Frequently Asked Questions on the

PELARGONIUM PATENT CHALLENGES

WHAT ARE PELARGONIUMS?

Pelargoniums are part of the geranium plant family, Geraniaceae, a plant family of world wide distribution. They form one of the most interesting groups within the Geraniceae – they have their centre of diversity in the Cape region of South Africa and are renowned in horticulture and medicine and for their aromatic oil properties. The two species (types) of *Pelargonium* that form the subject matter of the patent challenge are *Pelargonium sidoides* and *Pelargonium reniforme*. These two species are indigenous to South Africa, with *Pelargonium reniforme* being endemic to the Eastern Cape province (that is, its natural distribution is confined to the Eastern Cape – not found naturally anywhere else in the world), whilst *Pelargonium sidoides* grows densely in the Eastern Cape province, but is also found in other provinces in South Africa and in Lesotho – it is endemic to South Africa and Lesotho.

WHO IS CHALLENGING THE PELARGONIUM PATENTS AND WHY?

The African Centre for Biosafety (ACB), acting upon the mandate of a local community in the Eastern Cape, South Africa, has recently challenged two patents granted by the European Patent Office (EPO) in respect of two species of *Pelargonium*. The patents were granted to a German phyto-pharmaceutical company specialising in natural medicines, called Dr Willmar Schwabe Pharmaceuticals (Schwabe). The patents are contested because they unlawfully allow Schwabe to appropriate as its sole property, the traditional knowledge of local peoples of South Africa regarding the medicinal use of the two *Pelargonium* species, *Pelargonium sidoides* and *Pelargonium reniforme*. This form of misappropriation is commonly referred to as biopiracy.

African Centre for Biosafety

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Which patents are being challenged?
The two patents being challenged at the EPO are firstly, the water and alcohol based extraction method for the two species of *Pelargonium* (EP 1 429 795 B1); and secondly, the use of Pelargoniums for the treatment of HIV and related diseases (EP 1 651 244 B1).

WHAT IS A PATENT?

A patent is a western concept and confers an exclusive monopoly right to an inventor to prevent all others from selling, producing, distributing or licensing a specific invention. This right lasts for usually 20 years, and is enforceable in the country or region where the patent was granted.

WHAT IS THE PURPOSE OF A PATENT?

The intention of a patent right is to reward the inventor for his/her time, effort and money spent on the invention by allowing him/her to exclusively profit from the invention or product, through giving him/her privileges to prevent any one else from commercially exploiting the same invention.

WHAT ARE THE REQUIREMENTS FOR A PATENT TO BE GRANTED?

In order for patents to be granted the invention must be:
- **New** – it cannot duplicate an already existing invention;
- include an **inventive step** in the sense that when the invention is compared with existing public information, it would be not obvious in the trade; and
- it also has to be an **useful** invention.

ARE PATENTS APPLICABLE GLOBALLY?

The three requirements of patentability constitute global uniform criteria introduced by one of the agreements of the World Trade Organisation (WTO) called the Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS was introduced to curb piracy of modern inventions, and effectively protect the markets of inventors. Almost all countries in the world are members of the WTO including South Africa. Members of the WTO are required to change their national laws to implement the provisions of the TRIPS agreement.

CAN LIFE BE PATENTED AND OWNED?

The TRIPS agreement allows not only for the patenting of technological inventions, but also for the patenting of certain life forms. TRIPS requires its members to make provision for the patenting of micro-organisms (e.g. fungi, viruses and planktons), and non-biological and micro-biological processes requiring human intervention in their making.

In the case of the Pelargoniums, although the plant itself cannot be patented, the use of the plant, its extracted compound through human means, as well as the process of extraction can be patented. Thus certain life forms and processes can be owned by individuals and corporations alike and this has become the trend especially in the pharmaceutical and genetic engineering sectors.

