

## CASE STUDIES

### CASE STUDY 4: The San people and the Hoodia Plant

#### Background

The forebears of the San people settled in the southern African region some 150,000 years ago. The San currently number about 100,000 and live in the Kalahari region of South Africa, Botswana and Namibia. In apartheid South Africa most of the Khomani San in the Northern Cape region were classified as coloured, did not own land, and worked as farm laborers or domestic help for whites. Their language, culture and hunting practices were dying out by the early 1990's, but after the collapse of apartheid in 1994, the new South African government moved to return ancestral lands to the Khomani San. Land claims were developed based on oral history research and archived information about the traditional lands occupied by the indigenous group, prior to disruption by colonial forces; in recent years the San had not existed as a geographically distinct community. During the 1990s, as they resolved their land claims with the government, the San people also established national and regional councils. In March 1999, a settlement was reached establishing land ownership in the Kalahari region,<sup>1</sup> and the land agreement was formally signed on May 23, 2002.<sup>2</sup> However, to date the communities are poor, in ill-health and lack education and jobs.

The Council for Scientific and Industrial Research (CSIR) has a broad mandate in research and development for technology in South Africa. One arm of the CSIR, Foodtek Chemical and Microbial Products, is involved in a number of bioprospecting activities in South Africa and is developing natural products chemistry capacity. While CSIR is a statutory scientific council established by parliament in 1945, its funding from the state has been declining, and as of 1996 only 40% of its funds came from the government, and the remaining 60% was derived from commercial contracts.<sup>3</sup> CSIR has increasingly sought commercial contracts for product development based on compounds identified through natural products research, as it is not equipped to do clinical or toxicological studies. The organization has thus been under pressure to obtain commercial investments as well as to respond to its mandate from the South African government.

The San have used the hoodia plant as an appetite suppressant for many centuries, especially during hunting expeditions where little food was available for many days. In 1963, CSIR became aware of the plant's traditional uses, from a 1937 paper by a Dutch ethnobiologist, and from San trackers who had worked for the South African military. In the 1980s, the CSIR revived its interest in the plant and isolated its active ingredient, a compound called P57, which it then patented in 1995.

In 1997 the CSIR licensed P57 to a small British biotech company, Phytopharm, which conducted double blind clinical trials of the chemical, confirming its appetite suppressing qualities. In a phase I trial, obese people were given P57 or placebo, and the group receiving the active compound spontaneously reduced their daily food intake by 1000 calories.<sup>4</sup> Phytopharm then sub-licensed the product to Pfizer for \$21 million. A lawyer representing the San people in the contemporaneous land negotiations with the South African government found out about the license to Phytopharm of the CSIR P57 patents. The lawyer also became aware that the head of Phytopharm believed that the Khomani San had disappeared. When the Phytopharm CEO was informed of his error, he expressed concern about proper compensation for the San community, "I honestly believed that these bushmen had died out and am sorry to hear they feel hard done by. I am delighted that they are still around and have a recognisable community. The ownership of medicinal plants is extremely complex, but I have always believed that this type of knowledge is the most valuable asset of indigenous tribes. Instead of weaving baskets and taking tourists around, royalty payments from medicines could transform their prospects."<sup>5</sup> At CSIR, the head of the P57 project said that he had intended to tell the San about the drug development once a successful product had emerged, so as not to raise false hopes.

The attorney representing the San in the land claims communicated the news of the patents to the newly established San political organization, which decided to challenge the lack of compensation for their traditional knowledge. An urgent meeting was called between the Working Group of Indigenous Minorities in Southern Africa (WIMSA), representing San people in several countries in the region, and representatives of CSIR in June 2001. The attorney described the timing of the patent issue as opportune, since the San had recently organized politically to address the land claims and other heritage problems, and so were in a good position to enter negotiations. Under the auspices of WIMSA, a South African San Council was formed in November 2001, which represented the claims regarding traditional knowledge and benefit sharing in negotiations with CSIR.

