward and effective for the CSIR-San benefit-sharing agreement, which has clear milestones, reporting mechanisms and traceability mechanisms, it is less so for the SAHGA benefit-sharing agreement. Because of the nature of *Hoodia* trade by the myriad of companies trading it as a herbal supplement, it is difficult to track the way in which *Hoodia* material is used. Moreover, many *Hoodia* traders wish their trade volumes to remain confidential, yet this information is vital to calculate the agreed levy to the San. The SAHGA agreement depends to a large extent on good faith and the proactive declaration by growers of volumes traded and monies owed. After close to one year of the agreement's existence, and in the absence of the long-awaited regulations which will make benefit-sharing agreements compulsory, many growers have proved reluctant to provide the necessary

information. *Hoodia* sales are also currently severely depressed as a result of increased crackdown by compliance institutions on new and unregulated products. Currently the environmental government agencies responsible for issuing permits are not legally required to provide SAHGA with this vital information, however with the promulgation of the regulations and with an amendment of the SAHGA constitution, it is anticipated that the intended benefit sharing payments will flow to the San within the next year.

Some of the greatest threats to benefit-sharing lie outside of the region. Although no conclusive figures exist, it is well known that extensive *Hoodia* populations have been established elsewhere in the world. Some of this genetic material may have been acquired before the entry into force of the Convention on Biological Diversity, and some could just as easily have been smuggled out of the region without the required permission. It is therefore possible that a *Hoodia* industry could thrive outside of southern Africa, without channelling benefits to the original knowledge holders. This concern accounts for a newly-implemented regional decision to prohibit export of live *Hoodia* genetic material outside of those countries with wild populations (South Africa, Botswana, and Namibia).

7. Conclusion

The *Hoodia* case study tells a complex story of many strands, and from it a number of important lessons and conclusions can be drawn that are important to integrate into ongoing debates about ways in which benefit sharing for communities can be made more equitable. One of the most crucial lessons to emerge from the case is the need to get it right from the start. Obtaining the prior informed consent of communities holding knowledge about biodiversity from the very outset of a project – and engaging them as active partners – is an absolutely fundamental principle of benefit sharing. The *Hoodia* case study illustrates what can go wrong when this principle is ignored.

The negotiating process between the CSIR and the San has demonstrated the importance of building trust between role players and of having in place a political climate conducive to fair deliberations. It has also reaffirmed the importance of having community-based institutions through which holders of traditional knowledge can be represented in negotiations, and benefits channelled. The process has highlighted the prominent role played by NGOs, legal representatives, and intermediaries in benefit sharing – in this case not only in assisting the San to attain their rights but also in shaping San politics and economic development.

One of the major impacts arising from the commercialisation of *Hoodia* has been the wide-ranging interest it has aroused about the importance of protecting traditional knowledge and ensuring that holders of such knowledge receive fair compensation. Amongst the San, the *Hoodia* case is considered an important empowering tool to enable more informed decisions to be made about their intellectual property and ways to protect it. At government level, the case has led directly to an increased focus and prominence for biodiversity and its potential value, and in South Africa, the inclusion of prior informed consent and benefit sharing within new biodiversity legislation and the requirement of disclosure of origin prior to the granting of patents. At the international

level, the case is widely considered to set precedents about the ways in which holders of traditional knowledge should be compensated for their knowledge.

There is clearly an urgent need to introduce new forms of protection for traditional knowledge that not only give communities rights over their knowledge but also enable the wider preservation and promotion of such knowledge systems. The *Hoodia* case demonstrates not only the value of having an integrated system to protect and promote traditional knowledge, but also the importance of so-called 'defensive protection', to prevent the misappropriation of traditional knowledge.

Some of the lessons are still to be learnt and some are only unfolding. If significant monies are eventually received by the San there will be extremely difficult issues to deal with in terms of determining who benefits and how benefits are spread across geographical boundaries and within communities, and of minimising the negative social and economic impacts and conflicts that could arise with the introduction of large sums of money into impoverished communities. The due compensation of other communities such as the Nama, Damara and Topnaar will also require careful consideration. Overwhelmingly, there will be a need for continued legal, administrative and technical support to enable beneficiaries to claim what is rightfully theirs, and to do so in a manner that consciously and cautiously brings tangible and effective benefits to the original holders of *Hoodia* knowledge.

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