What are the problems associated with TRIPS?
TRIPS has brought about great inequity in the world. Whereas a large number of patents and other forms of intellectual property rights (IPRs) are granted over biological resources and

Traditional Knowledge (TK) to applicants in industrialised countries, developing countries are often the providers of biological resources and Traditional Knowledge and reap very little if any benefits. The holders and custodians of TK are the indigenous and local people from developing countries who have since the beginning of time, interacted with their natural surroundings and acquired a deep understanding of such resources and their uses. It is also these people who have played a vital role in the conservation of biological resources.

The Convention on Biological Diversity (CBD) is used as an intervention at the international level to address some of the inequities.

WHAT IS THE CONVENTION ON BIOLOGICAL DIVERSITY AND HOW DOES IT AFFECT ITS MEMBERS?

The CBD is an international agreement that was signed at the Rio Earth Summit in June 1992, and deals with the conservation and sustainable use of biodiversity as well as the equitable benefit sharing arising out of the exploitation of biological resources. The CBD has been ratified by a large number of countries including South Africa who ratified the CBD on 2 November 1995. From that date, the CBD provisions have became part of South African law. In order to strike a balance between protecting the interests of the providers and users of biological resources and TK alike, the CBD demands that countries that have ratified the CBD, comply with the following:

Prior to accessing biological resources and its associated TK, the user country must ensure that prior informed consent (PIC) from the holders of such resources and TK in the provider country is obtained. If access is given, then both the user and provider countries must ensure that such access is given on mutually agreed terms (MAT), and that an appropriate and adequate benefit sharing agreement must be entered into on MAT.

WHAT IS THE TRADITIONAL KNOWLEDGE ASSOCIATED WITH THE PELARGONIUMS?

P. sidoides and *P. reniforme* are well known amongst local communities of South Africa for their potent medicinal properties to treat various illnesses. In particular, the Pelargoniums have been used by local communities for respiratory tract infections, common coughs and colds, tuberculosis and stomach ailments, amongst many other illnesses. The formal written documentation of such use goes as far back as the 1800s. However, the knowledge of the use and the practical application of such knowledge has a long ancestral lineage, going back to time immemorial, among local communities of South Africa.

HOW WAS THE TRADITIONAL KNOWLEDGE OF PELARGONIUMS COMMERCIALISED AS UMCKALOABO?

The traditional knowledge (TK) of the pelargoniums was ‘discovered’ by an Englishman and taken by him from South Africa to the United Kingdom in the late 1800s. Subsequently in Europe and in the UK, it was formally documented and medically tested in the 1900s. Subsequent to the British Medical Association publishing its findings in 1909, Umckaloabo was re-tested in Europe, and the results were published in a series of papers between 1920 – 1937.

As a result, Schwabe Pharmaceuticals together with its partners Spitzner and ISO-Arzneimittel, began to produce a tincture called Umckaloabo from the roots of both *Pelargonium* species based on the TK. Schwabe and its partners have successfully marketed Umckaloabo in Europe and Umcka in the USA as a natural medicine to treat coughs, colds and respiratory tract infections, and as a result have made huge profits over the years.

HOW MANY PELARGONIUM PATENTS HAVE SCHWABE APPLIED FOR?

Schwabe have applied for four patents at the European Patent Office (EPO) in respect of the two *Pelargonium* species. Once a patent is granted by the EPO, the monopoly right is recognised and enforceable in the 34 countries in and around Western Europe (see box), which are signatories to the European Patent Convention (EPC). The EPC is a standardised patent application which speeds up patent applications in all of the member states of the EPC without the applicant having to apply in each member states separately. Three out of the four *Pelargonium* patents have EP numbers followed by B1 which means that the patent has been granted, whilst the last patent has an A1 which gives an indication that it is published, but is not yet granted.

