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UNDERSTANDING BIOPROSPECTING: CAN INDIGENOUS POPULATIONS BENEFIT FROM THE SEARCH FOR PHARMACEUTICALS IN AREAS OF HIGH BIODIVERSITY?

by

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Abstract

Bioprospecting is a controversial issue, and anthropologists and other scientists are quick to take sides. The idea of large corporations pumping money into conservation and development programs, while developing what could be the latest life-saving drug simply sounds too good to be true, and often times is. However, if all parties work together and proceed with caution, these benefits could become more than a fantasy. Looking at case studies from Costa Rica, India, South Africa and Panama this paper attempts to find patterns among successful bioprospecting agreements and note shortcomings and identify risks. This information will be used to suggest how indigenous communities can maximize benefits while protecting their rights in bioprospecting relationships.

Introduction

Biodiversity prospecting, or bioprospecting, is "the exploration of biological material for commercially-valuable genetic and biochemical properties" (Laird and Wynberg 2008).

Bioprospecting is used by a number of industries, from cosmetics to agriculture to biotechnology. The focus of this thesis is on the role of bioprospecting in the pharmaceutical industry. Currently, a large number of drugs on the market require natural-compounds for their production. In fact, "a third of the products that comprise the US\$ 200 billion plus prescription drug industry" (Onaga 2001) are naturally based compounds, meaning they came from plants, invertebrates, fungi or microorganisms. The majority of these compounds are found in areas of high biodiversity, such as rainforests or coral reefs, typically located in Third World countries along the equator or in the Southern Hemisphere, where a high concentration of remaining indigenous populations live.

There is a long history of the wealthier northern hemisphere companies taking advantage of its neighbors in the South leading some anthropologists to wonder if bioprospecting is just another form of colonialism, or "bioimperialism" (Moran, King and Carlson 2001). Shiva (2007) argues that bioprospecting is simply a sophisticated form of "biopiracy", a practice that "creates impoverishment within donor communities by claiming monopolies on resources... and forces communities to pay for what was originally theirs."

International agreements have been developed in recent years to protect the traditional knowledge of local peoples. The Convention on Biological Diversity (CBD) has had a particular focus on the legal issues concerning bioprospecting (Kursar et al. 2006). According to Zedan (2005), "the Convention is the first international instrument to take a holistic view of the conservation of biological diversity by integrating ecological, social, and economic perspectives.

Indeed, the core bargain between the North and the South in the negotiation of the Convention is the South's commitment to conserve biological diversity and the North's to share in the costs and benefits of sustainable use." The CBD serves to ensure that developing countries benefit from the "exploitation of their genetic resources" (Zedan 2005).

Pharmaceutical companies have an economic interest in protecting areas of high biodiversity, as these areas are most likely to produce the compounds that could be used in future drugs, and thus future profits for drug corporations. If proper regulations are in place, local indigenous people may also gain from benefit-sharing agreements and new technologies brought into the country from pharmaceutical companies and their profits. An example of a positive benefit-sharing approach is Merck's contractual agreement with Costa Rica's National Biodiversity Institute (INBio). Under the agreement, Merck paid \$1 million over two years to INBio for the right to collect soil, insect and plant samples. INBio scientists process the samples before sending them to researchers at Merck, who then test the samples for chemical activity. "If INBio can create more jobs, profits, and a better-educated constituency by cataloging and selling rights to the country's natural resources than by destroying its resources, it makes economic sense to keep the resources intact" (Blum 1993). This approach has been fairly limited thus far, but could be modified for further research.

In contrast to the success of INBio and Merck's agreement, consultations between South Africa's Council for Scientific & Industrial Research (CSIR) and the San of the Kalahari Desert, which is the oldest surviving ethnic group living in Southern Africa, paint a less rosy picture of bioprospecting. In the late 1990s, the CSIR began negotiations with US pharmaceutical giant Pfizer to commercialize the appetite suppressant qualities of a flowering, cactiform plant, *Hoodia gordonii*. This plant is important to the culture of the San and has been used traditionally for

thousands of years. The negotiations began without involving the San. The two parties did eventually sign a benefits-sharing agreement, although it is often met with criticism for limiting the San's legal claim on Hoodia and providing little in terms of actual payout (Wynberg 2004).

