

KNOWLEDGE NOT FOR SALE

Umckaloabo and the
Pelargonium Patent Challenges



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(photograph courtesy of the *Sunday Times*)

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“The community wants to stop [companies] from saying they were the first to know that this medicine is important, because we grew up knowing that ... they are like thieves, just stealing the indigenous knowledge.”

Nomthunzi Sizani,
spokesperson for the Alice communityⁱ

Introduction

The African Centre for Biosafety (ACB) is a non-profit, activist NGO based in South Africa, specialising in promoting biosafety and challenging biopiracy, agrofuels and the commodification of biological resources and associated traditional knowledge.

We represent a community from Alice, in the Eastern Cape province of South Africa, who has, since time immemorial, had unfettered access to various medicinal plant species, including *Pelargonium sidoides* and *Pelargonium reniforme*. Based on their ancient traditional knowledge, numerous members of the community use the two *Pelargonium* species to treat various ailments in animals and humans. The community produces tinctures from the roots of the *Pelargonium* species, using water and alcohol extraction methods, to treat various respiratory infections and diseases, including tuberculosis (TB).

German based Schwabe Pharmaceuticals, specialising in phytomedicines, produces alcohol extracts from the roots of the pelargoniums in syrup form, under the brand name, Umckaloabo. Umckaloabo is sold in Europe as a natural medicine for the treatment of respiratory tract infections such as bronchitis and common coughs and colds.¹ Schwabe markets Umckaloabo as a unique natural African traditional remedy. Indeed, Umckaloabo is the 20th most sought after medicine in Germany, reaping huge profits for Schwabe Pharmaceuticals.² During 2006 alone, Schwabe cashed in a staggering 80 million Euro in sales.³

Schwabe produces Umckaloabo from the roots of *Pelargonium sidoides* and *Pelargonium reniforme* grown in the wild in South Africa. These are exported from South Africa by a Schwabe-owned South African company, Parceval, to Schwabe in Germany. *Pelargonium sidoides* is endemic to South Africa and Lesotho and *Pelargonium reniforme* is endemic only to South Africa.⁴ Both species occur naturally in the Eastern Cape province of South Africa, including the Alice area.

i. Jordan, B. 7 October 2007. **Drug companies looting SA's bounty of medicinal plants.** *The Sunday Times*. <http://www.thetimes.co.za/PrintEdition/News/Article.aspx?id=580773> (accessed 17 March 2008).

There is no evidence that Schwabe sought out and obtained the prior informed consent on mutually agreed terms (MAT), from holders of the traditional knowledge in South Africa. It is common knowledge that these are required by the international legally binding treaty, the Convention on Biological Diversity (CBD), to which South Africa has been a Party since 2 November 1995. The CBD is a self executing treaty in terms of South Africa's Constitution, and came into effect in South Africa on 2 November 1995. Schwabe has thus been in contravention of the CBD since 2 November 1995.

It is significant to note that Schwabe is an old hand at understanding the international legal obligations of the CBD. It has for example, funded a pilot study that began in 2003, to develop model access and benefit sharing protocols in Ecuador. The study is called 'ProBenefit' and was conducted by Schwabe in collaboration with several partners, and co-financed by the Federal German Ministry for Education and Research.⁵

Compounding this scenario, Schwabe has been granted two patents by the European Patent Office (EPO) concerning the two *Pelargonium* species. The first patent (Patent on Extraction method to produce Umckaloabo) has resulted in a monopolisation of the two plant species of *Pelargonium* by Schwabe, because it allows Schwabe, through the monopoly on and propriety over the extraction methods, to control the entire trade with the roots of the two *Pelargonium* species, as well as all extracts, tinctures etc in Europe – this is tantamount to a clever circumvention of the European Patent Convention, which disallows patents on life (patents on plant varieties).⁶

Accordingly, and upon the instructions of the Alice community, the ACB, supported by a Swiss based NGO, the Berne Declaration, has submitted a formal legal challenge to the patent. The patent is also being challenged by two Swiss companies, Frutarom and Alpinamed and a Germany company, Finzelberg.

