CHAPTER 2
VALUE ADDING IN THE SOUTHERN AFRICAN NATURAL PRODUCTS SECTOR: HOW MUCH DO PATENTS MATTER?

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Abstract

Southern African countries are actively engaged in natural product development but, in common with other developing countries, typically export their biodiversity as raw materials with little or no processing, technological input or other value adding. IPR protection for innovations relating to biodiversity has been accelerated by the TRIPS Agreement and there is concern that this will strengthen the market power of Northern innovating firms and raise prices in developing countries. At the same time there is recognition that IPRs can assist developing countries in obtaining access to technological capacity and provide commercial opportunities for encouraging inward investment.

Virtually all species under commercial development in Southern Africa have patents associated with their processing and/or use, mostly under foreign ownership. Two questions comprise the focus of this paper: (1) What is the role of IPRs in stimulating industrial activity in the Southern African natural products sector? (2) Does the existence of IPRs stimulate or restrict value adding in countries of origin of biological material and traditional knowledge?

Three Southern African plants currently traded in global markets are analyzed: *Harpagophytum* (devil's claw), *Aspalathus linearis (Rooibos)* and *Hoodia*. It is concluded that IPRs seldom restrict value adding, but may instead stimulate trade and may provide further commercial opportunities. Low awareness among local firms, however, prevents such opportunities from being exploited. Low levels of value adding stem from a complex mix of factors including market access, buyer dominance, a lack of strategic alignment among producers and insufficient technical and financial capacity. Traditional knowledge has played a central role in catalyzing industrial activity in all of the cases examined but this is poorly reflected and acknowledged in value chains.

1. INTRODUCTION

South Africa is actively engaged in natural product development and bioprospecting[1], with the past decade witnessing a flurry of activity in the exploration of local biodiversity for commercially valuable genetic resources and biochemicals (e.g. CSIR, 2001; PhytoTrade Africa, 2006; Wynberg, 2004; Diederichs, 2005). This is due largely to the

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country's extraordinarily rich and unique biodiversity (Endangered Wildlife Trust, 2002), well-documented and vast traditional knowledge base, and strong research, institutional and technological capacity which, combined with considerable business capacity, place South Africa and the Southern African region at the forefront of new strategies to glean economic benefit from biological resources (Geldenhuys and van Wyk, 2002; Wynberg, 2004).

In common with other developing countries, South Africa and her neighbors have historically exported their biodiversity in the form of raw plant material, traded as bulk commodities with little or no processing, technological input or other value adding before export. The situation has been exacerbated by trends within industries in importing countries toward greater consolidation and vertical integration – along with increased control over price and demand (Laird and Wynberg, 2008). Intellectual property protection for innovations related to biological organisms has been accelerated by the inclusion of IPRs over biological resources within the TRIPS Agreement (Gebhardt, 1998; Dutfield, 2000). A concern is that IPR protection will strengthen the market power of Northern innovating firms and raise prices in developing countries (Chen and Puttitanun, 2005). At the same time, there is recognition that IPRs can assist developing countries obtain access to technological capacity, and this in turn can help to achieve economic and social development and reduce poverty (Commission on Intellectual Property Rights, 2002). The exclusivity provided by patent protection may also provide commercial opportunities for encouraging inward investment and revenue flow in developing countries (Maskus, 2000). Additionally, patents owned by developing country organizations may provide the opportunity for licensing, a source of revenue that can be used to finance other projects.

Technology transfer is a central component of both TRIPS and the 1992 Convention on Biological Diversity (CBD), the latter recognizing the sovereign right of countries over their biological resources and their right to determine access to these resources. The CBD notes that access to genetic resources should be on the basis of prior informed consent from providers of resources and knowledge, and on mutually agreed terms that provide fair and equitable sharing of the results of research, development and commercialization. It also calls for the fair and equitable sharing of benefits derived from the use of traditional knowledge. Article 16 of the CBD aims to ensure that access to and transfer of technology to developing countries is facilitated both by government institutions and the private sector. To date, however, there has been little evidence of this having been achieved (CBD, 2007) and, where it has, its extent and interpretation have often been contested (e.g. Lettington, 2003; Laird and Wynberg, 2008).

Virtually all species under commercial development in Southern Africa have patents and/or patent applications associated with their processing and/or use, mostly under foreign ownership. This represents a 10- to 20-fold increase over the past decade (Wynberg, 2006). Despite the burgeoning natural products industry in the region, there has been little research conducted on the effects of associated patents and applications, and the extent to which they constrain or facilitate value addition and technology transfer

in the sector. As a general rule, subject matter of a patent must be new and inventive over traditional knowledge but this has not always prevented patents from being granted (Dutfield, 2004). Recent changes to the South African Patent Amendment Act (20 of 2005) require applicants to furnish information relating to the use of indigenous biological resources or traditional knowledge in an invention. However, many countries do not have such information disclosure requirements and the topic remains complex, poorly understood and highly controversial.

This chapter aims to enhance understanding of the economic impacts of IPRs on local value addition in the natural products sector in South Africa and neighboring countries. Two research questions frame this analysis: (1) What is the role of IPRs in stimulating industrial activity in the southern African natural products sector? (2) Does the existence of IPRs stimulate or restrict value adding in countries of origin of biological material and traditional knowledge? Patents comprise the primary focus of the analysis, although the paper also includes some discussion of the role of geographical indications and other IP tools. Through improved knowledge it is intended that policy-makers can make informed and evidence-based decisions about the development and adoption of appropriate policies and strategies to promote local value addition whilst facilitating technology transfer and protecting traditional knowledge. The chapter begins by describing the methods used for the study, and then examines three case studies of Southern African species currently traded in global markets – devil's claw, *Hoodia*, and *Rooibos* tea. The final section integrates findings from each case study and draws conclusions from this research.

2. METHODS

Case studies were selected as the unit of analysis for the study, with three Southern African species identified for detailed investigation:

- Devil's claw (*Harpagophytum* species), a plant used widely for the treatment of rheumatism and arthritis;
- *Hoodia* species, succulent plants indigenous to Southern Africa and long used by the indigenous San to stave off hunger and thirst on long hunting trips; and
- *Rooibos* tea (Aspalathus linearis), one of South Africa's oldest and most successful indigenous products.

Preliminary data were collected through reviewing the published and unpublished literature and identifying and analyzing existing patents and patent applications associated with each species. The patent search was carried out using the esp@cenet database, searching under the species name and common name and, where appropriate, under any characteristic chemical component (harpagoside and harpagide in the case of devil's claw).[2] Information about the status of patents and applications up until June 1, 2008 was obtained from INPADOC and the European, German, Japanese and US patent office databases. This analysis was accompanied by a review of the theoretical and applied literature on IPRs, technology transfer and value addition. Semi-structured

questionnaires were used as the primary method of data collection, and they formed the basis for focused one-on-one interviews with value chain participants and key informants.

To corroborate information and reflect different interpretations and perspectives, the technique of triangulation was used, which entails collecting material in as many different ways and from as many diverse sources as possible, to enable the understanding of phenomena from several different angles (Terre Blanche and Kelly, 1999). For each species, the same set of information was collected from different social players, compared and contrasted across respondents, and, where possible, corroborated or refuted with information gleaned from the literature review. Respondents included local traders involved in trading case study species, importers and foreign processors and producers, representatives of producer communities/traditional knowledge holders, relevant departments of trade and environment, and NGOs, researchers and other key informants working with case study species. Part of this data was drawn from earlier research conducted by one of the authors (Wynberg, 2006).

Data was analyzed in a number of ways. Each interview was read through thoroughly and accompanying notes and diagrams were made to highlight key themes. Information gathered was categorized and coded based on similarity of theme. Information from each interview was clustered into a number of key themes. This was expanded and verified through use of secondary data sources and other literature.

Although one-on-one semi-structured interviews comprised the main strategy for empirical data collection, quantitative data was also gathered on trade statistics and pricing at different levels of the value chain. This data was however limited by the reticence of commercial players to share sensitive information and the short time-frame of the study. Value chain analysis, a conventional form of commodity chain analysis, was used as one approach to understanding the position and behavior of actors in natural product value chains, and the opportunities for upgrading, meaning the possibility for developing country producers to move up the value chain and secure better returns (Kaplinsky and Morris, 2001; Gibbon and Ponte, 2005).

3. DEVIL'S CLAW

3.1. Overview

Devil's claw is a plant indigenous to the Kalahari region of Southern Africa. Roots of the plant are widely used as a medicine, both traditionally and in Western preparations. Indeed, traditional knowledge was the basis for initiating Western interest in the plant at the turn of the 20th century, catalyzed by a German soldier secretly tracking a local healer's use of the plant, thus marking one of the first and certainly one of the most significant "biopiracy"[3] incidents in Namibia (Volk, 1964; Wynberg, 2006). Traditional use of the tuber for fever relief, to treat blood diseases and muscular aches and pains, and

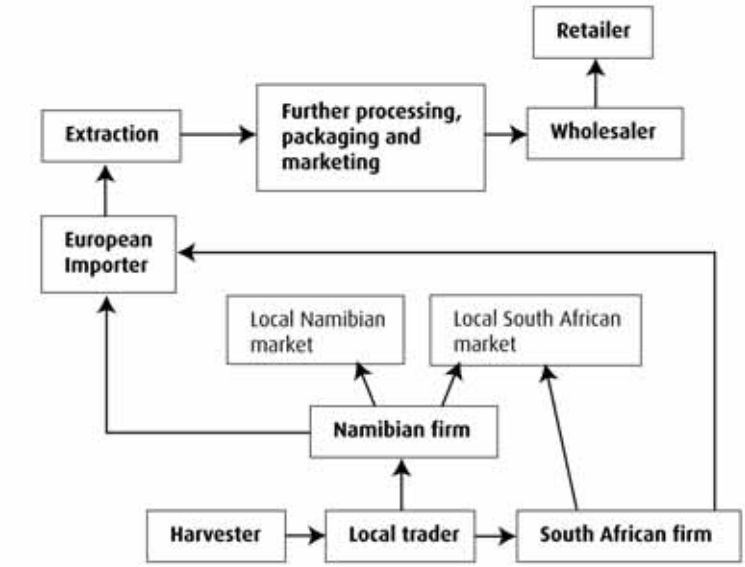
as an analgesic during pregnancy, is widely recorded, as is the use of pulverized root material as an ointment for sores, ulcers and boils and for difficult births (Watt and Breyer-Brandwijk, 1962; Giess and Snyman, 1995). Infusions of the dried root are also locally used as a cure for digestive disorders, as an appetite stimulant and for *post partum* complaints.