The San did not challenge the patent itself (which could have resulted in loss of profitability as the commercial knowledge then became public) but rather demanded some form of benefit from the commercial development process. In response the CSIR immediately acknowledged that some form of compensation was appropriate and began negotiations with the indigenous people's representatives. As a result, the San Council and the CSIR entered into a memorandum of understanding in February 2002 recognizing the San contribution in the form of traditional knowledge. WIMSA reports that benefits will be shared not only with the South African San but also with San peoples in other countries in the region: Namibia, Botswana, Angola, Zambia and Zimbabwe.<sup>6</sup>

Reaching an agreement took three years of "tough negotiations," to quote the San Council chair.<sup>7</sup> Under the terms of the agreement reached between CSIR and the San, announced in March 2003, CSIR will pay 6% of all milestone payments (estimated to be \$0.9 to \$1.4 million) it receives from Phytopharm, and 8% of all royalties from products developed from P57. Milestone payments are paid upon completion of agreed technical performance targets over a three to four year period.<sup>8</sup> Royalties would be based on sales, which were not anticipated before 2008.<sup>9</sup> Payments are to be made to a trust fund established for the San, the San Hoodia Benefit-Sharing Trust. The Trust includes representatives of CSIR, the regional San Councils, WIMSA, and an observer from the South African Department of Science and Technology. The trust fund can then be used for local development projects in the community. The San plan to use the money for education, jobs, and preservation of their language. As described in a press release, the trust is set up "to use income received from the CSIR for general upliftment, development and training of the San Community as approved by the Board of Trustees."<sup>10</sup> The agreement has been hailed as a landmark in more equitable sharing of benefits from traditional knowledge. At a ceremony celebrating the agreement a San participant, said "I am happy that others can benefit from our plants." But a San community development facilitator replied: "But it would be wrong if fat white people overseas get slim thanks to us while our children go hungry and uneducated."<sup>11</sup>

However, as of August 1, 2003, Pfizer discontinued its development program for P57 and returned the sublicense rights to Phytopharm.<sup>12</sup> The Phytopharm Chief Executive commented that considerable clinical and preclinical data have been obtained and that his company is now seeking other partners for commercial development. The drug has been through phase IIa trials and is reported to have clinical promise in the growing market for anti-obesity compounds. The hoodia plant has already made it to the "gray" market of internet sales of natural products, although the quality of these unrefined and untested supplements is unknown.

## **Discussion Questions**

1. Is the benefit-sharing agreement reasonable in terms of amount and type of benefit distributed to the San? How can it be determined that distribution of monetary gains through the San Trust fund is reasonable and genuinely beneficial to the San people?

2. In this case, the San were able to negotiate for benefits with CSIR after a patent had already been established. In some cases indigenous groups have been unsuccessful in making claims for benefit sharing. What kind of oversight could be exercised more generally on the part of the government of South Africa or other nations, to provide for benefits to indigenous communities that share traditional knowledge?
3. In this case, indigenous political organizations had already been formed for land claims issues. How can legitimacy of such organizations be determined, especially when the prospect of large financial gain enters the picture?

## **Bibliography**

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- 4 Mangold T. Magic molecule. The Age (Melbourne). 2003 June 23; Sect. A:3 (p. 6).
- 5 <http://www.thehoodiacactus.com/>
- 6 Presentation by Victoria Geingos and Mathambo Ngakaeaja, WIMSA, at summit meeting "Biopiracy—Ten Years Post Rio, 22-23 Aug 2002, Johannesburg, South Africa.
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- 8 As of March 2003 \$32,000 had been paid in milestone payments.
- 9 Nutraceuticals International Newsletter. South African indigenous knowledge deal. 2003 Apr 1.
- 10 Stephenson D. San Reach Landmark IPR Benefit-Sharing Accord for Diet Pill. Cultural Survival Quarterly 2003;27(3);7.
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## **Discussion**

### **Chairperson**

I will now ask the reporters from each group to make their presentations.