The second patent granted to Schwabe is in respect of the use of the *Pelargonium* species for the treatment of a wide range of AIDS related diseases, including bacterial, viral, and parasitic infections and inflammations, TB, all respiratory infections, sexually transmitted diseases etc. This patent has been challenged by the ACB and a member of the Alice community, Ms Funeka Nkqayi, as a symbol for the rest of the Alice community, on the grounds that it duplicates or misappropriates traditional knowledge.

In this briefing paper, we trace the historical appropriation of traditional knowledge and biological resources and the subsequent marketing of Umckaloabo by Schwabe in Europe. We also provide an overview of the 'on the ground situation' in South Africa, including a discussion of the legal implications of Schwabe's conduct. The balance of the paper is devoted to a discussion of the 2 patent challenges. In the conclusion, we set out the demands of the Alice community.

Background

Historical appropriation of the *Pelargonium* species and associated traditional knowledge

In 1897, an Englishman, Charles Henry Stevens who was diagnosed with tuberculosis (TB) came to South Africa in search of a cure. In South Africa, he met a traditional healer Kijitse, who gave him a tincture made from the *Pelargonium* roots, which miraculously cured him.⁷ Stevens coined the term 'Umckaloabo' to describe the plants. The word "Umckaloabo"



Umckaloabo

Source: Sonnenberg Apotheke
http://www.sonnenberg-apotheke.com/Heilpflanzen/Kapland-Pelargonie/a_Umckaloabo-Packshot.gif

originates from the merger of two Zulu words describing symptoms of diseases cured by the *Pelargonium* plants; namely “umkhuwane,” which describes coughing and fever related diseases, and “uhlabo,” which refers to chest pains.⁸

Stevens took the roots and the newly acquired traditional knowledge back to England in the altruistic hope of curing other TB patients with the concoction, which he called ‘Stevens’ Consumption Cure’. Once there, he began offering the concoction to people afflicted with TB and in so doing, attracted the attention of the British Medical Association (BMA). The BMA disputed the pelargonium’s healing properties and labelled Stevens a quack, culminating in protracted litigation in the British courts.

Subsequently, Umckaloabo was tested and its healing properties verified by Dr Secheyay of the University of Geneva in the 1930’s.⁹ These findings and further studies prompted the establishment of JSO Werks Regensburg (ISO-Arzneimittel), who began importing *P. sidoides* and *P. reniforme* roots from South Africa for the production and sale of Umckaloabo.¹⁰ Iso-Arzneimittel later became a part of the Schwabe Group.

Schwabe Group and the lucrative Umckaloabo

Dr Willmar Schwabe Pharmaceuticals founded in 1866, specialises in phytomedicines and is a well established phytomedicine company in Germany. Schwabe markets Umckaloabo by way of numerous joint ventures with other companies including Spitzner Arzneimittel¹¹ and Iso-Arzneimittel.¹² It also markets a similar product in the United States under the brand name Umcka, through its joint venture with Nature’s Way.¹³ All these companies belong to the Schwabe Group headed by Dr Willmar Schwabe Pharmaceuticals in Germany.¹⁴ Umckaloabo is marketed as a modern therapy for infections, containing highly concentrated extracts of active ingredients derived from the two *Pelargonium* species for the treatment of respiratory tract infections, strengthening the immune system, common colds and bronchitis.¹⁵

Schwabe owns 74% of the shares in a South African company, Parceval.¹⁶ Parceval is headquartered in Wellington, Western Cape province of South Africa, and procures wild

harvested *Pelargonium* roots from South Africa for Schwabe. Parceval also does the drying and dessication of the roots and exports these to Schwabe in Germany where Umckaloabo is produced. A 100 millilitre bottle of Umckaloabo syrup is sold in Germany for 30,68 Euros (R380, 85).¹⁷ According to the Financial Times Deutschland, Schwabe's sales figures have been increasing dramatically. It has gone from 8 million euros in 2000, to 55 million euros in 2003 and soaring to 80 million euros in 2006.¹⁸