Today the plant is widely traded on international markets, where it is used to treat arthritis and rheumatism. Extracts of the tubers are found in pharmaceutical preparations, herbal remedies and cosmetics, either in preparations in the form of raw or powdered material or as standardized extracts in the form of capsules, tablets, tinctures and ointments. A small market also exists for veterinary herbal remedies and herbal teas. A number of studies have demonstrated the efficacy of devil's claw as an anti-inflammatory (e.g. Lanhers *et al*., 1992; Chrubasik *et al*., 1996), and its properties are considered comparable to cortisone and phenylbutazone but without the accompanying side effects (Moussard *et al*., 1992). These factors, combined with the proven safety of the plant and its recognition by the international pharmacopoeia, has led to a rapid escalation in demand for devil's claw, evidenced for example by the fact that it accounts for 74 per cent of treatments for rheumatism in Germany (Grünwald, 2003).

Devil's claw has been traded internationally for some 50 years, with most material exported from Namibia to Germany. Although the trade has been erratic there has, over the years, been a steady increase in export volume, which has led to an expansion of the area from which material is sourced to include Botswana and South Africa as well as the more remote parts of Namibia. The net value of the trade is significant. Grünwald (2003) notes that in 2001/2002 devil's claw sales in Germany alone topped 30 million euros (US$34 million), representing the third highest sales of medicinal plants in the country. Based on the average size of the annual world devil's claw market of 400,000 kg., and an approximate retail value of US$200 per kg., the industry is worth an estimated US$80 million per annum.

A large number of steps characterize the devil's claw value chain, illustrated in Figure 1. Once material is exported, it is either milled or packaged for sale as a tea or herbal supplement, or subject to a greater degree of processing, including the extraction of active constituents through water or alcohol-based extraction methods. Extracts are then manufactured into diverse products, often with proprietary formulations, before being sold in pharmacies, supermarkets, or health food shops. A diverse group of players is engaged in these different steps and the material may pass through a number of agents, wholesalers, manufacturers, packagers and extractors, before reaching its final shelf destination, with the largest and most established markets by far being those in Germany.

Figure 1. A Typical Devil's Claw Value Chain



After Wynberg (2006).

3.2. Devil's Claw Patents and Patent Applications

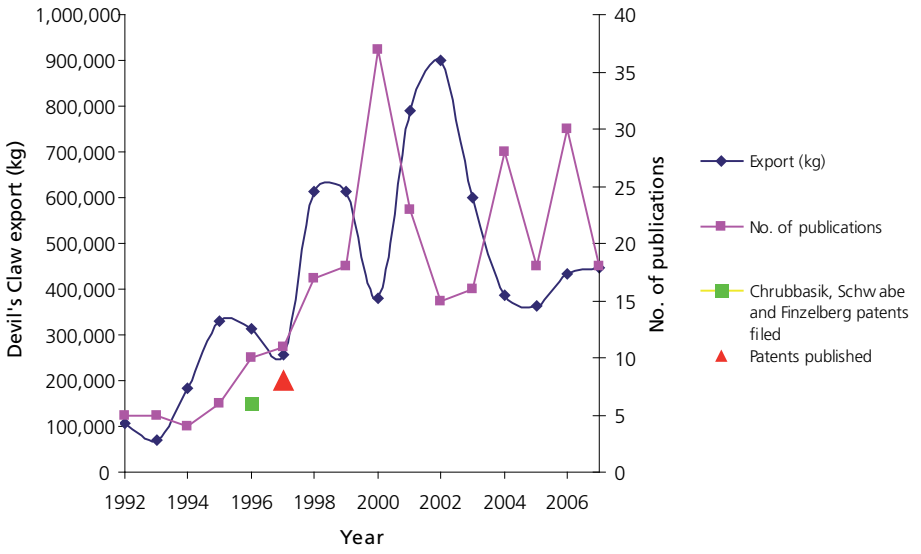
Devil's claw has been characterized by high levels of patent activity since the early 1980s. In large part this has closely followed research conducted on the active constituents of the plant, with publications seemingly driving innovation and catalyzing industry to think of potential uses. Licensing and publication activities in turn seem to be linked to spikes in trade, with key patent "publication dates" predating a significant upturn in the devil's claw trade in the late 1990s (Figure 2). Figure 2 highlights the increase in the number of devil's claw publications after the first patent was filed in 1989. A considerable increase in publications is also observed after a key patent filed by Chrubasik in 1996; 33 of these publications involve the patent holder (Chrubasik) as first or co-author.

Some 35 patents and applications had been lodged as of June 1, 2008. These fall into three categories:

(i) processes (7) for producing extracts or isolating chemical compounds;
(ii) compositions (18), including pharmaceutical, herbal and nutritional compositions and chewing gum for treatments based on known anti-inflammatory and analgesic activity; arthritic conditions, rheumatoid disorders, osteoarthritis, bone and joint inflammation, pain relief from neuralgia, arthritis and rheumatoid conditions; and
(iii) compositions for allegedly new uses (10): delaying weakening of cartilage, regeneration of deformed and damaged cartilage; osteoporosis; skin itching; rough-

ening, firmness and wrinkling of skin and adhesion of makeup; renal disease, dysfunction or damage; endometriosis and/or endometriosis-related proliferative and/or inflammatory process and/or analgesic therapy; skin inflammation and reduction of skin barrier function; anti-aging skin treatment; use as Maillard reaction inhibitor in foods and beverages; and hair treatment.

Figure 2. Relationship Between Exports, Publications and Key Patents for Devil's Claw



Three of the process applications were filed in Germany by different companies in early 1996, while four later process applications were filed in the Republic of Korea, the UK and the US. This is to be expected, given that Germany is the main processor of devil's claw and a major user of devil's claw products. However, no clear pattern of ownership is evident. As befits the largest processor and user of devil's claw products, Germany has the greatest number of applications for devil's claw compositions and uses, with other applicants from all over the world: Germany (8), France (5), the Republic of Korea (3), Japan (4), the UK (2), Canada (2), the US (1), Spain (1), Italy (1), Mexico (1).

3.2.1 Process Patents and Applications

For reasons unknown, only one of the patents and applications relating to processes for producing devil's claw extracts has been filed in South Africa.[4] This patent was filed by Finzelberg GmbH & Co. KG, one of the subsidiaries of the German company Martin Bauer GmbH & Co., which is the predominant European company involved with devil's claw. The Finzelberg patent has been granted in South Africa, and also in Europe (effective in Austria, Belgium, Denmark Germany, Italy, Luxembourg, Monaco, Spain,

Sweden, Switzerland, and the UK), Australia, Canada, China, and the US, with applications pending in Japan and the Republic of Korea. The Finzelberg extraction process involves a three-stage aqueous/alcoholic extraction process, which is said to give an extract having a high content of harpagoside, the major active compound in devil's claw. This technology is not available for use in South Africa by third parties without authorization, though it could be used in other Southern African countries where the patent is not filed or in South Africa itself under a license. However, the extent of the patent coverage for the major markets for devil's claw would make such production commercially unattractive.

There are, however, two other German-originating patent families with somewhat similar claims to processes for extracting devil's claw, neither of which has been filed in South Africa. The first was filed and granted in Germany only, by Dr. Chrubasik, who was actively publishing in the scientific literature on devil's claw at that time. The Chrubasik process is also an aqueous/alcoholic extraction, but is preceded by an initial purification step using an adsorbent resin. The other application was filed by Willmar Schwabe GmbH & Co., another German devil's claw processor, about six weeks after Chrubasik and two months before Finzelberg. The Schwabe process, too, involves aqueous/alcoholic extractions. Patents have been granted in Europe, Japan and the US.

Information provided by an adverse third party on the file of the Finzelberg European application indicates that the Chrubasik patent gives a product very similar in quality to the Finzelberg product, and that the Schwabe product is less effective. This and the fact that the Chrubasik patent was filed in Germany only whereas the Schwabe patent has been granted in Europe, Japan and the US, makes the Chrubasik process a commercial possibility for South African processors. While it is a disadvantage that the product cannot be exported to Germany, the major market for devil's claw, other valuable markets are open.

Three of the remaining four process applications were filed only in the country indicated (Dongkuk Pharm Co. Ltd. KR, Essential Nutrition US, Korea Institute for Science and Technology KR), so the process can be used in South Africa. In many countries, however, it is an infringing act to import the product of a patented process. As a general rule it is therefore prudent to avoid exporting such a product to any country where there is a patent for the process. The Essential Nutrition application was not granted in the UK, so the process can be practiced in Southern Africa and the product exported to the UK.

3.2.2 Composition and Use of Patents and Applications

Of the patents and applications that relate to compositions and/or uses in categories (ii) and (iii) above, seven have been dropped;[5] hence these products can be produced freely in Southern Africa and sold anywhere.

Of the remaining patents and applications, 13 have been filed in the named country only: Grosmond (France), Veradi (Italy), Rivadis (France), Farm KKI (Japan), Stanley (US), TS Aasu (Japan), Shin Jun Sik (Republic of Korea), MFE Marienfelde (Germany), Bioplanta (Germany), Chung Choung Buk Do (Republic of Korea), Ichimaru Pharcos (Japan), Naris Cosmetics (Japan), and Touch of Love Inc. (Canada). The products can therefore be produced anywhere in Southern Africa and exported to any country other than that in which the intellectual property exists, without requiring a license.

The final eight applications in this category have been filed in more than one country: Shin Jun Sik in the Republic of Korea, Japan and the US (granted); Salus Haus in Europe (only maintained in certain countries including Austria, France, Germany, Greece, Italy, Luxembourg, Spain, Switzerland and the UK); Cognis Iberia (European Patent); Cognis Deutschland (European Patent, but only France, Germany, Italy, Spain and the UK), Japan and the US; Velez-Rivera (Brazil, Mexico and the US); Flavin-Koenig (European Patent); Reimser Arzneimittel (European Patent); Henkel (International phase). The same principle applies, that the product can be produced in Southern Africa for export anywhere other than where a patent or application exists. However, if a patent has lapsed due to non-payment of renewal fees, or an application has been dropped, the claimed product can then be exported to that country.