These two examples indicate that bioprospecting has potentially significant benefits to alleviate poverty and to protect areas of the world's richest biodiversity. However, bioprospecting also can be viewed as just another way for the modern capitalist economy to exploit indigenous populations. The purpose of my thesis is to examine four specific cases from the literature and conduct a comparative analysis of the potential impact of bioprospecting on indigenous people and specifically address the degree to which prospectors have negotiated or have not negotiated with native peoples, how agreements have been forged, what role national governments played in the agreements, how native people have profited, and how profits have been used by native peoples.

Materials and Methods

The issue of bioprospecting and benefits-sharing is broad. To narrow the focus of this paper, four case studies were looked at in depth. These studies were chosen because they represented a spectrum of user/provider relationships and they each showed a unique approach and result. Studies from South Africa, Costa Rica, Panama and India were examined. These studies were readily available in the literature and provided different perspectives on the issue. The cases also show both positive and negative consequences from which suggestions will developed as to how future bioprospecting agreements can maximize benefits and minimize risks for local parties.

The provider community is not indigenous in each example, though that is where the focus of the thesis lies. The current working definition provided by the UN states, "Indigenous

communities, peoples and nations are those which, having a historical continuity with preinvasion and pre-colonial societies that developed on their territories, consider themselves
distinct from other sectors of the societies now prevailing on those territories, or parts of them.

They form at present non-dominant sectors of society and are determined to preserve, develop
and transmit to future generations their ancestral territories, and their ethnic identity, as the basis
of their continued existence as peoples, in accordance with their own cultural patterns, social
institutions and legal system." There are unique challenges that indigenous people face that other
local communities may not, yet most of the successful relationships that appear in the literature
did not involve indigenous populations. There may still be something to learn from the
arrangements between non-indigenous local peoples and drug companies, though it may take
additional assistance for marginalized indigenous peoples to reach similar success.

Results

A general summary of the results in the context of the party's involved, the negotiation process, role of Government/NGOs, and the monetary and non-monetary benefits to the local community are summarized in Table 1. Details for each case are provided in the following paragraphs.

South Africa: The San and Hoodia

The San of the Kalahari Desert are the oldest surviving ethnic group living in Southern Africa. Today they live in parts of South Africa, Namibia, Angola and Botswana. They have been using Hoodia as a thirst and hunger suppressant for thousands of years, a practice which drew the attention of researchers in the 1960s. At this time, South Africa's Council for Scientific & Industrial Research (CSIR) began studying the plants properties and ultimately filed to patent the "discovery" of its appetite-suppressant qualities in 1996.

The CSIR began negotiations with Pfizer to commercialize the drug, without first consulting the San. In fact the CSIR was quoted in a newspaper article "having told their international collaborators that the 90,000-strong San 'no longer existed'" (Wynberg 2004). Fortunately, NGOs Biowatch South Africa and Action Aid stepped in and alerted the media to exclusion of the San from the Hoodia negotiations in 2001 (Wynberg 2004). International pressures served as a catalyst to get the San involved in the agreements. In 2003, the CSIR and the San sign a benefit-sharing agreement. However, the San received no legal or strategic aid in the negotiation process and their requests for training and assistance were denied. The San, a traditionally egalitarian society, were "pressured by NGOs, donors and governments to organize themselves and appoint leaders" (Vermeylen 2007). The procedure ignored the San's traditional decision-making process and they were expected to "organize themselves in such a way that it was easier for the CSIR to deal with them" (Vermeylen 2007). By encouraging the San to function in a way that was familiar to Western culture, a group of San elites rose to power that previously had not been there. This new high status often came from the ability to speak Afrikaans, the language of the outside world. This new hierarchy created a great deal of tension among the San, who had always made their decisions through discussion and consensus. Using this system, however, only a small, select few voices were heard from an already marginalized people, yet very few living outside of South Africa were even aware of the proceedings with the CSIR. A lack of communication and full community consent plagued the negotiation process.