Status in South Africa

Wild harvesting and temporary ban in the Eastern Cape

Our research has revealed that Schwabe's agent, Parceval – at least since 1995 – has been the main supplier of the *Pelargonium* roots for the production of Umckaloabo.¹⁹ Acting for and on behalf of its principal, Schwabe, Parceval has extracted biological resources from South Africa to which the traditional knowledge of the Alice community is inextricably tied. Parceval also supplies the roots to local South African companies, who sell the same tinctures on the South African market. One of these companies, Bioharmony, produces a cough syrup from the *Pelargonium*, which it sells for R54 (4,35 Euros) on the South African market.²⁰

Parceval has admitted on their website (now removed) that although there have been attempts to grow the pelargoniums on their farm in Wellington in the Western Cape, most of its stock comes from wild harvesting.²¹ In any event, ACB's research has revealed that the roots of the *Pelargonium* are being harvested from the wild in South Africa to meet the international demands for Umckaloabo.²² Indeed *P. reniforme* roots are the 28th most traded plant species in South Africa.²³ Due to the extreme pressure put on the resource, and as a result of the unsustainable harvesting of *P. sidoides* in particular, both species are becoming increasingly difficult to come by in the wild.²⁴ Experts from the Eastern Cape have researched the impact of the wild harvesting and have sounded the alarm bells that such harvesting poses a serious threat to the survival of the species.²⁵

Harvesters from the Alice and other communities in the Eastern Cape are paid a mere R3-R15/kg (0,24 Euros – 1,21 Euros)²⁶, whilst the middlemen who sell the plants to Cape Town for export earn about R1000/kg (80,56 Euros).²⁷ Since *Pelargonium* roots burrow deep into the ground, the collection of just one kilogram could easily entail a whole day's worth of work. The amount being paid for the harvesting of the one kilogram is 10 times below the minimum wage for farm workers as is required under the strict South African labour laws.²⁸

The Eastern Cape Provincial Department of Economic Development and Environmental Affairs (DEDEA) responded to this situation in June 2006, by placing a temporary ban on the harvesting and export of both *Pelargonium* species from the wild.²⁹ The Lesotho government has on the other hand, as far back as 2004, listed all *Pelargonium* species as "Protected Flora" (Lesotho Government Gazette Extraordinary. Legal Notice No.93 of 2004. Proclamation of Monuments, Relics, Fauna and Flora). Nevertheless, pressure to supply the roots to Parceval has prompted illegal harvesting, with the result that at least nine harvesters were arrested for illegally harvesting both *Pelargonium* species in the Eastern Cape,³⁰ and nine harvesters in Lesotho.³¹



Pelargonium sidoides

Source: San Marcos Growers at www.smgrowers.com/info/images.asp?strLetter=P



Pelargonium reniforme

Source: Blumenschule at http://shop.blumenschule.de/product_info.php?products_id=2011

In an attempt to address the issues pertaining to the *Pelargonium* species, DEAT has advised the ACB that it has drafted an 'Operational Policy: Guidelines for Commercial Use of Indigenous plants.'³² We have, in numerous correspondences to the DEDEA, requested that they make the draft available for public comment and to expedite its implementation. However, despite numerous requests we have yet to receive a reply on the status and the effect of the policy. We have been instructed by the Alice community to approach the South African authorities to list both species on the relevant national Protected Species Lists in terms of domestic biodiversity legislation as well as to advocate for placing of both species on Appendix II of CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora).ⁱⁱ

New tactics and Schwabe's play for new sources for the *Pelargonium*

Schwabe has initiated various projects to ensure the steady supply of the *Pelargonium* roots to continue its Umckaloabo production. These include plantations in Nkuru, Kenya and Mexico and at various sites in and around the Alice and Peddie areas of the Eastern Cape.³³ Schwabe, through Parceval has also financed a *Pelargonium* cultivation project in the Free State Province of South Africa comprising of 20 ha of *Pelargonium*. Interestingly Schwabe is funding the wildlife trade monitoring group, TRAFFIC (a member of WWF and the IUCN) to manage a pilot project in Lesotho comprising of 1 ha of *Pelargonium sidoides*. This project has the blessing of the Lesotho government and will serve as a model for the further massive extension of *Pelargonium* cultivation in Lesotho. One of the main aims of TRAFFIC is to co-ordinate and implement a management plan for *Pelargonium sidoides* using the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP).³⁴ This work also includes the Schwabe funded *Pelargonium* projects