3.3. Intellectual Property and Value Addition

Seemingly, existing patents do impose restrictions on both the production and export of devil's claw in Southern Africa, and South Africa in particular, with respect to the significant Finzelberg patent. However, the extent to which these patents legally restrict economic activity is arguably and surprisingly negligible. Moreover, the intellectual property relating to devil's claw products, uses of devil's claw material, and processes for extracting devil's claw also potentially offer the opportunity to add value in Southern Africa and possibilities for licensing-in technology.

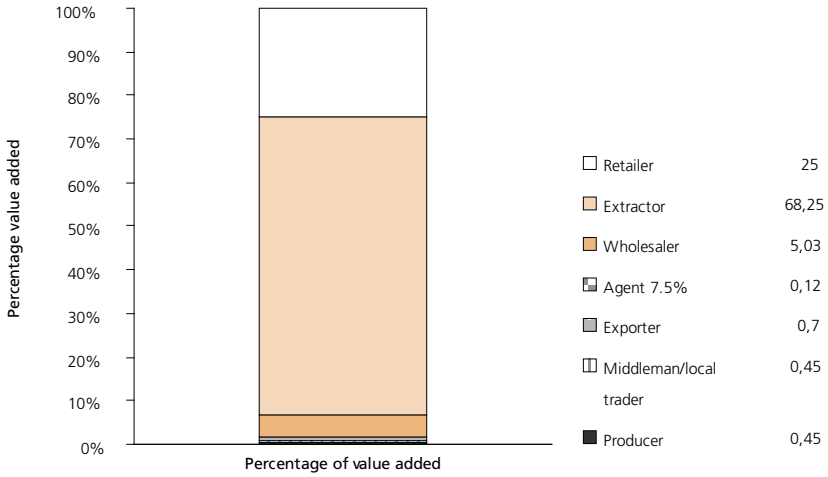
What then are the experiences of those engaged in the devil's claw value chain? Are existing patents and applications perceived to restrict local value addition or do they create opportunities to add value? Despite the fact that this research demonstrates negligible legal restrictions, the perception of commercial firms is somewhat different. A common view, for example, is that patents have played a restrictive rather than a facilitative role. Commented one South African firm: "Germany has spent years trying to develop all aspects of the IP of devil's claw; every time we try to come up with something new it is always covered by patents from elsewhere". This view suggests low levels of awareness of the complexities of patents and may well be based on one or more common misconceptions about patents and the patent system (see Box 1). The "patents" may well be patent applications, not granted patents, and they may be filed in only one country that is not particularly relevant. Nevertheless, whether right or wrong, such opinions affect commercial decisions.

While the link between value addition and patents may be debatable, the low levels of value addition for the devil's claw industry in Southern Africa are not. Indeed, negligible benefits are procured by harvesters and range states through the trade. In Namibia, foreign income earned from devil's claw in 2002 was an estimated US$3.3 million, based on an average export price of US$3.20 per kg. of raw material, while Botswana and South Africa in the same year earned US$94,720 and US$416,000 respectively. While these amounts are significant, they represent only 2.1–4.3 per cent of the value of the final product that is captured by producer countries.[6]

A more detailed breakdown is provided in Figure 3, which shows that based on a final retail price of US$200 per kg, most harvesters receive 0.45 per cent of the value of the final product, or about 0.2 per cent if the higher retail price of US$350 per kg. is used. Exporters and local middlemen, although popularly cited as the villains in the natural product trade, do not fare much better, capturing between 0.12–0.90 per cent of the US$200 per kg. retail price, although clearly their advantage lies in the larger volumes they trade. Agents obtain about 7.5 per cent commission on export sales, some 0.1 per cent of the retail price, while wholesalers secure approximately 4.6–5 per cent of the retail price. Processors, extractors and manufacturers capture a massive 68 per cent of value, while retailers obtain about 25 per cent of the value of the final price.[7]

Devil's claw is certainly not unique in this regard and a compelling case can be made to demonstrate that the nature of extractive markets tends to keep wages and prices for producers low, and that profit shares increase with increased processing as the product moves closer to the consumer (Southgate *et al*., 1996; Neumann and Hirsch, 2000). For example, Hersch-Martinez (1995) tracked the commercial path of six medicinal plants from the field to national markets in Mexico, and reported that only 6 per cent of the consumer price returned to custodians of the resource. King *et al*. (1999) noted that harvesters received between US$0.30 and US$0.65 per kg. for unprocessed cat's claw (*Uncaria tomentosa*) in Peru, yet the price of bulk, unprocessed cat's claw in the US fetched US$11 per kg. – a 37-fold appreciation with little value added. In an analysis of the volatile coffee trade, Biswas and Potts (2003) remark that of the US$26.40 required to buy a 1 kg. bag of soluble Ugandan robusta in a UK supermarket, 14 cents goes to the farmer for each kilogram of dry beans. Even accounting for the loss of weight during the refining process, this represents a price inflation of more than 7,000 per cent. However, it is important to note that, while levels of inequality in wealth accumulation and distribution have intensified in recent years with globalization and the attendant rise to power of supermarkets and transnational corporations, such trends probably have little to do with IPRs. Indeed, their role is poorly understood and documented along such chains.

Figure 3. Devil's Claw Value Chain, Indicating Proportional Value Captured by Each Role Player Along the Chain



All figures pertain to 2002. After Wynberg (2006).

These figures illustrate that the devil's claw trade is characterized by an extremely low level of value adding that takes place locally and within the country of origin, and a lack of investment in supply areas. Apart from initial slicing and drying, and the sorting and bagging of raw material before export, between 60–80 per cent of all devil's claw supplied by Namibian exporters goes to international buyers that simply clean, grade, grind and repack it, while only 12 per cent of exports goes directly to extractors and manufacturers (Lombard, 2003). Agents, who redirect supplies to other buyers, also play a major role, accounting for 19 per cent of exports in Namibia (Lombard, 2003). The situation is very similar in South Africa and Botswana. Although there are obvious costs and investments involved in the development of a market for a plant such as devil's claw, in reality the trade is monopolized by a small cohort of international companies and increased profits (or favorable changes in exchange rates) are seldom passed down the chain to producers. In a similar vein, processing activities take place almost exclusively in Europe, and the bulk of the material is exported in a raw and largely unprocessed form.

The picture that emerges is thus of patents playing a central, but not overwhelming role in the strategic positioning of foreign companies in the devil's claw market. Existing patents have enabled firms to develop value-added products through extracts which, as Figure 3 describes, represent the lion's share of the value chain. Although Southern African firms are not precluded from utilizing many of these patents, their mere existence has acted as a perceptual barrier of risk for many local firms. This has been exacerbated by the domination of five to 10 companies in the European trade, the most central being the German Martin Bauer GmbH & Co., estimated to control 75 per cent of world trade in devil's claw. Important subsidiaries established under the Martin Bauer umbrella in-

clude Paul Muggenburg, responsible for supplying and sourcing raw material; Plant Extract, which produces extracts; and Finzelberg GmbH & Co., which manufactures herbal extracts for the pharmaceutical industry. Other key players include Serturner-Lichtwer (France/Germany), SalusHaus (Germany), Strathmann (Germany), Indena (Italy), A.M. Todd (US), Bioforce (Switzerland), Organic Herb Trading (UK) and Arkopharma (France). The dominance of German pharmaceutical companies is, of course, far from coincidental, reflecting in part the German colonial legacy of control in Namibia, early demand from German consumers for devil's claw (a market for extracts that has been ongoing for 30-40 years) and the substantial investment made by Germany in clinical trials, IP protection, processing technology, and R&D (Krugmann *et al*., 2003).

The dominance of European firms in the devil's claw trade is enhanced to a large extent by a lack of cohesion and coordination among Southern African suppliers of devil's claw. Rather than align strategically, Southern African exporters typically undercut one another in pricing, and compete intensely for clients. This has led to what has been described as a "divide and rule" situation, where importers play off exporters against one another, and secure rock-bottom prices (Krafft, 2002). This is also reflected in the highly volatile nature of the partnerships developed, illustrated by the fact that since 1996 most of the principal importers of devil's claw have changed their suppliers (Lombard, 2003). The situation is made all the more complex by the fact that devil's claw straddles the border of at least four countries (Namibia, Angola, South Africa and Botswana), and that coordination between these countries is poor. Supply control in one country thus leads to demand shifting to another country. Moreover, the lack of quality standards gives price negotiating power to buyers (Cole and Bennett, 2007). While tools such as geographic indications represent a potential avenue to overcome such constraints, in practice they require a substantial body of infrastructure and capacity to implement effectively.

Under these conditions there is very little incentive for foreign firms to develop license agreements with local firms. As one South African firm commented: "We come from a very weak position and they [German firms] don't even entertain us. They have adequate material and suppliers will even undercut prices. They have registered products; they have market position; they are untouchable. We need to work together to play the international markets and present a united front".

While market access is a crucial factor that impedes value addition, so too is technical capacity. As described above, there are numerous opportunities to add value to devil's claw through existing patents that are not applicable in Southern Africa, but few examples where these are taken up. This can be attributed to a number of factors. One reason is that a stand-alone facility to extract only devil's claw would be inefficient and simply not feasible. Other products would be required to spread the risk, as well as substantial volumes to make the plant viable. One South African extract firm commented: "The process is not an easy one. You need to raise the capital, you must develop the technology and you need a marketing position. The moment you start manufacturing extracts strong analytical capacity would be needed, requiring work with universities

and subcontractors. In a country like Namibia this would be very limited and would therefore require a regional approach. You would also need raw material suppliers to align themselves with the project".

In conclusion, there are a number of patents that have a restricting impact for Southern African countries, but these do not comprise the *raison d'être* for the almost negligible local value addition for devil's claw. Low value adding stems from a complex variety of different factors, including market access, buyer dominance, a lack of strategic alignment amongst Southern African producers, insufficient technical and financial capacity and a multitude of patents and applications that detract potential investors. The next case study, that of *Hoodia*, reveals an equally complex but altogether different picture.

Box 1. Misconceptions about Patents

There is widespread lack of knowledge as well as misunderstanding about patents and the patent system, which leads to negative views such as "every time we come up with something new it is always covered by patents from elsewhere".