### **Rapporteur**

In our group, which was chaired by Roger Chennels, the discussion returned repeatedly to the exceptional nature of the case. We spent most of our time on the subject of benefit sharing, and on how the notion of benefit sharing is sometimes portrayed as a panacea for all of the ills of collaborative research. This may not be the case as, in some ways, benefit sharing draws out the worst of the complexities of pharmaceutical and high-tech industries, and in others, it may not be the most appropriate solution for the community.

We considered the practical aspects of the case, notably how the trust fund would be used, how much money would be in the fund, and who would decide where the benefits would go. The answers were very interesting. The San people were present from the outset in the decision-making process about how the money would be used and Roger participated in these discussions as their lawyer. The San decided to divide the fund into three portions, one for each country involved, rather than dividing the fund according to the number of people in each country, as this seemed to be the fairest solution. A positive outcome of this benefit sharing agreement is that the San have begun take pride in their knowledge and culture. Unfortunately, a negative side effect

has been that the government of Namibia, where many San live, has felt excluded from the process. This reminds us of the need to take account of geographical complications in benefit sharing agreements.

The second question which we considered was whether this case represents a polarisation in bio ethics. The system of patent applications and benefit sharing has developed largely from the fact that Western researchers need to access these communities. We discussed whether there is a need for, or indeed an opportunity for, the people in developing countries to adopt a leadership role in project development. Is it possible for this polarisation to be reversed and for the south to take the initiative in the bioethics research process?

Thirdly, we discussed the choice which Ricky made. This poignant anecdote made us question whether we should praise his choice as noble, or regret the fact that he felt unable to sustain his life in any other way. It is important that we accept his choice and then seek to understand the dynamics behind it. Indeed, it was noted that his decision to treat his family and friends to a celebration was in no way different to how a westerner might react to coming into unexpected wealth.

The final point we considered was obesity, the health crisis that the hoodia plant will be used to treat. It was pointed out that obesity is not only an affliction of the rich but that it also affects poor people who are unable to afford to eat the right food. Parallels were drawn with tobacco, which is used as an appetite suppressant by women who want to stay slim, just as it is sometimes chewed by poor people in India who cannot afford to buy food.

### **Chairperson**

Thank-you. We will hear all four presentations before we open the floor to discussion.

### **Rapporteur**

We addressed three questions during our discussions. The first of these was benefit sharing, notably whether the benefits were of a fair amount and type. In order to answer this question, it is necessary to understand what fair means in this context and to consider whether the notion of benefits should be defined by the community itself or by the outside parties in the agreement. We noted that it could be inappropriate to introduce money to a community which does not have the mechanisms to deal with it. In such cases, it may be necessary to phase in the concept of benefits in order to provide the community with the capacity to define appropriate levels of benefits and to decide how they are used. The geographical spread of the community must also be considered. For example, the San are spread across three countries and development needs could vary greatly between the different groups. While there is a moral obligation to set benefit sharing within a development context, there is also an obligation to maintain cultural autonomy.

It was noted that groups should have the opportunity to form partnerships with competent organizations which would then take on the responsibility for developing benefit sharing capacities within the context of sustainable development. Furthermore, although development is not viewed from the same perspective throughout the world, it would be beneficial to develop a standard approach which could be implemented across the board and then adjusted and re-defined relative to individual circumstances.

On the subject of legitimacy, we considered why researchers rarely question the legitimacy of local community groups which negotiate on behalf of indigenous minority groups. In many cases, communities already have bodies with established legitimacy derived from, for example, land claim negotiations. It was argued that these long-standing groups should be considered preferable to bodies which are created specifically to negotiate on a single project. Legitimate negotiating organisations should take account of the feudal or hierarchical system that exists in the society and should be honest brokers which truly represent the needs of the community. The

success of the San's negotiations with the CSIR following the hoodia case was in part due to the fact that there were no other political agendas behind each party's negotiating position and to the fact that the government played the role of honest broker. It should be remembered that South Africa entered the post-apartheid democratic era in 1994.

### **Rapporteur**

Our reflections led us to conclude the following: conventional medicine must be preserved at all costs. In the case discussed, the creation of a local scientific council would have created the conditions for the development of health centres. Instead, the countries of the North sent funds. Meanwhile, financial aid is not always appropriately used in addition, we emphasized interest in a collaboration between conventional medicine and modern medicine. For example, the technological exploitation of plants can bring about surprisingly interesting results: it is what we call phytochemistry.