ii. CITES Appendix II species are not necessarily threatened with extinction, but may become so unless trade in specimens of such species is subject to strict regulation in order to avoid utilization incompatible with their survival. <http://www.cites.org/>

in the Eastern Cape. TRAFFIC will thus hold tremendous power to influence the future resource management policies concerning the two *Pelargonium* species and the rights of the affected communities in both Lesotho and South Africa.

It is our view that Schwabe is growing South Africa's endemic and indigenous biological wealth elsewhere in the world in a concerted attempt to avoid complying with South Africa's bioprospecting legislation (see discussion below) and beyond the scrutiny of South African activist groups. Significantly, these tactics defeat the purpose of the CBD, which is the promotion of the conservation of plants in their natural habitat.

In South Africa, Parceval has established, with funding from Schwabe, a Working Group, comprising of various players, including TRAFFIC and the Eastern Cape Development Corporation, the Council for Scientific and Industrial Research (CSIR), and so forth.³⁵ All these players have a stake in promoting the trade in the *Pelargonium* roots and represent a formidable lobby group in Schwabe's favour.

Schwabe violates the law

Violation of international law

It is common knowledge that the United Nation's Convention on Biological Diversity (CBD) is the international, legally binding treaty that regulates access to biological resources and associated traditional knowledge. The CBD obliges Germany, a Party to the treaty, as a user country of biological resources and traditional knowledge, to require that German companies access such resources and knowledge from a provider country on mutually agreed terms (MAT) and on the basis of explicit prior informed consent (PIC) from the provider country.³⁶

The CBD also creates legally binding obligations on Germany to ensure the sustainable use and conservation of the biological resources and the protection and preservation of the knowledge and practices of traditional people.³⁷ These obligations arose from the date when Germany ratified the CBD, namely, 21 December 1993.

The CBD was also ratified by South Africa, on 2 November 1995,³⁸ and in terms of the South African Constitution, South Africa was bound by the provisions of the CBD from the date of ratification.³⁹ This means that Schwabe in accessing the biological resources and associated traditional knowledge in South Africa, was under the legal obligation to comply with the PIC and MAT requirements of the CBD from 2 November 1995. As already noted earlier, we have found no evidence that Schwabe has done so.

Violation of South Africa's domestic laws

South Africa's National Environmental Management Biodiversity Act⁴⁰ (Biodiversity Act) expressly outlaws bioprospecting activities in the absence of PIC, and compliance with other relevant requirements such as a material transfer agreement (MTA) and a benefit sharing agreement (BSA).⁴¹ In essence, the Biodiversity Act confirms that all bioprospecting of the pelargoniums by Schwabe through its agent, Parceval, without the requisite PIC, MTA and BSA is illegal⁴² and has been so, due to the ratification of CBD on 2 November 1995. In any event, the ban on wild harvesting of pelargoniums imposed in June 2006 in the Eastern

Cape makes all such harvesting from June 2006 by Schwabe, through its agent Parceval, also illegal.⁴³

The South African government also promulgated secondary legislation (regulations) which came into effect on the 1 April 2008. These regulations set out the detailed procedural requirements for the bioprospecting permitting system.

The wide definitions contained in both the Biodiversity Act⁴⁴ read together with its Bioprospecting Regulations⁴⁵, make it clear that the entire body of South Africa's bioprospecting legislation regulates not only bioprospecting of genetic resources, but also biological resources. Thus, it is beyond question that Schwabe's bioprospecting activities with regard to the two species of *Pelargonium* and their associated traditional knowledge falls within the scope of such legislation. Interestingly, this broad approach to the implementation of the CBD provisions is supported by the majority of the Parties to the CBD, in the current international negotiations for a legally binding regime on Access and Benefit Sharing.