Typical misunderstandings relate to:

The scope of patent protection. Patents have territorial effect. They are only legally effective in the country where they are granted. If an invention is not patented in any particular country, it can be used in that country and products can be exported to any other non-patent country.

The difference between granted patents and published patent applications. Most of the readily available documents are patent applications, not granted patents. Some applications will not be granted and many will be granted with narrower scope of protection for the invention than in the claims of the published application. Searches should be carried out to determine where a patent application has been filed, if it has been granted, and, if so, if it has been maintained or dropped. Only then can its significance to proposed commercial activities be determined.

The myth of the "international patent". There is no such thing. A document published by WIPO under a number such as WO2008/12345 is not an international patent (that is, a document that is legally effective in all countries). It is merely a patent application that establishes a holding position for filing subsequent applications in the applicant's choice of countries by a defined deadline. Because of the costs of patenting, an international application may often be pursued in a few countries only or may even not be pursued at all nationally.

4. *HOODIA*

4.1. Overview

The pivotal role played by patents in stimulating research, development and trade, and the importance of traditional knowledge in contributing toward these factors, is vividly demonstrated in the case of *Hoodia* species, succulent plants indigenous to Southern Africa and long used as food and 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 (Marloth, 1932) and led to the inclusion of *Hoodia* species in a 1963 project screening 300 edible wild plants of the region for their nutrient content and safety for use as bush foods by the South African-based Council for Scientific and Industrial Research (CSIR), one of the largest research organizations in Africa.

In 1997, following nine years of confidential development, a patent application was filed in South Africa by the CSIR that included the use of plant extracts and the active constituents of the plant responsible for suppressing appetite and treating obesity. This was done without the consent of the San, the original holders of knowledge about these properties, although the CSIR was eventually pressurized to enter into negotiations with the San and to develop a benefit-sharing agreement (see Box 2). The CSIR proceeded in 1998 to grant a license for the further development and commercialization of the patent to Phytopharm, a small UK company specialized in the development of phytomedicines (Phytopharm, 1997). The agreement granted Phytopharm an exclusive worldwide license to manufacture and market *Hoodia*-related products and to exploit any other part of the CSIR's IPRs relating to *Hoodia* species. Through a program dubbed "P57", Phytopharm developed this drug to a more advanced stage, leading to a license and royalty agreement in August 1998 with Pfizer, the US-based pharmaceutical giant, for further development and commercialization. However, the closure of Pfizer's Natureceuticals group led to the later withdrawal of Pfizer from the agreement.

In 2004, Phytopharm granted the consumer giant Unilever PLC. an exclusive global license for *Hoodia* gordonii extracts, with their likely incorporation into existing food brands as a functional weight-loss product for the mass market (Phytopharm, 2004) (Figure 4). Under the terms of the agreement, Unilever would buy exclusive rights to the product for an initial 6.5 million pounds sterling, rising to 21 million pounds sterling once it had achieved certain milestones. Phytopharm would also receive an undisclosed royalty on sales of all products containing the extract. Developments included clinical safety trials, manufacturing and the cultivation of some 300 hectares of *Hoodia* in South Africa and Namibia (Povey, Unilever research and development program director, pers. comm., 2007). Agreement was also reached between Unilever and the chemical company Cognis to develop a R750 million extraction facility for *Hoodia* in the Western Cape, South Africa (Department of Trade and Industry, 2008). This situation changed significantly in November, 2008, with the announcement by Unilever that it was to abandon plans to develop *Hoodia* as a functional food, because of safety and efficacy

concerns. Phytopharm will now seek other partners to further develop *Hoodia* and bring products to market (Phytopharm, 2008) although it is still too early to predict what this would imply for value-adding.

Much is at stake if a successful product is developed: the global value of functional foods, defined as "any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains" (Bloch and Thomson, 1995) is estimated at US$65 billion (Phytopharm, 2007), with the market value for the dietary control of obesity at over US$3 billion per annum in the US alone (Phytopharm, 2003). The growth potential of functional foods is predicted to be 50 per cent from 2005 to 2010, with an accelerating trend toward new products. Potential profits are thus highly significant, and could result in substantial returns not only for the companies involved, but also for the impoverished San.

A parallel *Hoodia* market has also emerged since 2001, based on trade in raw material (Figure 5). The CSIR patent covers *Hoodia* extracts (including pressed sap), but not non-extracted raw material. The publicity generated by the CSIR-Phytopharm-Unilever agreements, the marketing opportunities of San use of the plant, and the CSIR patent led 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* species in Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (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 being advertised on the Internet and sold in drugstores and pharmacies as diet bars, pills, drinks and juice, all traded by a myriad of companies "free-riding" on the publicity and clinical trials of Phytopharm and Unilever. 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 (Wynberg and Chennells, 2009).

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 a supply of *Hoodia* 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.

Figure 4. License and Benefit-Sharing Agreements Developed Between the San, CSIR, Phytopharm and Unilever

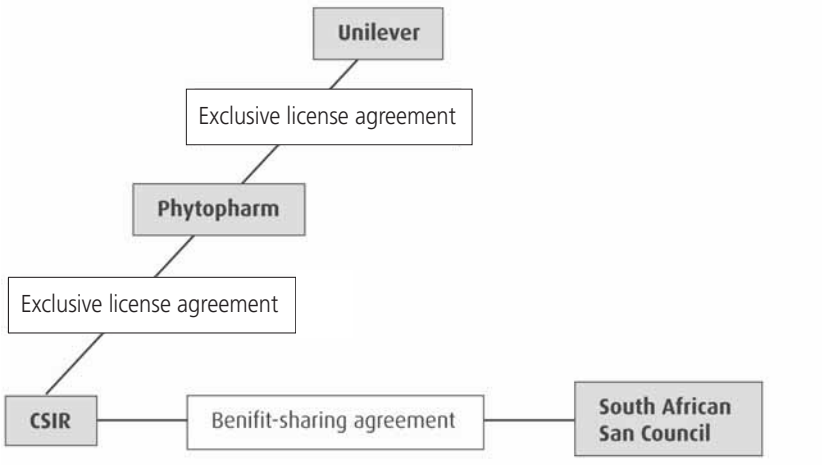
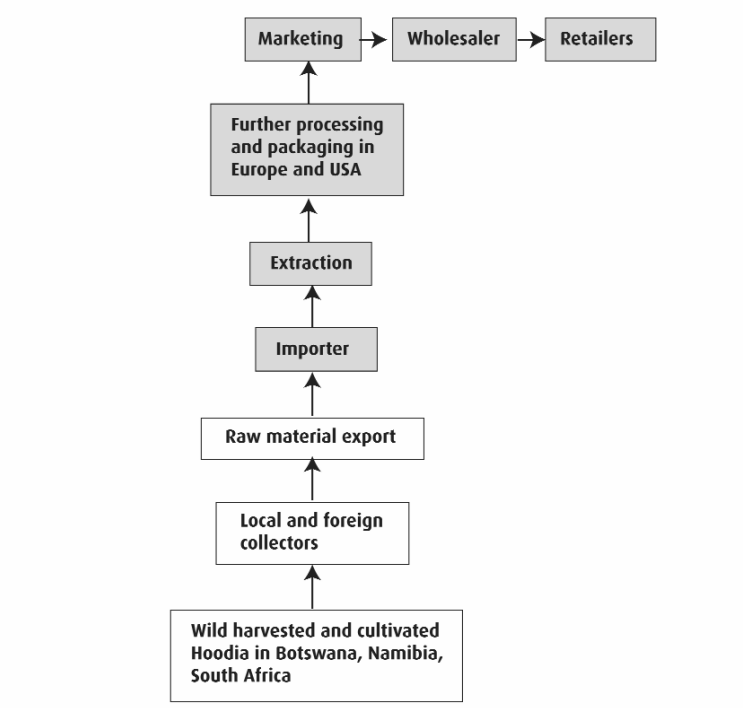


Figure 5. *Hoodia* Value Chain Based on a Non-Patented Dietary Supplement



4.2. *Hoodia* Patents and Patent Applications

Hoodia is atypical and possibly unique in that all commercial activity results from a single patent application. According to the esp@cenet database, the initial CSIR South African application was followed by an international application that was pursued in 81 countries (either directly or via regional applications such as a European application), including the US, Europe, South Africa and other African countries. A filing program of this extent is highly unusual. Often applications are filed in the applicant's home country only. More extensive programs typically extend only to about three to six countries.

The international application includes claims to processes for preparing a *Hoodia* extract comprising an appetite suppressant agent either by using a solvent for extraction or by pressing sap from solid plant material; extracts produced by the processes; extracts obtainable from *Hoodia* and containing a defined appetite suppressant steroidal glycoside; compositions containing the extracts: use of the extracts and compositions for appetite suppression and treatment of obesity. Also claimed are the appetite suppressant steroidal glycoside itself and other compounds in the same chemical family, chemical processes for producing the claimed steroidal glycosides; chemical intermediates used in the processes; and compositions containing the appetite suppressant steroidal glycosides; use of the steroidal glycosides and compositions for appetite suppression and treatment of obesity. Foodstuffs and beverages containing the extracts and steroidal glycosides are also claimed.

It is unusual to have all these different features claimed in one patent application. Usually, extracts and extraction methods for plant material known to have traditional uses form a "first generation" of patent applications, with the identification of active chemicals, their modification and chemical synthesis in a "second generation". In some cases, knowledge of the pharmaceutical activity of the chemical family to which the identified compounds belong can lead to proposals for new uses of the plant extracts unrelated to the traditional uses.

Because of the varied nature of the claims, in many countries it has been necessary to "divide" the application, so in some countries there may be several separate applications each directed to a different category of claim. This may include for example extracts and extraction processes, steroidal glycosides and processes for their production and chemical intermediates. Patents for some aspects of the invention have been granted in Europe and the US, but in both territories there are still applications pending.

In Europe, only one patent has been granted to date[8], with claims directed to the use of a *Hoodia* extract containing a defined appetite suppressant steroidal glycoside in the treatment of obesity and for reducing total calorific intake of a human or animal. There are pending divisional applications on other aspects of the invention.

In the US there are two granted patents to date, one claiming an extract obtainable from *Hoodia* (by solvent extraction or as pressed sap) which comprises a defined ap-

petite suppressant - steroidal glycoside, compositions containing the extract and the use of the extract for treating obesity and appetite suppression, the other claiming a method of appetite suppression using the defined appetite suppressant, steroidal glycoside. The first application also claims the appetite-suppressant steroidal glycoside itself, compositions containing the glycoside and processes for its chemical synthesis. Divisional applications are directed to other aspects of the invention.