### **Rapporteur**

A number of interesting, sometimes contentious, points were raised during our discussion. We started by discussing reasonable benefit sharing. One major argument related to the importance of providing the San people with education so that they are able to develop their advocacy skills and maintain their independence during negotiations. However, it was argued that we are not entitled to decide that the San must be educated, particularly as education might result in the community losing some of the characteristics by which it defines itself.

We questioned whether the benefits of the hoodia plant should be limited only to the San, or whether they should be shared with communities throughout the world. Again, there was no agreement on this matter. While some people believed that the whole world should benefit from this knowledge, others argued that it would be unfair to appropriate knowledge from a small, under-developed, oppressed community and distribute it among everyone. It was felt that some of these problems might be resolved if the San had an independent negotiator to speak on their behalf.

The amount of benefits to be shared provoked further debate. In response to arguments that the San should be given 50% of the benefits, participants questioned the logic by which such a figure was obtained. They asked why 50% should be any more appropriate or reasonable than 1% or 3% or 90%. Although we tried to make comparisons with cases in developed countries in order to draw parallels and see how such issues were resolved, we could think of no similar cases in the West at present.

Finally, we considered which steps could be taken to prevent similar scenarios arising in the future. It was felt by some people that pharmaceutical companies try to impose ready-made conditions and procedures on communities and that researchers should play an active role in fighting against this by forming special lobbying groups to make it clear that such approaches are no longer acceptable. There is a tendency to approach local communities with preconceptions about how knowledge and benefits should be used. Instead, we should engage in dialogue and investigation before starting a project in order to understand the requirements of the community in question. It was suggested that an independent organisation, possibly under the auspices of the World Health Organisation, should be responsible for auditing procedures. In addition, developing countries should clarify their own position in respect of these issues and implement ethical and legal frameworks which take account of developments in research.

### **Chairperson:**

Thank you very much. I am sure that you will agree that there has been considerable overlap between the reports of the different groups, but also remarkable diversity in the way these matters have been approached. A number of interesting points of view have emerged. I would

like us to discuss these issues in the order of the questions which were posed. The first question relates to perceptions of benefits, that is to what they consist of, how we can ensure that they are distributed in an appropriate and equitable way, and how they can have a positive impact on the wider community.

**Comment:**

Before dealing with the issue of benefits, it would be appropriate to ask if the notion of sharing must evolve towards the notion of exchange. In fact, by evoking sharing, we admit that the benefit of such sharing comes from a classification of benefits by the North. Conversely, the notion of exchange involves considering the benefits of countries of the North and those of the South as being on a same hierarchical level.

Traditional cultures are vulnerable. Would the initial exchange not be a commitment to actively preserving cultures in danger in a way that allows them to evolve? The sharing of benefits will, I believe, only apply within this context.

**Comment:**

The question of meaning must be key in our approach to the notion of sharing. As long as this question will not have been dealt with head on, everyone will represent sharing according to a necessarily conflicting cultural horizon.

**Comment:**

I share Mr .Ameisen' s view. The culture of business consists in making profits, as shown by the Pfizer case study. This almost antinomic distinction between making benefits and being beneficial to others is essential. To talk about sharing is to talk about persuasion, negotiation, equity and non-stigmatisation. These are the bioethics values that interest us. It would therefore be useful to review North/South relationships, not according to relationships of power but in relation to what I would call "co-vulnerability".

**Comment:**

I would like to share my fears as to the way our discussion is going. We are talking about ethics but, since yesterday, all of our definitions of the benefit concept differ.

It would therefore be appropriate if we all agreed on the meaning of benefit. Under-developed societies need help. Nonetheless, the importance given to money shows a disquieting commonality of this under-development. Developing societies need structures (such as schools or healthcare centres) more than they need money.