The regulations also set out specific permitting requirements with regard to bioprospecting that results in commercialisation of the resources and/or associated traditional knowledge.⁴⁶ In this regard, bioprospectors are required to disclose all pertinent information to all stakeholders, obtain the necessary PIC and Material Transfer Agreements from those giving access to the resources and traditional knowledge and enter into a benefit sharing agreement with such stakeholders.⁴⁷ Full disclosure of information is required pertaining to the resource, the quantity that is being collected, and any environmental impact arising from such collection.

In the context of a benefit sharing agreement, the regulations contemplate a range of monetary and non-monetary compensatory measures to be agreed upon between the parties, including, training, conservation, co-ownership of intellectual property rights, co-authorship, inclusion in research, milestone and/or upfront payment etc.

These regulations thus provide greater clarity and guidance to the obligations that always bound Schwabe, since 2 November 1995, when South Africa ratified the CBD. At least for the purposes of bioprospecting activities involving the *Pelargonium* that may take place after 1 April 2008, Schwabe and Parceval will have to search for all the relevant stakeholders, inform them of the bioprospecting activity and obtain their explicit prior informed consent to exploit such resources and associated traditional knowledge. They must also conduct the necessary environmental impact assessments before any permission for such bioprospecting can occur.

The *Pelargonium* patent challenges

Patent Challenge Number 1

Patent Number 1 was granted by the European Patent Office on 13 June 2007 and is titled "Method for Producing Extracts of *Pelargonium Sidoides* and/or *Pelargonium Reniforme*" (EP 1429795). It allows Schwabe Pharmaceuticals the right, for the next 20 years, to preclude all other persons from making, selling, or licensing the pelargoniums that have been extracted by water and alcohol in all European countries that are Parties to the European Patent Convention (EPC).

The African Centre for Biosafety and the Berne Declaration have on 10 March 2008, filed a challenge to this patent, supported by affidavits filed by a traditional healer from the Alice Community, Milile Rwexu, and a biologist from South Africa, Dr William Stafford.⁴⁸ In this objection, we have asked the EPO to fully revoke the patent.

Briefly, the grounds of our objection can be summarised as follows:

- a) We have argued that Articles 1, 8(j), 15, and 16 of CBD demand that when accessing biological resources and its associated traditional knowledge, prior informed consent be obtained from the traditional knowledge holders or provider countries. This means that Schwabe was in the first instance, required to reveal the purpose of accessing the resources, namely for commercialisation of a medicinal product as well as for patenting the invention based on traditional knowledge. Second, it was required to obtain permission for such commercialisation and utilisation of the resources. Third, it was required to share the commercial and other benefits with the providers of the resources and knowledge on mutually agreed terms. Since there is no evidence that Schwabe has done any of this, the patent contravenes Article 53 of European Patent Convention, which excludes patents that are *contra boni mores* or contrary to ethics and public morals or order.
- b) We have furthermore argued that if the effects of a patent amounts to the patenting of plant and plant varieties (which is prohibited in terms of Article 53 of the European Patent Convention), the patent claims which achieves this effect should not be allowed either. It stands to reason that if a letter bomb is clearly unacceptable, how could the process for making it be acceptable? In other words, if the patent of the main extraction method of the *Pelargonium* species amounts to the monopoly of the *Pelargonium* species, it should not be allowed, since it has the same effect as patenting of plant varieties themselves. The patent allows Schwabe to control the entire trade with the roots of the two *Pelargonium* species, as well as all extracts, tinctures, etc. because no one else would be allowed to make *Pelargonium* tinctures or extracts in the same way. Hence, the patent of the main extraction method of *Pelargonium* species is a clever way by Schwabe of circumventing Article 53 of the EPC, which expressly disallows patents on life (patents on plant varieties).
- c) we have also shown by way of supporting documentation, that there is little or no inventive step involved in the extraction process of pelargoniums, since it is a standard textbook procedure in herbal chemistry and biology. It is also not novel, in that it duplicates extraction methods used by the Alice and other communities since time immemorial.