Reasons for the extensive filing program are unknown but may be related to the fact that *Hoodia* products can be used in the pharmaceutical sector for treatment of clinical obesity and in the non-pharmaceutical sector for weight loss. Obesity is not just a problem in the Western world; it is becoming a universal problem with the adoption of Western diets and lifestyles. Furthermore, there is increased desirability to be slim. By adopting an extensive filing program the CSIR has kept open the opportunity for its ultimate licensee to exploit the appetite-suppressant properties of *Hoodia* worldwide.

4.2.1 Subsequent Patent Applications

Since the publication of the CSIR application, 22 further applications or families of applications have been filed, by various companies.

Two early families of applications (filed in 1999 and 2000), relating to the use of *Hoodia* extracts or the steroidal glycosides for treatment of gastric conditions and for diabetes treatment, were filed by Phytopharm (the CSIR's licensee) and then assigned to Unilever. Some patents have been granted, including in South Africa.

Seven applications were filed by Unilever in 2006. Three relate to formulations for nourishing appetite-suppressant products containing a steroidal glycoside, for example, in the form of a *Hoodia* extract. Two relate to processes for producing improved *Hoodia* extracts containing steroidal glycosides, and two relate to processes for preparing an aqueous edible dispersion of steroidal glycosides, preferably starting from a *Hoodia* extract. These applications are still in their international phase, with deadlines for national phase entry in 2008 and 2009.

Cognis (Cognis IP Man GmbH, Germany) filed four applications in 2006, relating to various cosmetic and/or pharmaceutical compositions, compositions for oral or topical administration and chewing gum compositions, all containing *Hoodia* extracts or the steroidal glycosides.

The remaining applications were filed by different applicants. There is one German-only application (Aquapharm Health and Nutrition) for a process to produce a *Hoodia* extract. A UK-originating application was directed to cultured *Hoodia* cells, but it was dropped.

In two recent patent applications, WO2008/074656 and the corresponding US 2008/0253762, Unilever claims a process for harvesting plants from the Apocynaceae family (which includes *Hoodia*) comprising:

(a) removing the plants from the soil;
(b) leaving the intact plants to cure to a moisture content of less then 90 per cent by weight;
(c) cutting up the cured plants; and
(d) further drying the cut plants, to obtain dried plant material comprising a steroidal glycoside of a specific defined formula (formula 2).

The "curing" step does not require any special processing. According to the patent application, the plants "are simply left until they have achieved a moisture content of less than 90 per cent by weight". The plants can be left on the soil from which they were removed, or under a shade net or in a building. The minimum suggested time is one day, the maximum 150 days.

The Unilever claim appears to cover what is done in harvesting and processing *Hoodia* in Southern African countries where it occurs naturally. Harvesting, generally of intact plants, is carried out by hand and may stretch over several days. This means that the harvested plants are left to lie outside or in a shed for several days until cutting into strips or slices starts. Cutting is a tedious process and it can take several weeks before the last of the harvested plants has been processed. During the time before the plants are cut, they will inevitably lose moisture, i.e. they will "cure". The cut pieces are then dried.

If the Unilever claim does indeed cover typical harvesting and processing of *Hoodia*, and those processes are not carried out under conditions of confidentiality, a consequence is that the claim is potentially invalid because of the public "prior use" of the process. In many countries public "prior use", wherever in the world it occurred, is an admissible ground for challenging a claim. However, a notable exception is the US, where public "prior use" is admissible only if it occurs in the US. Public prior use in Namibia or South Africa would thus be irrelevant. Investigations into the practice of US *Hoodia* growers are currently underway.

If the US patent application were to be granted, which is far from certain given the relevant documents on file, it could interfere with the ability of Southern African *Hoodia* producers to export their product to the US. Unilever's recent decision to abandon *Hoodia* development may, however, nullify this concern.

4.2.2 Appetite-Suppressant or Weight-Reduction Compositions

Other applications are directed to appetite-suppressant or weight-reduction compositions. Although the applicants may intend to use non-extracted *Hoodia* products that do not fall within the CSIR patent, it is not always easy to determine if the *Hoodia* material

used does actually fall within the CSIR use of the term "extract", which includes pressed sap as well as extracts obtained using solvents. For example, some applications refer to the use of a "juice" or "puree" of plant material. If a puree is homogenized whole plant material, it is arguably not an extract. However, a "juice" arguably could be. Some applications specifically refer to dry material (e.g. a milled plant), which does not fall within the CSIR claims.

Fleischner (US, US application only) proposes compositions and methods for body weight reduction using defined amounts of *Hoodia gordonii* and other defined compounds and extracts. The *Hoodia* material to be used consists of whole plants without the roots. No further details are given, but this presumably refers to dried, milled material.

Rifkin (US, US application only) describes appetite satiation and hydrating beverages containing various components including an extract, a concentrated powder, a puree or a juice of *Hoodia*. Of these, the puree may be non-extracted material.

Century Systems (US, US application only) claims a herbal composition for appetite suppression containing defined amounts of *Hoodia gordonii* and Cassia nomane and optionally further components. The *Hoodia* used is any part of the plant, preferably prepared by drying and milling (i.e. non-extracted material). It is stated that not all sources of *Hoodia* gordonii are equally effective. A preferred variety is available from a firm in Texas.

Shatkina (US, US and European patent only) relates to a replacement meal including an appetite suppressant containing various components including an extract from *Hoodia* that can be dry powder, juice or pulp. It is not clear if the dry powder is a powdered extract or powdered non-extracted material. Pulp and juice may or may not be considered an extract as is pressed sap.

Holt (US, Canadian application only) claims a herbal composition that contains various components including *Hoodia* material that is preferably powdered material from the whole plant, referring to Fleischner (see above) for use of the whole plant, not just extracts.

Smartburn Formulations Ltd. (US, US, European patent and Australian applications) relates to compositions for rapid weight loss and appetite control containing various components including *Hoodia*. In the description, the *Hoodia* material is described as *Hoodia* extracts that do not contain extracts of root material, but the example refers to "plant without roots". It is not clear, therefore, if an extract or dry material is used.

Soft Gel Technologies Inc. (US, PCT only) claims compositions containing a pine nut oil and a *Hoodia* extract.

4.3. Intellectual Property and Value Addition

As described above, the commercial development of *Hoodia* is based on two approaches: (1) a patented *Hoodia* extract, under development by Phytopharm and, until recently, Unilever as a functional food (Figure 4); and (2) commercialization of *Hoodia* as a raw, ground-up, non-extracted material through incorporation into herbal supplements (Figure 5), which does not fall within the CSIR patent.

The industry sectors that develop and commercialize *Hoodia* material are thus very different, the former representing the food industry, represented by the largest consumer company in the world; the latter the herbal supplements market, which is characterized 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 was on safety and efficacy and the company placed emphasis on having sufficient active material to achieve effective weight loss. This was estimated by Unilever to be orders of magnitude greater than the amounts currently sold in herbal supplements (K. Povey, Unilever, pers. comm., 2007). Thus Unilever required vast amounts of material, and had planted several hundred hectares of *Hoodia* prior to its decision to withdraw from *Hoodia* development. 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 happened 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.

What does this mean in respect of value addition? A key question is to assess the different ways in which value is added to the variety of products, and the influence of the original CSIR patent and later patents on these processes. Here the main distinguishing feature is whether or not products incorporate extracts. Non-extracted *Hoodia* plant material, for example, that is dry, milled or powdered, can be produced freely in Southern Africa as the only applications that have been filed and patents granted in South Africa, are the initial CSIR application and the two Phytopharm applications (for treatment of gastric conditions and diabetes). All three patents relate to *Hoodia* extracts, not to non-extracted material, though it should be noted that the extracts include pressed sap.

Non-extracted *Hoodia* can also be exported freely to any country where there are no patents or applications that relate to the use of such material. However, some countries such as the US have patents or applications to pharmaceutical, herbal or nutritional compositions that utilize non-extracted *Hoodia* material.

In many countries, including the US, it is "indirect" (or "contributory") infringement to import, sell or offer for sale a product that is not itself patented but that will be used for

something that is patented. For example, it is potentially indirect infringement to import or sell or dry *Hoodia* material where a patent relates to the appetite-suppressant composition containing this material.

If the item that is imported or sold can only be used for the patented purpose, the situation is clear: there is indirect infringement. As a general rule, if the item that is imported or sold has substantial other, non-infringing uses, as is the case with *Hoodia*, then these circumstances will be taken into account. If the item is imported or sold with the knowledge that it will or could reasonably be used for the patented purpose, there will be indirect infringement.

The potential infringer is the party that imports the item into the country with the patent. Under British law, property will pass from a vendor to a buyer where and when the vendor and the buyer have agreed that it shall. Other legal systems may have different approaches, but in those countries where the legal system is based on British law this approach should apply. To remove potential ambiguities, it is good practice to specify in a sales agreement where and when the ownership of the property is transferred.

An exporter may therefore be able to avoid infringement by ensuring that the sale takes place under terms such that the ownership of the property passes from the exporter to the importer outside the country where the relevant patent exists, for example, in the exporter's home country. The same considerations apply if the exporter sells to a trader who then sells on to an importer. Transfer of ownership in the exporter's home (patent-free) country may avoid infringement. In the case of *Hoodia*, none of the appetite-suppressant and weight-reduction patent applications relating to non-extracted material referred to above appear to have been filed in Southern Africa so, provided the ownership of *Hoodia* material passes to the purchaser in Southern Africa, the exporter should not infringe.

Compositions containing non-extracted *Hoodia* material can be produced in Southern Africa and exported to any country where there is no patent (or, to be safe, pending application) for that particular composition, or for the use of that composition. The US compositions described above all contain various defined components in addition to the *Hoodia* material. There will only be infringement in the US if the composition contains all the defined components.

4.4. Value Adding Experiences

This analysis is to a large extent borne out by experiences within South Africa. The existence of the CSIR patent has meant that no firms which sell *Hoodia* as a dietary supplement currently manufacture extracts. However, some local firms are exploring their own intellectual property to look at other angles of value addition such as the manufacture of final products such as pills or food bars.

