



Ethnopharmacological communication

Intellectual property rights, benefit-sharing and development of “improved traditional medicines”: A new approach

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ABSTRACT

Ethnopharmacological relevance: Protection of intellectual property rights and benefit-sharing are key issues for all ethnopharmacological research. The International Society of Ethnobiology has produced helpful guidelines on access and benefit-sharing which are widely viewed as a “gold standard” but the question remains how best to apply these guidelines in practice. Difficult questions include ownership of traditional knowledge, making appropriate agreements, and how appropriately to share benefits.

Materials and methods: We present the case study of the development of an “improved traditional medicine” for malaria in Mali and we report how benefit-sharing was applied in this case.

Results: The knowledge about the selected plant came independently from several families and traditional healers. The IPR approach was to recognise that this traditional knowledge belongs to the people of Mali and was used for their benefit in developing a new “improved traditional medicine” (ITM). The traditional healer whose method of preparation was used, and who collaborated in clinical trials, did not request any financial reward but asked for the ITM to be named after him. The most sustainable benefit for the community was sharing the results of which preparation of which medicinal plant seemed to be the most effective for treating malaria. Attempts at providing a health centre and training a health worker for the village did not prove to be sustainable.

Conclusions: Respect for intellectual property rights and benefit-sharing are possible even in a context where the knowledge is not owned by a clearly identified person or group of people. The most sustainable benefits are intangible rather than material: namely recognition, improved knowledge about which traditional treatment is the best and how to prepare and take it.

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1. Introduction

The need to respect intellectual property rights (IPR) of traditional societies over their medical knowledge is referred to in WHO's Traditional Medicine Strategy 2014–2023 (WHO, 2013), and is a legal requirement of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, which entered into force on 12 October 2014. However there are many cases in which medicinal plant products have been developed without respecting the intellectual property rights of the traditional knowledge holders, or indigenous resource rights. We shall start by showing a few examples, in order to illustrate the type of problems encountered.

1.1. Case 1. *Prunus africana*

The case of the *Prunus africana* tree, from Equatorial Africa, illustrates what can happen if there is no attempt to respect intellectual property rights (IPR) or access and benefit-sharing (ABS). The bark of *P. africana* was exploited from the 1960s for use in prostate medication by French and Spanish companies. This resulted in a vast depletion of wild stocks of the species across Central Africa. Had there been consideration given to (a) the traditional ownership of forest resources and (b) the traditional and customary ownership of the medical knowledge associated with the use of the species, harvest rates would have been monitored, local communities could have benefited from royalties rather than as mere bark collectors, and monitoring of the harvest would have been a feature of sustainable production. However, none of this was the case, and *P.*

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africana stands today as a text book case for the consequences of ABS agreements not being applied – species loss, exploitation of traditional medical knowledge, and exploitation of local labour rather than creation of local microenterprises (Bodeker et al., 2014).

1.2. Case 2. Hoodia and the San People

This second case illustrates that standard patents and ABS agreements can be unhelpful to the traditional knowledge holders. *Hoodia gordonii* is a cactus-like plant that grows primarily in the semi-desert areas of South Africa, Botswana, Namibia and Angola, and used as a food and water substitute by the San People of the Kalahari. The South African Council for Scientific and Industrial Research (CSIR) included *Hoodia* in investigations of edible wild plants in the region. In 1995 CSIR filed an application to patent the active components of *Hoodia* for their appetite suppressant properties (Wynberg and Chennells, 2009). CSIR made an agreement for the San to obtain 8% of payments received from the licensee by CSIR and 6% of royalties from sales of the final product.

This patent was subsequently sold to Phytopharm, a UK-based herbal company, along with exclusive global manufacturing and marketing rights to any related intellectual property. Phytopharm subsequently partnered with Pfizer, who purchased the worldwide marketing rights from Phytopharm for a reported \$32 million to develop and market diet pills based on the traditionally known hunger suppressant properties of *Hoodia*. Phytopharm had earned over \$10 million while the San were still waiting for benefits (Alikhan and Mashelkar, 2009).

After dropping the development of *Hoodia*, Pfizer sold the rights back to Phytopharm for a nominal amount. Phytopharm then partnered with Unilever to produce a *Hoodia*-based weight management product, licensed in the EU as a functional food – the SlimFast shake (Wynberg and Chennells, 2009). Unilever withdrew four years later due to safety and efficacy concerns. Phytopharm then exited the functional food business and returned the patent to CSIR, completing a full circle.