It is significant to note that several other companies involved in the manufacturing extracts of various plants have also objected to this patent on similar grounds, including Frutarom (Switzerland), Alpinamed (Switzerland) and Finzelberg (Germany).

Patent Challenge Number 2

This patent claims exclusive use of *P. sidoides* and *P. reniforme* for treating AIDS and AIDS-related diseases. The AIDS related diseases include the use of the two *Pelargonium* species for a vast number of bacterial, viral, and parasitic infections and inflammations; including TB, all respiratory tract infections, sexually transmitted diseases, etc. This patent precludes

everyone in those European countries that are contracting parties to the EPC from using the two species of *Pelargonium* for AIDS and opportunistic diseases such as TB, bronchitis, and various other infections and inflammation. In this patent, we have asked the EPO to revoke the patent on the following grounds:

The use of pelargoniums for HIV and its related diseases is not novel, and the patent contains very few inventive steps of significant importance to warrant a new invention. We have shown that the Alice community has been using the *Pelargonium* species prior to the discovery of AIDS, for a wide variety of viral and bacterial infections and inflammation since time immemorial. This traditional knowledge and use belonging to the Alice community, and that is in the South African public domain, cannot be monopolised by a single company.

Conclusion

We are resolute in supporting the Alice community's demands that Schwabe do the right thing and withdraw both patents with immediate effect. Furthermore, Schwabe should desist from seeking further patents in respect of the two *Pelargonium* species and/or associated traditional knowledge.

Schwabe failed to comply with the prior informed consent and MAT requirements of the CBD, as it was required to do, from 2 November 1995 when South Africa ratified the CBD. This illegality must be remedied by Schwabe by it providing compensation to the Alice and other communities holding traditional knowledge in South Africa. Such compensation should include the profits derived by Schwabe through the sale of Umckaloabo.

Schwabe's over exploitation of the two *Pelargonium* species has driven the two species to becoming threatened and in need of special protection. Thus in addition to the monetary compensation to the affected communities, Schwabe should also rehabilitate the *Pelargonium* species to their once thriving status.

The Alice community calls upon the South African government to lend its support to community resource management initiatives in the cultivation and harvesting of the *Pelargonium* species to support local livelihoods. Such initiatives should ensure meaningful participation by holders of the traditional knowledge and appropriate local experts. Within this context, the production of Umckaloabo should be localised to South Africa and Lesotho. This would result in the remedy being produced and sold at a fraction of the price than is currently done by Schwabe. The South African and Lesotho product could then be made available to the international market, after satisfying local demands and priorities, taking into account the high TB and HIV incidence in Southern Africa.

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34. TRAFFIC East and Southern Africa vacancy announcement, 15 April 2008. <http://www.traffic.org/job-opportunities/>
35. Personal communication Uli Feiter, Parceval, 20 February 2008.
36. Article 15 of the Convention on Biological Diversity.
37. Article 8(j) of the Convention on Biological Diversity.
38. CBD. **South Africa – Overview.** <http://www.cbd.int/countries/?country=za> (accessed 18 March 2008).
39. Section 231 of the Constitution of the Republic of South Africa, 1996.
40. National Environmental Management Biodiversity Act 10 of 2004, Government Gazette no 28711 of 16 March 2007.
41. Sections 81, 82 and 101 of the Biodiversity Act.
42. Section 81 and section 82 of the National Environmental Management: Biodiversity Act 10 of 2004.
43. Fax communication with Ms Pam Yako, Director General, National Department of Environmental Affairs and Tourism, 6 June 2007.
44. Chapter 6 of Biodiversity Act
45. Regulation 2 of the Bioprospecting Regulation No 138 of Government Gazette 30739.
46. Regulations 2 - 5 of the Bioprospecting Regulation No 138 of Government Gazette 30739.
47. Regulation 8 (1) read together with Section 82 of the Biodiversity Act.
48. Opposition EP 1 429 795-Pelargonium Patent Holder Schwabe GmbH & Co KG, 76227 Karlsruhe Opposers: African Centre for Biosafety, Johannesburg (ZA) and Declaration of Bern, CH-8004 Zurich.