In fact, far from constraining value adding and local economic development, the influence of the original CSIR patent and later patent applications seem to have catalyzed an entire industry based on a product previously unexploited. Without the patents and the considerable research and development associated with this process it is unlikely that the herbal supplements sector, characterized by numerous small firms, would have developed the *Hoodia* industry at all.

The value adding impacts of the CSIR patent have also been substantial. The licensing of the patent by the CSIR has provided an important – albeit undisclosed – source of revenue for the CSIR and has been used to finance other projects. The license agreement also originally led to the construction of an FDA-approved medicinal plant extraction facility at the CSIR for the manufacture of material for use in *Hoodia* clinical trials, as well as the establishment of a Botanical Supplies Unit – both the first of their kind in the world. South Africa and Namibia are also the main locations for cultivation of *Hoodia*, generating employment opportunities. As evidenced by the initial interest in Cognis to develop an extraction facility for *Hoodia* in South Africa, there are also opportunities for technology development, although continued ownership of such facilities by foreign investors has led to questions about whether such transactions are genuine technology transfers of the kind that would result in widespread technology adoption in South Africa. Nonetheless, extraction in South Africa is certainly better than extraction in Germany, as occurs with devil's claw, as local people would be employed and local economies stimulated. While one product is unlikely to change South Africa's ability to become a conducive environment for technology transfer, it can catalyze a longer-term process of state support and investment in the natural products industry. Whether this is a sufficient condition for value addition is the topic for the third and final case study, that of the *Rooibos* tea industry in South Africa.

Box 2. Hoodia, the San and Benefit-Sharing

An issue that has dominated the case has concerned the way in which the San will benefit from commercialization of their traditional knowledge.[9] Up until 2001, the San remained oblivious to the fact that their knowledge of *Hoodia* had commercial application, and that this knowledge had led to research, scientific validation, and the filing of international patents by the CSIR. They were, moreover, excluded from lucrative deals being struck to develop commercial products. In 2003, however, following intense negotiations, an agreement was reached between the CSIR and the San, to give the San a share of royalties from product sales. In terms of the agreement,[10] the San will receive 6 per cent of all royalties received by the CSIR from Phytopharm as a result of the successful exploitation of products. This will be for the duration of the royalty period or for as long as the CSIR receives financial benefits from commercial sales of the products (Provisions 1.5 and 2). The San will also receive 8 per cent of the milestone income received by the CSIR from Phytopharm when certain performance targets are reached during the product development period. In the event of successful commercialization, these monies will 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 San peoples of Southern Africa.[11]

In addition to spelling out the details with respect to benefit sharing and administrative aspects such as accounting, the agreement also broadly covers IP issues and, importantly, sets out comprehensive measures to protect and indemnify the CSIR. "Knowledge" is 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 specifies that "any intellectual property that may be developed or created by the CSIR, including any patent, trademark 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 has no right to claim any co-ownership of the patents or products derived from the patents.

Despite acknowledgement by the CSIR that San traditional knowledge led to the commercial development of *Hoodia*, a different picture has emerged at the Board of Appeal of the European Patent Office (EPO). Indeed, the CSIR European patent application was initially refused, based on the belief that use of *Hoodia* for appetite suppression, weight loss and treatment of obesity was based on traditional knowledge of the San people. This was strongly refuted by the CSIR, whose arguments are set out clearly in the file history of European Patent Application EP0973534. The case went to appeal, and the Board of Appeal at the EPO accepted the CSIR's arguments and allowed claims to the use of a *Hoodia* extract that contains an effective amount of a defined appetite-suppressant steroidal glycoside in the manufacture of a medicament for treating, preventing or combating obesity, and to a non-therapeutic method of reducing total calorific intake of a human or animal by administering a *Hoodia* extract containing the defined appetite-suppressant steroidal glycoside. (Further applications claiming other aspects of the invention are still pending.)

The CSIR's position at the Appeal was that statements that may have been made after the filing date of its initial (priority) patent application by or on behalf of their exclusive licensee, Phytopharm PLC, and repeated by the media, embellishing with hindsight the prior traditional knowledge of the indigenous peoples of Southern Africa and that the teachings of the documents relating to such knowledge raised during examination of the European patent application, were fabrications issued without the authorization of the CSIR. The Board of Appeal held that there was no convincing evidence that documents published after the filing of its patent application reflect the reality about what was known before the application was filed and therefore did not consider those documents, but only the ones published before the application was filed.

The CSIR's position was that, to the extent that *Hoodia* was eaten by the San, it was as a bush food, to satisfy hunger and thirst. The only documented use of *Hoodia* in this context is that *Hoodia* was said to "quench" hunger and thirst for extended periods. The CSIR maintained that "quenching" hunger was simply the effect of eating

a filling and slowly digestible food, not a pharmacological effect on appetite, and that the periods are only extended in the context of the normal periods between meals for San people. The CSIR produced supporting evidence in this regard from a person who had been involved with the San for many years.

The CSIR produced evidence that the discovery of the appetite-suppressant effects was a result of screening hundreds of varieties of bush food for their nutrient content. One of the responses looked for in the testing, as an indication of toxicity, was suppression of appetite and loss of weight of the test animals. In the case of *Hoodia*, however, a pharmacological suppression of appetite was observed that turned out not to be associated with toxicity, which is unusual and therefore surprising. Testing in humans confirmed the appetite-suppressant effect. Analysis of the extracts and further testing resulted in identification of active steroidal glycoside compounds, and further work led to their chemical synthesis. Plasma levels of the major active compound that were found to reduce daily calorific intake in humans after administration of the chemical were compared with those resulting from sucking the sap or eating 50g of plant material. Low plasma levels resulting from eating a typical amount of *Hoodia* or sucking its sap suggested that the active compound obtained through typical San usage of the plant was too low to have any pharmacological appetite suppression effect.

The CSIR also pointed out that its invention has led to widespread imitation and considerable commercial activity by others. It indicated that the sudden eruption in imitations of the invention was strongly indicative that the invention was not obvious over traditional knowledge. If it had been obvious, it argued, the commercial potential would have prompted others to market *Hoodia* extracts for treatment of obesity, but this did not happen prior to the invention.

5. *ROOIBOS*

5.1. Overview

Rooibos tea is one of South Africa's oldest and most successful indigenous plant products, and has been cultivated on a commercial basis since the 1920s. The industry is based upon *Aspalathus linearis*, a leguminous plant indigenous to western parts of South Africa, the area where production is still centered. *Rooibos* has a long history of traditional use, having been harvested, prepared and consumed by the Khoi and perhaps the San for centuries (Thunberg, 1795; J. van Pitten, pers. comm.). Today, *Rooibos* is seldom prepared in the traditional way but rather in much the same way as Ceylon tea. Additionally, *Rooibos* has become increasingly popular as a health tea as it contains no harmful stimulants and is caffeine-free. Health-related qualities of *Rooibos* tea are ascribed mainly to its low tannin content, the presence of various minerals (albeit limited), and the antioxidant properties of several unique flavonoid C-glycosides such as aspalathin and nothofagin (von Gadow *et al*., 1997a; von Gadow *et al*., 1997b; Erickson,

2003), thought to protect against free radical damage that can lead to cancer, heart attacks and strokes. Increasingly, *Rooibos* tea is also used as an ingredient in cosmetics, slimming products and as a flavoring agent in baking, cooking and cocktails.

One of the most interesting aspects of the *Rooibos* industry is the extent to which it has received government support. Following the collapse of the domestic *Rooibos* market due to oversupply and renewed competition from imported teas after the Second World War, producers established the Clanwilliam Tea Cooperative in 1948. In 1954, at the request of the Cooperative, the Minister of Agriculture instituted the *Rooibos* Tea Control Scheme, a statutory, one-channel marketing system and for nearly 40 years its Board acted as the sole buyer from producers and also as the sole seller to approved exporters and tea processors. Through the establishment of the *Rooibos* Tea Control Scheme, the *Rooibos* industry could be assured of direct government protection and support, including subsidies for affiliated producers, research and the provision of extension services. This had clear ramifications, not only for the *Rooibos* industry which entered a period of substantial growth and development, but also for producers excluded from the scheme which in apartheid South Africa meant the mostly colored farmers who had traditionally gathered and cultivated *Rooibos* tea. In 1993 the Control Board was abolished and the Clanwilliam Tea Cooperative was transformed into a public company called Rooibos Ltd., which took over the assets and many of the functions of the Control Board. Since this deregulation the *Rooibos* tea industry has changed dramatically. Privatization, combined with the lifting of sanctions with the advent of a democratic South Africa, has opened up the industry not only to new producers, processors, packers, and distributors, but also to new marketing channels and investment opportunities (Hayes, 2000).

Rooibos tea has now emerged as a global product, highly sought after by health-conscious consumers, accounting for about 10 per cent of herbal tea sales globally (Snyman, 2004). Over the past 50 years *Rooibos* tea sales have grown from an average of 500–600 tons in the 1950s to a 20-fold increase of over 10,000 tons in 2003. Although domestic consumption has increased steadily, representing about 18 per cent of the South African tea market in 2004, export sales have been spectacular, exceeding local sales for the first time in 2001, with an annual growth rate of more than 30 per cent (Snyman, 2004). Volumes of organic *Rooibos* have increased in parallel and *Rooibos* tea is also the only Southern African species widely traded as a fair-trade product and certified as such. Today, more than 5,000 people are employed in South Africa by the industry, which in 2004 traded about 9,500 tons and had a domestic turnover of some 475 million rand (US$74 million), excluding export sales and non-tea products such as cosmetics and extracts (Snyman, 2004).