**Comment:**

I would like to add to Mr .Ameisen' s intervention. Other than the sharing of material benefits, there is a need to monitor the protection of heritage, such as that of the San society. Furthermore, and because it has to do with the case studied, it is the Council for Scientific and Industrial Research that initially imported the active substance, without having referred to the community that had been using this plant for centuries. The local council is therefore responsible for the first pillage. The responsibility of local authorities is also in question.

**Chairperson:**

It is time to move on so I will take only one more quick comment on this issue.

**Comment:**

The question of benefits depend on the perspective of the individuals involved. The current discussions and comments give the impression that benefit sharing should over-ride all the other aims of research. I believe that building solidarity among human beings and developing the potential for communities to be autonomous is a crucial point which we cannot afford to overlook when discussing benefits as, in my view, these should be the principal benefits.

**Chairperson:**

Thank you. To summarise, we have heard an overwhelming call to re-visit how benefits are defined and conceived of in their broadest sense. Benefits must be considered not only in financial terms, but also in relation to their capacity to empower and develop a community and give it the capability to act autonomously. They must be viewed from the point of the view of the communities involved.

We shall now move to the next question, which considers how to define 'honest brokers' and legitimate parties within negotiation processes. Several participants have noted the importance of determining the benefit agenda; it is also important to determine who speaks for the people and which brokers should be trusted. Although the groups have summarised their views on this point it would be interesting to hear individual comments.

**Chairperson:**

The question of legitimate brokers depends on the circumstances of the country. However, when possible, the government should always be the first choice. In the case of the San, the government is democratic and should, therefore, be their representative. When democratic government does not exist, it becomes necessary to look elsewhere. For this reason, it is necessary to investigate ways of empowering the communities so they can represent themselves. During the discussion, it has not been mentioned that the three San graduates were involved in the process. If they were not involved, I would like to know why that was the case. If educated members of the community are not included in the negotiations then the process of empowerment will never develop.

**Comment:**

I would like to note that people from developing countries do need bioethics. I appreciated the San study presentation and believe it provides interesting lessons about education.

Although three people from the community are educated, the man in the anecdote burned his money. No-one who has studied and who associates money with knowledge and education would ever do that. It is also quoted that a San representative remarked that it would be wrong if fat white people overseas benefited from the San's knowledge while their children went hungry and uneducated. This statement shows that these people do think about education and do understand the importance of developing their community. In my opinion, local or governmental authorities should represent their interests.

**Comment:**

I disagree that the government, even when it is democratic, is necessarily the best option for legitimate representation. Many governments are not accepted by the population, are backed by vested interests, or are not morally empowered by their mandate.

I would also question whether the three San graduates can or should represent a community which has lived in the bush for centuries. These graduates are not, in fact, 'representative' of the San community; they are exceptions to the rule.

**Comment:**

All of the countries of the South encounter a certain amount of potential conflicts of interest when it comes to choosing between short term (economic benefits) and long term benefits (survival of a culture). It would be appropriate to plan for an international mediation on ethics that would decide on these exchanges.

**Comment:**

While I agree that governments are not always the best honest brokers, if they are not involved then nothing at all can be achieved. Particularly in a situation such as this, which involves three governments, it would be wonderful to have a process which is so transparent that the government is unable to act in an incorrect or unethical manner and which would force them to work for the good of the San people.

**Comment:**

I would like to note that the Europeans here are talking as if they were not, one day long ago, in the same position as the San. The bottom line for all of us must be to ensure that there is development in this community, so benefit sharing and sustainable development must be a goal, I also think that it is offensive to say that some governments do not care about the economic development of their country. We should remember that the resources which the San use do not belong to the San: they belong to the government. As property rights do not exist in many developing countries the governments of these countries, however corrupt, must be involved. We should work to make them less corrupt but we cannot ignore or bypass their role in negotiation, governance, and the creation of regulatory systems.

**Chairperson:**

Thank you for those extremely helpful comments. Let us now turn to the last question, which asks what kind of regulatory mechanisms we could propose and whether they are necessary. If they are necessary, what kind of framework for national or international regulations could be recommended?