The treatment of the San was not the only concern regarding this agreement. In fact, the case of the Hoodia plant pokes many holes in the entire benefit-sharing system. Without assistance in the negotiation process, the San and the CSIR reached an agreement that the San would receive six percent of royalties and eight percent of all milestone payments that CSIR

collects from the sale of Hoodia (Vermeylen 2007). Wynberg (2004) estimates that this would account for approximately 0.03 to 1.2 percent of the products net sales. This money would be divided equally among the four countries the San are living in, and used for development projects and to fund the San Council. Unfortunately, the commercialization of Hoodia hit some roadblocks. Pfizer dropped out of the project in 2004, when Unilever picked it up, hoping to sell it as a supplement rather than a prescription drug (Vermeylen 2007). This dramatically cut the profit margin. In the 2008 Sustainable Development Overview, released a year after Vermeylen published his study, Unilever too backed out of plans to use Hoodia in diet products after investing 20 million Euros. In its Sustainable Development Overview Unilever reports, "Innovation also carries uncertainties and does not always lead to positive outcome... We stopped the project because our clinical studies revealed that products using Hoodia would not meet our strict standards of safety and efficacy" (Unilever 2008).

Although the project fell through, under their agreement with the CSIR, the South African San were prevented from "using their knowledge of Hoodia in any other commercial applications...(and) to claim any benefits from the dozens of new Hoodia-based products that have recently emerged in the market, which blatantly use San traditional knowledge of Hoodia in their promotion" (Wynberg 2004).

Perhaps it would have been more viable for the San to pursue options based on nonpatented herbal medicines (Wynberg 2004), Thomas Kursar and his colleagues agree that monetary benefits should not be the focus of negotiations, stating,

Because the success rate for drug discovery is exceedingly low, financial benefits, such as milestone payments or royalties, are highly unlikely. Furthermore in the case of royalties, the time frame is long, perhaps 10 to 12 years from discovery to receiving benefits. Thus this model, with the source country offering biological materials and the developed country supplying research, provides few or no benefits for the source country (Kursar et al. 2006).

The San did not know that they could pursue non-monetary benefits, as established in an addition to the CBD, known as the Bonn guidelines. The Bonn guidelines, added in 2002, include "benefits such as access to and transfer of technology, training and joint research, acknowledging sources, reporting research results, scientific cooperation, institutional capacity-building, employment opportunities and ongoing relationships" (Vermeylen 2007). Had the San been informed about the non-monetary benefits, they might have more to show from their negotiations with the CSIR.

Costa Rica: INBio and Merck

The negotiations and agreements that took place between Merck and the Instituto

Nacional de Biodiversidad de Costa Rica (INBio) were of a very different form than those that
occurred in South Africa between the San and the CSIR. Despite their differences, there are
similarities between the two and there is something to be learned from comparing cases on both
ends of the spectrum. Costa Rica's high biodiversity and natural beauty is world renowned, yet it
is at high risk of being destroyed as development pushes forward. One reason for this
destruction is the "incompatibility of short-term economic growth with the sustainable
development of natural resources" (Blum 1993). Blum (1993) continues, "When an
economically struggling country has a choice between logging a forest to sell timber for high
profits and leaving the forest intact without monetary compensation, the nation usually chooses
the profitable alternative. Because immediate economic gains to the nation are more important
than future environmental costs, deforestation occurs without regard to its long-term effects on
biodiversity preservation." Faced with this common challenge, researchers in Costa Rica came
up with an uncommon solution; partnering with a multinational company.