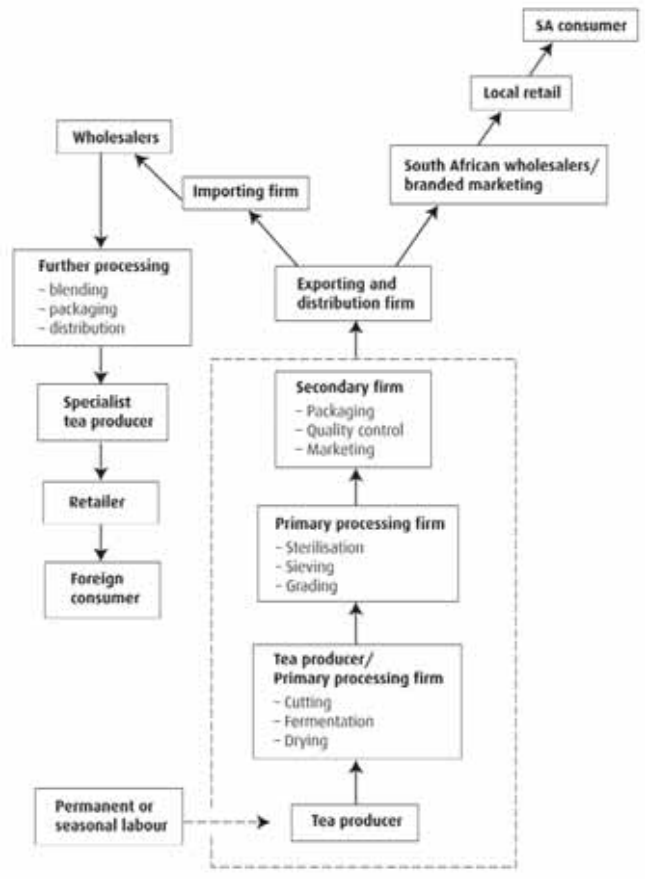
Like many other commodities, the *Rooibos* value chain is characterized by the variety of ways in which the original product, the leaf of the *Rooibos* plant, can be processed, blended, packaged and distributed. Key steps include:

- the cultivation and harvesting of the tea and its transport to a tea court;
- the cutting, fermentation and drying of the tea on a tea court;
- the sterilization, sieving and grading of the tea;

- tea packaging;
- the distribution of the tea, either to local wholesalers and retailers, or through export and import;
- further processing, blending, packaging and distribution;
- retail of the tea; and
- its final consumption.

Figure 6 illustrates a typical *Rooibos* value chain for conventional tea. These steps vary considerably depending on the final product (e.g. tea, extract, cosmetics), the different players and commercial actors involved, the location of producer and processing facilities, the different types of value adding that occur in various locations, and the varied markets (e.g. organic, conventional and fair-trade) across the world. Green tea, for example, will bypass the fermentation stage, and material for the cosmetic industry will typically pass through an extraction process (Tiedtke and Marks, 2002). Bulk tea exports will likely change hands more frequently than packaged tea.

Figure 6. A Typical Value Chain for Conventional Rooibos Tea



After Wynberg (2006).

5.2. Rooibos Patents and Patent Applications

The patents and applications relating to *Rooibos* have a very different filing pattern from *Hoodia*, where all patenting activity followed the initial South African patent application of the CSIR for *Hoodia* extracts, active compounds in those extracts and the use of the extracts and compounds. According to the esp@cenet database, the pattern of patenting activity is similar to, but even more extreme than, that for devil's claw. The *Rooibos* applications are predominantly for compositions exploiting properties of *Rooibos* and its extracts, with a small number of applications for new processes.

5.2.1 Categories of Application

The 95 entries for *Rooibos* in the esp@cenet database fall into the following categories:

- processes for producing *Rooibos* extracts (13)
- teas and similar beverages, health foods and processes for their production (23)
- pharmaceutical compositions and uses (24)
- cosmetic compositions and uses (15)
- deodorant compositions and uses (8)
- weight-loss compositions and uses (2)
- foods (5)
- smoking (1)
- others (3)
- unknown (1)

5.2.2 Geographical Range of Patenting

Of these 95 *Rooibos* applications, 67 were filed by Japanese companies, representing a remarkable predominance from that country. This may in part result from the relative cheapness of an initial Japanese application (significant costs can be deferred for several years).[12] Of those 67 applications, 15 were granted and appear to be in force, 10 are pending, and 42 were withdrawn or rejected, or were granted and have ceased.

Of the remaining 28 entries, the breakdown by country of applicant is as follows: the Republic of Korea (13), Germany (3), South Africa (4), the US and Canada (2), Russia, Greece, Bulgaria, joint Germany/Denmark (1).

Eighty-four of the applications were filed only in the home country of the applicant. Of the 11 applications filed in more than one country, one was dropped and two are still in the international phase.

5.2.3 Process Patents and Applications

Two of the process applications originate in South Africa. The first (ZA9306388), filed in 1993 by Forever Young CC, claims a method for producing a *Rooibos* extract that involves the use of enzymes to achieve at least partial destruction of fiber and cellulose tissue of the needles and chips. It is not known if this patent is still in force. The second, filed initially in South Africa in 2004 by the University of Stellenbosch Agricultural Research Council and then as an international application, appears to have been pursued in Europe only. It also relates to the use of enzymes in the production of a *Rooibos* extract and is having problems at the EPO. There does not appear to be a corresponding South African patent. A German-originating application filed in 2005 by Raps GmbH and pursued in Germany, Canada and at the EPO, relates to a solvent extraction process. The German application has been granted but the other two are still pending.

A Japanese patent, filed in 1986 by Shisheido and now ceased, relates to an antioxidant produced by a specified process. Two Japanese-only applications filed in 1993 by Nippon Ruibosuteii Honsha KK (one granted but ceased, the other withdrawn) relate to the use of an alkali or alkaline salt in the production of *Rooibos* extract. A further Japanese application, filed in 1994 by Asugen Seikyaku KK and now withdrawn, is directed to a simple extraction process. A patent filed in the name of Mitsui Norin KK in 1994 and granted in Japan, Europe and the US relates to a process for preparing an antiviral agent from *Rooibos*. Inabata Koryo Co. Ltd. has a granted Japanese patent, filed in 1997, to a process for obtaining *Rooibos* tea. Arita Noria filed a Japanese application in 2000 to a method for extracting minerals from *Rooibos* tea, but the application was withdrawn. A Korean-only application filed in 2000 by Dodo Corp. uses an aqueous/alcoholic extraction. Another Japanese-only application, filed in 2002 by Iwahara Masayayoshi, describes forming an epidermal powder by mixing *Rooibos* plant stems while rubbing them together, thereby peeling the epidermis and powdering the peeled epidermis. The application was rejected. A Korean-only application by Hanacos Co. Ltd, filed in 2002, relates to an extraction process involving a Sephadex purification step.

5.2.4 Composition Patents and Applications

Of the 82 patents and applications that relate to compositions of various kinds, 59 were filed by Japanese and 11 by Korean applicants. Of those 70 applications only two were filed in more than just the home country. One is in the name of Shirimatsu Shinyaku Co. and Itochu Fine Chemical Corp. and relates to an antimicrobial composition. Patents have been granted in the US and, via a European application, in France, Germany, Italy and the UK. The other is in the name of Mitsui Norin KK, and relates to an anti-viral and anti-cancer agent comprising an extract of *Rooibos*. Patents have been granted in Australia, Europe (France, Germany, Italy, Netherlands, Switzerland and the UK), the US and applications appear to be pending in Canada and China.

Of the other 12 composition applications, three, including a South African application, were filed in several countries including Europe and the US. The South African application, assigned to Gardian CIPLA (PTY) Ltd. is pending in South Africa, the US, Europe and, possibly, Australia. It relates to food supplements comprising an extract of *Rooibos*. A family of applications filed by Neutrogena Corp. has claims that have been amended, in Europe at least, and no longer include *Rooibos* as an ingredient. A joint application by Cortex Technology APS and Daimler Chrysler AG is pending in Europe and the US. Two further applications (Accelis Formulations and Symrise GmbH) are still in the international phase.

5.3. Intellectual Property and Value Addition

What are the links between these patents and value adding in South Africa? Despite strong government control and support of the *Rooibos* industry, and the effective creation of a monopoly prior to 1994, this has not led to enhanced value adding in the export market and South African companies have had little success with exporting branded and packaged products. Less than 5 per cent of *Rooibos* exports in 2003 accounted for value-added products, most of the remaining 95 per cent being bulk exported for use as a filler for herbal teas or, to a very limited extent, packaged by importers as teabags and sold as *Rooibos* tea (Snyman, 2004).

However, it is clear that the reasons for this low value adding cannot be attributed to patents. Most patent applications have been filed in the applicant's home country only, particularly Japan and the Republic of Korea, and existing patents thus present few restrictions to local value adding. In fact, it could be argued that far from impeding local value adding, existing patents provide commercial opportunities for production in South Africa and for export to all except the applicant's home country, and even there the product can be exported if the patent or application has been dropped, as is the case with many of the Japanese applications. As explained previously, if an application has not been filed in a country, the claimed invention can be worked in that country by using the patented process or by making the patented composition. Similarly, the product can be exported to any country where the application has not been filed. Even where an application has been filed in more than one country, the filing programs for *Rooibos* are not extensive, leaving many markets open.

Aside from patents, a complex mix of market and price constraints prevents local companies from adding value to *Rooibos* tea. One of the most prevalent is dominance by a handful of key international tea brokers. Most *Rooibos* is exported to Germany, Japan, Netherlands, the UK and the US which accounted for a combined total of about 81 per cent of all international *Rooibos* sales in 2008. Of these sales, Germany occupies a dominant position, representing 50 per cent of all *Rooibos* traded. In the German market, 15 to 20 tea agents buy *Rooibos* and redistribute it to blenders and packers, and the firms Hälssen & Lyons and Martin Bauer in particular play leading roles (Hayes, 2000). The dominance of German traders and tea brokers is a characteristic prevalent in many herb

and tea commodity chains, aided often through historical links and relationships. For example, the giant German herbal trader Salus Haus was given exclusive rights by the *Rooibos* Tea Control Board to trade *Rooibos* in the late 1950s (Department of Agriculture, 1958), and still plays a prominent role in the trade.

Other factors constraining value adding include high entry barriers into foreign markets, and import tariffs on retail-packed teas (Hayes, 2000; Snyman, 2004). These factors are exacerbated by the fiercely competitive nature of the *Rooibos* industry, more especially in the bulk market. Hayes (2000) remarks on the "senseless rivalry" that characterizes the industry, and the willingness with which South African *Rooibos* exporters are prepared to undercut other exporter's quotations to enable survival in a highly competitive and monopolized environment. These comments are remarkably similar to those expressed by different players in the devil's claw industry.

Further analysis of the *Rooibos* value chain highlights the significance of packaging in value adding. Table I summarizes findings from a 2005 study to compare value adding across different *Rooibos* value chains and illustrates that the bulk export of both conventional and fair-trade organic *Rooibos* tea results in South Africa capturing just 7 per cent of total value. Products that are packaged, in contrast, result in South Africa capturing 36 to 43 per cent of the retail price.