While Phytopharm had earned substantial revenues in the tens of millions of dollars, through research and development funding and the sale of licensing rights, the San had received about 500,000 Rand (US\$73,000) over a seven year period from the agreement with CSIR and were reported to be “happy with the arrangement” (Makoni, 2010). This case highlights that it is possible for a company to keep making money from a product through the development process while the customary owners await benefits.

1.3. Case 3. Pelargonium

Another landmark case in the field of traditional medicinal knowledge and IPR is that of *Pelargonium sidoides*, commonly known as the ‘African geranium’. Native to southern Africa, this was used in Zulu traditional medicine for treating coughs and was first brought to Europe around 1900 (Bladt and Wagner, 2007). In 2007, a series of patents was obtained by Schwabe Pharmaceuticals, a German company, on a method of producing *Pelargonium* extracts. These patents were related to the company’s highly popular treatment for bronchitis, named Umckaloabo, produced from extracts of the root of *Pelargonium sidoides* and *Pelargonium reniforme*. Umckaloabo was 20th of the top-selling over-the-counter remedies in Germany and represented a major source of revenue for the company.

Schwabe’s patent for the extraction process was challenged in 2008 by members of the rural Eastern Cape community of Alice, represented by an African NGO, the African Centre for Biosafety (ACB) and a Swiss NGO, the Berne Declaration, as well as by several of Schwabe’s competitors, including the Swiss plant extract company Alpinamed. The positioning of the case was of one of

biopiracy – i.e. illicit appropriation by an international corporation of the intellectual property of an indigenous community. The African Centre for Biosafety in South Africa and the Bern Declaration in Switzerland called the patents “an illegitimate and illegal monopolization of genetic resources derived from traditional knowledge and a stark opposition to the Convention on Biodiversity” (Hall, 2013).

Given the long history of *Pelargonium* use in Europe, it was not a surprise that in 2010 the European Patent Office (EPO), in overturning Schwabe’s patent for extraction, simply noted that this was because “it did not fulfil the inventive-step requirements of the European Patent Convention.” The EPO took a safe path on the grounds of a technical failure in the application process, but also noted that it had considered the “parties’ arguments on other grounds for opposition, and conducted an in-depth discussion of aspects of the biodiversity conventions” (Intellectual Property Watch, 2010). Schwabe subsequently announced the withdrawal of five patents related to *Pelargonium*, which was hailed as a victory against biopiracy by ACB and its partner organisations.

1.4. The need for new approaches

From these examples it is clear that the classic method of patenting cannot easily be applied to the development of phytomedicines. Patents have not protected IPR for companies, and have not provided benefits for traditional knowledge holders. As African countries develop “improved traditional medicines” (Willcox et al., 2012), new approaches are needed to address the issues of intellectual property rights, access and benefit-sharing.

The International Society of Ethnobiology has produced helpful guidelines on access and benefit-sharing which give good broad principles as well as a set of questions for researchers to review at each stage of the research process (International Society of Ethnobiology, 2006). The ISE Guidelines are widely viewed as a gold standard in the ethical conduct of ethnobiological research and serve as the frame of reference for best practice in applied research projects (Bodeker et al., 2016).

The question we wish to address in this article is: how best to apply these guidelines in practice? Challenges include the following:

1. In the case of traditional knowledge, who is the owner? Is it an individual, a family or a community?
2. Is it necessary to protect IPR, and if so, how?
3. How to make an appropriate benefit-sharing agreement without raising false hopes? (noting that most research projects on medicinal plants do not lead to a commercial product)
4. How to share benefits equitably with communities and traditional healers?

In this article we present a case study of how these questions were tackled in Mali during the development of an antimalarial phytomedicine. The scientific aspects of the research have already been published elsewhere (Willcox et al., 2011a), so this article will purely focus on the handling of intellectual property rights. The translational aspect of almost all ethnopharmacological research is severely challenged by the very issues raised in the paper. The case study of *Argemone mexicana* is an illustration of the problem, solutions tried and lessons learned. We will discuss lessons learned for future similar projects.

2. Benefit-sharing at every step of a research programme: case study

2.1. Stage one: identifying the most promising plant

A “retrospective treatment outcome study” was used to identify malaria treatments in Mali (Diallo et al., 2006; Graz et al., 2005).

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