INBio is "a private research and biodiversity management center, established in 1989 to support efforts to gather knowledge on the country's biological diversity and promote its sustainable use. The institute works under the premise that the best way to conserve biodiversity is to study it, value it, and utilize the opportunities it offers to improve the quality of life of human beings" (INBio 2011). They are non-profit and non-governmental. In 1991 they teamed up with Merck to protect biodiversity and promote the discovery of new compounds that may be used in drugs. INBio received \$1 million dollars from Merck over 2 years, plus 5 percent of royalties on the sales of any products developed from samples found in the study area. Costa Rica's Ministry of Natural Resources, Energy and Mines will receive money from the agreement as well, \$100,000 from INBio and 50 percent of any royalties. This money will be used for biodiversity conservation projects throughout the country (Gershon 1992).

By putting money into a private research institution, the Merck-INBio agreement is helping to provide jobs for scientists allowing them to stay in their home country and is strengthening the economy by keeping research and development jobs in Costa Rica. Although no drugs from this deal have made it to the market yet, Merck claims that a number have "market potential" (Cullen 2008).

Of course the agreement is not without its flaws. One of the main criticisms of the arrangement is that INBio is private, and dispute the organization's power to make decisions for the country, arguing, "INBio has no right and no authority to represent Costa Rica" (Gershon 1992). Many also believe that the Costa Rican government should get a bigger cut of INBio's payment from Merck. However, these criticisms have not stood in the way of the deal being renewed in 1994, 1996 and 1998 (Cullen 2008).

Panama: Collaboration with the International Cooperative Biodiversity Group (ICBG)

Comment [dcg1]: You need to make some comments about the monetary and non-monetary benefits to the local community. There appears that there is not any.

One of the problems with traditional bioprospecting benefit-sharing agreements is the provider country's dependence on a raw material. Exporting raw biotic resources generates little revenue for a source country. Value is added when the material becomes a commercial product. By basing research in the host country, its economy will benefit from new jobs, training and infrastructure, improvements in scientific capacity, policymaking, resource management, tourism, conservation, and perhaps even start-up biotech companies (Kursar et al. 2006). In the late 1990s a team of researchers collaborated with the International Cooperative Biodiversity Group (ICBG) of Panama in an attempt to prove that drug discovery, conservation and economic development could go hand in hand. The partnership's goal was to ensure that Panama "receives immediate advantages from bioprospecting" (Kursar et al. 2006). Similar to the Merck-INBio agreement, the collaboration between the ICBG and Panama went beyond monetary benefit-sharing and worked to incorporate infrastructure for more long-term economic development.

Comment [dcg2]: This should be moved into the discussion section.

<u>Using</u> funds from the ICBG and the Smithsonian <u>Institute</u> two new laboratories were built in Panama and several others were updated. Research is done on over 100 compounds, searching for new cancer fighting drugs, as well as treatments for tropical diseases. These new facilities not only provide jobs for Panamanian scientists, but also research experience for the students. They also bring in about \$500,000 a year for Panama. Although outside help is required to get started, "a self-sustaining research capacity can be developed in a relatively short time, such that investigators can independently obtain their own funding" (Kursar et al. 2006).

Kursar et al. (2006) argues that, "one of the more remarkable characteristics of bioprospecting is that issues of great importance that are often at odds- conservation, sustainable economic development, and human health- become interconnected and mutually beneficial."

Following their work in Panama, Kursar and his colleagues conclude that bioprospecting deserves "strong encouragement at both the national and international levels."

The ICBG has projects outside of Panama, as well, that have achieved varied levels of success. However, anthropologist Shane Greene writes, "Of the eight ICBG grants awarded, the two that were clearly the most controversial, ICBG-Aguaruna and ICBG-Maya, entailed direct negotiations between indigenous peoples and bioprospectors and the intervention of interested third-party NGOs claiming to act on behalf of or in conjunction with those indigenous peoples" (2004).

India: Community-based Enterprise, Rural Farmers and the GMCL

Like the Panamanians, communities in India are interested in linking bioprospecting to economic development for marginalized people. Without outside funding, the Indians turned to a bottom-up approach, developing a community-based enterprise, called Gram Mooligai Company Limited (GMCL), which "supplies medicinal herbs to pharmaceutical enterprises playing an intermediary role between these companies and the local farmers, and it commercializes ayurvedic medicines produced by local communities under the brand of 'VillageHerbs'" (Torri, 2009).