Increasingly, the local *Rooibos* industry is reacting to such trends through vertical integration and increased attempts to establish total control over its supply base. There are also growing innovations within the local industry through the development of *Rooibos* extracts, an instant *Rooibos* tea, new types of drink, and more aggressive entry into niche markets. The reliance on patents for such innovations, however, is questionable. One of the only local firms to hold a patent for an extraction process for *Rooibos* noted that "the patent was not really necessary but it gave us a competitive edge in the initial stages and kept other players out of the market". Other local firms have displayed little or no interest in using patents as an opportunity for value adding, despite good commercial prospects. Patenting in countries such as Japan and the Republic of Korea could also be fruitful in view of the apparent interest there in *Rooibos* products.

Despite little focus on patents in the local *Rooibos* industry, much attention has been given to the possibilities of using geographical indications to protect products. This followed registration of the name "*Rooibos*" as a trademark in the US, effectively thwarting export attempts to the US from South Africa, and leading to litigation in the US courts. Although the case was settled out-of-court following a district court ruling, it has contributed toward the motivation to amend IP law to allow trademarks and geographical indications to be able to provide protection of certain names and features associated with traditional knowledge such as *Rooibos* tea (Troskie, 2007). Such initiatives offer valuable ways to enhance the local industry but their more detailed consideration falls outside the focus of this paper[13].

Table 1. *Rooibos* Value Chain, Indicating Proportional Value Captured by Each Player, Within Different Trade Models

Value Chain	Conventional *Rooibos* (local sale conventional tea, value adding South Africa)		Organic *Rooibos* (bulk export)		Fair-trade *Rooibos* through intermediary (value adding South Africa)		Fair-trade *Rooibos* through intermediary (bulk export organic)		Fair-trade direct (value adding South Africa)	
	Selling price (US$ per kg)	% value captured	Selling price (US$ per kg)	% value captured	Selling price (US$ per kg)	% value captured	Selling price (US$ per kg)	% value captured	Selling price (US$ per kg)	% value captured
Producer/ harvester	2,53	15.8	2,75	4.2	2,48	6.3	2,48	3.0	2,89	3.7
Producer organization	-	-	-	-	1,46	3.7	1,46	1.8	11,94	15.3
Middleman/ local trader	5,79	36.2	1,56	2.4	10,54	26.6	2,05	2.5	19,03	24.0
SA retailer	5,72	35.7	-	-	-	-	-	-	-	-
SA VAT	1,97	12.3	-	-	-	-	-	-	-	-
FLO premium	-	-	-	-	-	-	-	-	0,82	0.8
ATO premium	-	-	-	-	1,45	3.7	0,6	0.7	3,28	4.2
European trader	-	-	40,62	62.6	16,02	40.4	59,14	71.8	35,83	46.0
European retailer/ Netherlands worldshop	-	-	15,72	24.2	5,49	13.9	11,98	14.5	-	-
European/ Netherlands VAT	-	-	4,24	6.5	2,25	5.7	4,66	5.7	4.41	5.7
Total	16,01	100.0	64,89	100.0	39,69	100.0	82,37	100.0	78,00	100.0
Net value captured by producer country (US$)	16,01	100.0	4,30	7.0	14,48	36.0	5,99	7.0	33,86	43.0
Net value captured in Europe	0	0	60,59	93.0	25,21	64.0	76,38	93.0	44,14	57.0
Consumer price as multiple of producer price	6		24		16		33		27	

All figures are converted to US$ and pertain to 2004.

Figures are derived from a survey conducted of players within each value chain and from Wynberg and Custers (2005) and Wynberg (2006). The FLO and ATO premiums refer to the premiums paid by FLO or an ATO to producer organizations. In 2004 this was 10 per cent of the free-on-board (FOB) price.

6. DISCUSSION AND CONCLUSIONS

Results presented from these case studies demonstrate that patents can both hinder and promote value adding in the Southern African natural products sector, and that it is difficult to be definitive about the specific role played by patents in value adding at a generic level. While there are certain patents that restrict particular devil's claw extraction techniques in specific territories, other extraction techniques are available to local industry to enable similar extracts to be made within Southern Africa. However, such subtleties are not always recognized by local firms who typically give up in the face of perceived restrictions. Similarly, the *Hoodia* case has demonstrated that patents do restrict certain extraction techniques, but that without such patents the industry is unlikely to have existed in the first place. For *Rooibos*, patents simply play no role at all at present in inhibiting value adding in the local industry.

The question as to whether patents stimulate industrial activity in the natural products sector is less definitive. Certainly for devil's claw and *Hoodia* patents have played a catalytic and positive role in stimulating trade, research and industrial activity. Although the *Rooibos* industry has thrived without the overt influence of patents, its substantial development would not have been possible without strong government support. Having said this, the suite of *Rooibos* patents and applications in Japan and the Republic of Korea for example, could open up markets and products for local exploitation. This is an opportunity that has not yet been seized by local firms.

It is also clear that the significant research, marketing and IP investments made over the past 50 years have contributed substantially to the growth of the Southern African natural products sector and the realization of its benefits. However, without prior traditional knowledge in all of the cases examined there would probably have been no industry at all. This is a factor that has been underplayed in the sector, although increasingly it is being recognized through benefit-sharing agreements and attempts to include traditional knowledge holders more actively within the local industry.

Findings have also been presented that demonstrate extremely low levels of awareness of the importance of intellectual property and technology transfer in local firms. Typically, local firms do not comprehensively investigate the extent to which they are free to operate and, where patents exist, need to be convinced that their mere existence does not necessarily constitute a business risk and indeed that they may not be valid at all. PhytoTrade Africa, a company that trades a variety of African natural products on behalf of small producers, remarks that investors are often scared off by the presence of patents – even if these are not legally effective. "Patents muddy the waters for investors wanting to do research and development, even if applications are not granted. A big investor would be put off [by patent applications] as the territory is too murky and unsure. The quality of the patent is key as it is often very poor. This has an impact on development as the burden of proof rests with those trying to take it forward." Moreover, little attention has been given to the possibility of licensing-in as a strategy for companies to start upgrading themselves technologically.

An important conclusion from this research thus points toward the need to design industry-specific interventions such as talks, seminars and courses to raise awareness and capacity among local firms about the nature and application of patents and their implications. Issues of liability and risk are especially crucial for local firms, including ways in which "indirect or contributory" infringement is interpreted and the options open to them to pass on ownership of raw material in Southern Africa – and thus minimize risk. It is also important for any party using, or considering the use of, patents and applications to monitor the intellectual property regularly. A patent may lapse in a country due to non-payment of renewal fees, an application may be dropped or rejected, or the claims may be narrowed so they are no longer relevant. If so, the claimed product can be exported to that country. Because applications are not published until 18 months after the initial filing date, searches should be updated regularly as there may be relevant applications in the pipeline.

Finally, all three cases reveal that in addition to the existence of an IP option, factors that influence value adding are complex and interdependent. Key factors accounting for low levels of value adding in the Southern African natural products sector stem from restricted market access, buyer dominance, a lack of strategic alignment amongst producers, and insufficient technical and financial capacity to meet quality control standards. Local firms would do well to build long-term strategic relationships with both competitors and commercial partners whilst enhancing their awareness of the IP environment to facilitate local value addition.

Notes

1 The exploration of biodiversity for commercially valuable genetic and biochemical resources.

2 A further database, providing comprehensive information on international patent applications filed under the Patent Cooperation Treaty (PCT) is PatentScope, the WIPO on-line database, available at: *www.wipo.int/pctdb/en*.

3 "Biopiracy" has emerged as a term to describe the ways that corporations from the developed world claim ownership of, free ride on, or otherwise take unfair advantage of, the genetic resources and traditional knowledge and technologies of developing countries (Dutfield, 2004).

4 Note that this is according to the esp@cenet database. Information regarding patent applications filed at the South African Patent Office is not available on-line and has not been checked.

5 Newnham x 2, von Beckerath, Moati, Sincholle, Weisman and Moreau.

6 This estimate is based on 2002 data and assumes an average retail price of US$200 per kg, based on an Internet survey of existing devil's claw products sold by companies such as the Organic Herb Trading Company, available at *http://www.iherb.com* and Solgar. However, this figure varies considerably, depending on the product sold, its quality and the type of processing, and may be as high as US$350 per kg. (but is likely not as high as the US$700 per kg. proposed by GRAIN (2000)). An example of one calculation follows:
- Solgar sells a bottle of 60 devil's claw vegecaps for 13.35 pounds sterling.
- Each pill comprises a 300 mg. extract of devil's claw and 150 mg of raw devil's claw powder.
- The industry standard extraction rate for devil's claw is 6:1
- Thus each bottle comprises ((300 mg. X 6) + 150 mg.) X 60 = 117,000 mg
- This equates to 114 pounds sterling per kg., or US$200 using 2002 exchange rates.

7 Because of the notoriously secretive nature of the devil's claw trade, these figures are at best an approximation. A more comprehensive analysis of the value captured at specific steps along the processing and manufacturing chain and the margins secured at each point has not been possible, largely due to reluctance on the part of industry players to divulge this information. However, it is important to recognize that the manufacturing and retail components of the chain in themselves comprise myriad steps and variations. For example, the manufacture of devil's claw pills may typically be subcontracted by pharmaceutical firms, and then distributed wholesale before reaching the retailer. Products may also have margins associated with the use of brand names. Different extraction and processing techniques will also have different sets of associated costs. This information is vital for a fuller analysis of the value chain to be undertaken.

8 i.e. by 1 June 2008

9 See Wynberg, 2004, and Wynberg and Chennells, 2008, for a detailed account of this issue.

10 Benefit-Sharing Agreement between the CSIR and the South African San Council, March 2003.

11 Deed of Trust of the San *Hoodia* Benefit-Sharing Trust.

12 The official fees on filing a Japanese patent application are only 15,000 yen (about 90 euro or US$140). In contrast, the basic official fees on filing a European Patent application are in the order of 1,230 euro (US$2,000), on filing a US application about US$515 for a small entity, i.e. a person, small business concern or non-profit organization or US$1,030 for a large entity, and on filing a PCT (international) application in the order of 2,610 euro to US$3,365 (all fees as at June 1, 2008).

13 On this issue, see Chapter 3 by Biénabe *et al*.

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