**Comment:**

The origins of research ethics lie in the need to protect research participants. Individual benefits for people who take risks by participating in research should not be replaced by communal benefits. When we discuss communal benefits, we should be clear whether these would be supplementary to existing benefits.

Secondly, and perhaps more controversially, I would argue that community benefits might not even be an ethical imperative. As soon as pharmaceuticals companies become involved, any agreement automatically becomes a commercial proposition. My simplified idea of commerce is that each party aims to maximise its own level of benefits and, in this situation, I do not see a need for governing regulations. I am confused about where ethics stops and straightforward commerce begins.

**Comment:**

Current levels of development vary greatly between different communities. In my opinion, an international organisation should lay down ground rules which establish a uniform minimum level. I think that it is necessary that an international agreement or agency takes the responsibility in this matter as individual countries should not be made responsible for enforcing such standards on their own.



**Chairperson:**

The chairs of the four groups will now summarise their views of the discussion.

**Comment:**

As other interveners have already stated, we all need to be conscious of the fact that financial aid is not enough. A genuine sharing of benefits means creating the educational and healthcare structures in these countries.

Also, ethics committees are isolated in countries as vast as those that make up South America or Africa. We could maybe come up with a law on ethics coordination for these different bodies.

**Comment:**

I believe that we need to seek guidance from national and international structures if we are to find mechanisms which are capable of addressing these issues, particularly capacity building, empowerment, and developing trust. Roger Chennels noted that he has worked with the San for ten years; we do not have this amount of time to build relationships with indigenous communities prior to embarking on research. However, we must aim to incorporate these goals into our work.

**Comment:**

I find it very interesting that people assume that representation is a problem for all indigenous groups. While it certainly is an issue for some groups, it is not true for all of them, so we should be wary of developing a one-size-fits-all solution. Furthermore, the fact that an organisation has a long history does not mean that it is representative of the community. Research is required into methods of representation if we are to develop accurate guidelines.

On the question of legitimacy, I would like to note that democracy and corruption are not incompatible. There are a number of examples of corrupt democratic governments so democracy should not be the only basis for deciding whether a government is an 'honest broker' .

We have seen that fair benefit sharing relates to the level of benefits but also to the types of benefits and to how these meet the needs of the group. I subscribe to the view that we need legally binding international and national agreements. Leaving individual informal groups to negotiate within a country is not an acceptable way of managing this problem.

These discussions have also shown that the celebrated idea of prior informed consent is not particularly useful as a tool as so many unpredictable factors are at play during the project process. Rather, we should aim for sustainable development which meets the primary needs of the community as much as for benefit sharing.

**Comment:**

I am pleased that discussion is still continuing on this extremely interesting case. The case is still very active so it is very powerful and useful to receive such excellent input from the Forum. I greatly appreciate the ideas which have been forthcoming.

The first point I would like to discuss is whether South Africa did the right thing. In fact, the company in question is a private research organisation which is entirely owned by the government, so it is both the government and not the government. More importantly, it is a commercial organisation and I feel that it is difficult to criticise a commercial organisation for taking a commercial decision when their first concern is for their shareholders and the bottom line.

When dealing with commercial companies we must speak the language of commerce and accept that, although they may do lip-service to ethics, they are focused on profit.

Although the development framework is not the key focus here, I have heard more common sense on this subject today than I have in development forums. High-level UN agencies do not question the issue of benefits or the patronising approach of westerners towards developing countries. I am pleased that this arrogance and lack of consideration of ethical questions has not been present during the current debate.

It has been stated that a government has a duty to develop its people. In response to that, I would like to note that the government in Botswana is, at present, engaged in a policy of developing the San. Should the San not also have the right to disengage from this process?

The government has moved them off their land and into houses, telling them that they must be 'normal' and stop living like animals. The government is, albeit in good faith, destroying an ancient culture, denying the San their freedom of choice, and squeezing them into a development framework which they do not fit. We should remember that the governments of indigenous people are often far removed from the reality of their lives.

Unfortunately, we do not have time to discuss the issue of representation in more detail. However, I would like to note that, for the San, the issue has been largely resolved as the case has been going on for so long.

Thank you.