The GMCL is composed of a number of small village organizations or *Sanghas*. Each *Sangha* is composed of no more than 20 (usually between 10 and 15) members, who are all women and all of the same socio-economic and caste background. This homogeneity helps to prevent conflicts within the group and encourages joint decision-making. The majority of the members are landless, and the program relies heavily on social capital to run smoothly. The women in the *Sanghas* are herb gatherers and collectors. They collect 17 medicinal plant species

from fallow farms, barren land and wetland banks. The GMCL also promotes the cultivation of 5 species, as well as teach the use organic farming methods (Olaganathan et al. 2005).

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When the GMCL negotiates a deal with a pharmaceutical company, they offer the order to the *Sanghas* who will then collect the herbs for 70 percent of the buyer's negotiated price.

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Comment [dcg3]: To what does it

This system produces a modest income for poor families that has the potential to continue to grow. It has proven to recognize and protect medicinal plants, restore faith in traditional knowledge in ethnomedicine and makes rural healthcare available to over 3,000 families (Olaganathan et al. 2005). The program also empowers women by improving their social standing. The success of the GMCL has "increased their sense of identity and their empowerment as a community" (Torri, 2009).

Discussion

Negotiation Progress

The negotiation process varied significantly between the four cases studied (Table 1).

Clearly, the situation the San faced with the CSIR was less than ideal. They were not respected throughout the decision making progress and the proper assistance was not available to them.

This early example of a benefit-sharing agreement points out flaws in the system and to the importance of open communication between all parties involved.

In Costa Rica and Panama the negotiation process looked very different. In both of these examples, decisions were made with assistance from outside forces, and the help of the national government. Also in these cases, the providers were involved in the negotiation process from the beginning. Even so, in the Merck-INBio agreement in Costa Rica, not all were happy with the final agreements (Gershon 1992). The case in India between the *Sanghas*, the GMCL and national and international drug companies is different still. This approach included more

Comment [dcg4]: You indicated you were going to deal with: negotiated or have not negotiated with native peoples; how agreements have been forged: what role national governments played in the agreements, how native people have profited, and how profits have been used by native peoples.

These have not all been covered in the discussion, which they should.

Comment [dcg5]: What does early mean?

community-involvement. Because the GMCL is owned by the women who collect herbs for it, there is less clash of interest as the two parties are working for the success of the project.

Benefits to Local Community

Comment [dcg6]: You have identified similarities and differences, which is good. Can you give the reader of what would be a good way to go.

As one would expect, each arrangement produced very different results. Each case had pros and cons, unique of course to the situation at hand. The studies in South Africa and Costa Rica both included a benefit-sharing agreement with a pharmaceutical company. In both cases, a long negotiation process established the percentage of royalties and any additional milestone payments the local peoples would receive from the sale of products addressed in the legal agreements. Royalty agreements are criticized because until the pharmaceutical company in the negotiations produces a drug that goes to market, there are no royalties for the provider communities. If drugs never surface from the deal the local peoples never receive royalties. Another criticism of the benefit-sharing approach is if the drug does become available for sale, and hits it big for the pharmaceutical company, then the percentage of the royalties agreed upon may seem insignificant.

In Costa Rica the benefits from the agreement between INBio and Merck were not only through royalties. Perhaps more importantly, they received initial payments from Merck for conservation and were given an opportunity to improve their scientific capacity. In both Costa Rica and Panama the benefits seem to be more long-term. Both arrangements provided significant opportunity for economic development through R&D and encourage conservation. Critics argue that this is not an all-encompassing approach to dealing with bioprospecting and may not work well in other Latin American countries or in other nations around the world. "INBio can be one model, but it shouldn't be the only model" (Gershon 1992).

The idea of going beyond benefit-sharing and royalty agreements however is more universal. In the past decade "the importance of non-monetary benefits has increasingly been recognized" (Wynberg 2004). Rather than waiting around for a royalty's check that may or may not arrive, the communities that experienced the most success built bioprospecting into their economy and way of life. This approach was used in India, sustainable bioprosepecting was introduced to the community and while the potential rewards may not have been as grand as in some of the other scenarios, the risks were minimized and the benefits were more stable. Shortcomings and Suggestions for Improvement

A shortcoming in the literature is acknowledging the different issues and needs of indigenous peoples compared to those of local peoples. This distinction is underrepresented in the literature and is missing from much of the regulation regarding bioprospecting. In some ways comparing the specific needs of indigenous peoples to those of the general public of developing countries is mixing apples and oranges. Indigenous peoples are often marginalized within their home countries and may not have access to the same resources, yet there could still be something to learn from such cases. At the very least it could point to areas in which indigenous groups may need to seek addition help. Fortunately, there are a number of NGOs that support indigenous peoples rights and help communities sort through legalities and better negotiate with Westernminded corporations. Today, bioprospecting is characterized by misunderstanding, mistrust, and regulatory confusion. Further research could improve understanding of the risks of bioprospecting and its potential benefits

The only constant throughout all cases is that there is no one model that communities can follow to maximize their benefits and minimize their risks from bioprospecting. However, those who had the most success were those who took advantage of the opportunity to become involved

with the process and create local infrastructure to further research and development of the drugs. Those who sit back and wait for royalties maybe disappointed with the amount they end up receiving from the sale of the drug. When the providers receive monetary benefits, they risk unequal distribution or reward throughout community. Negotiating for non-monetary benefits, such as schools, hospitals or protected areas can mitigate this problem.

Conclusions

The cases in which there was the most success shared some traits. These shared traits could be a part of a collaboration model. The characteristics of successful collaboration are identified by Friend and Cook (1996) as collaboration being voluntary, based on parity, working for a shared goal, having shared responsibility and accountability, based on shared resources and emergence. Of the studies looked at, the GMCL's work with rural Indian farmers seemed to include the best collaboration. All parties were involved from the beginning and were able to voice their concerns. The economic benefits are consistent and the arrangement respects the traditional society.

Though there is not one model that can be use for every bioprospecting arrangement, there are characteristics that should be present in all cases. All parties need to be involved from the beginning of the decision-making progress. There needs to be a respect for all parties and assistance from NGOs and other aids should be available. Provider communities need to be made aware of all of their options, monetary and not. Open communication and trust is key.

Table 1

Country	Parties Involved	Negotiation Process	Role of Government/NGOs	Benefits to the Local Community (monetary and non-monetary)
South Africa	The San; South Africa's Council for Scientific & Industrial Research (CSIR)	The San received no outside assistance during negotiations with the CSIR; were expected organize in a Westernized fashion,	Biowatch South Africa and Action Aid alerted the media to CSIR's potentially exploitive actions	6% of royalties, 8% of milestone incomes; accounting for approximately .03 - 1.2% of net sales
Panama	Panamanian Government; International Cooperative Biodiversity Groups (ICBG); American Researchers	Collaboration between the ICBG and an American research team; received outside funding and support	Assistance from NGOs and foreign agencies provided initial funding for this project; National government was involved	Long-term economic benefit (\$500,000/year); improved scientific capacity; jobs created for local scholars
India	Rural farmers in Karnataka and Tamil Nadu, India; Gram Mooligai Company Limited (GMCL)	The GMCL negotiates with purchasers; Sanghas have the choice to fill the order or let it go to another group	Initiated by an NGO; communities buy shares and eventually become owners of the GMCL they work for	70% of GMCL asking price; income to poor/landless farmers; protection of herbs/plants used in traditional medicine
Costa Rica	INBio; Merck	Negotiated and signed deal in 1991; renewed in 1994, 1996 and 1998; renegotiated in 1994 to \$1.2 M every 2 years	Environmental NGOs have criticized INBio's private status; Costa Rican legislature worked to increase public scrutiny	INBio received \$1M, plus 5% of royalties; money and land are set aside for conservation; improved scientific capacity

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