The patents are enforceable in the following 34 countries: Austria; Belgium; Bulgaria; Switzerland; Cyprus; Czech Republic; Germany; Denmark; Estonia; Spain; Finland; France; United Kingdom; Greece; Croatia; Hungary; Ireland; Iceland; Italy; Lichtenstein; Lithuania; Luxembourg; Latvia; Monaco; Malta; Netherlands; Norway; Poland; Portugal; Romania; Sweden; Slovenia; Slovakia; Turkey.

Reference: EPO. **Member states of the European Patent Organisation**. http://www.epo.org/about-us/epo/member-states.html

PATENTS ON THE PELARGONIUM EXTRACTION METHOD (EP 1 429 795 B1)

WHAT IS THIS PATENT ABOUT?

Schwabe Pharmaceuticals was granted a patent right over the extraction method for the two *Pelargonium* species on 13 June 2007 by the EPO. The extraction method uses water and alcohol to remove the active ingredients from the *Pelargonium* plants.

WHO IS OBJECTING TO THIS PATENT?

The ACB has been supported by the Berne Declaration, a Swiss NGO, in objecting to this patent. There are three other objections to this patent, on similar grounds, by the companies Frutarom (Switzerland), Alpinamed (Switzerland, and Finzelberg (Germany).

WHAT ARE THE GROUNDS FOR OBJECTING TO THE PATENT ON EXTRACTION METHODS?

1 European Patent Law does not allow patents to be granted if it goes against public morals or order. Going against public morals and order includes non-compliance with the provisions of the CBD regarding the obtaining of prior informed consent (PIC) and benefit sharing (BS) based on mutually agreed terms (MAT), as explained above. Bearing in mind that South Africa ratified the CBD on 2 November 1995, Schwabe was obliged from the 2 November 1995, to obtain the PIC of the community to use their TK regarding the *Pelargonium* extraction method. To date, we have not found any evidence that Schwabe has asked for PIC and BS based on MAT from the TK holders as required by the CBD. Therefore, it is our contention that Schwabe violated public morals by blatantly ignoring international and national laws and therefore, the patent was granted erroneously by the EPO, in violation of European Patent Laws.

2 Although this patent does not explicitly claim a monopoly on the two *Pelargonium* species, the effect of enforcing this patent would have the same result as if the *Pelargonium* species themselves were patented. European patent laws do not allow the patenting of plant species or varieties.

The patent on the extraction method is the primary method of extracting the active ingredients from the plants to produce the blockbuster natural medicines – Umckaloabo and Umcka. Thus in the course of Schwabe obtaining the patent, it also obtained control over the entire market and trade of the Pelargoniums, since Schwabe will be the only one able to use the extraction method to produce the tinctures. The extraction method is also the main extraction method used by both traditional communities and scientific communities alike. The patenting of the extraction method allows Schwabe to effectively monopolise the use and trade of the two *Pelargonium* species.

However, since European Patent Law prohibits patents on plant varieties, it is our contention that this patent which mimics monopolisation of plant varieties (namely, the Pelargoniums) should also be prohibited. *If the letter-bomb is clearly unacceptable, how could a process for making it or even using it be acceptable?*

Thus this patent on the *Pelargonium* extraction method implicitly amounts to monopolising of the two *Pelargonium* species and thus also allows Schwabe to exercise control over the *Pelargonium* market and *Pelargonium* trade. This is clearly prohibited by the European Patent Law.

3 It is our contention that the patent on the extraction method does not disclose sufficient information for the reproduction and duplication by others, as is required by European patent law. The patent lacks vital information such as geographical origin of the plants, the specific temperature and duration of extraction and the specific reaction required between the Pelargoniums and the solvent, and is therefore in breach of the requirements of European Patent law.

4 We have claimed that the extraction method is non-novel since prior to the patent application, the same extraction method has been published through written form, through use and through oral disclosure, by both traditional communities as well as in the scientific world.

5 We contend that there is nothing about the extraction method that would lead persons skilled in the trade to conclude that inventive steps are involved. Almost all the steps can be found in standard text books on Chemistry and Physics.

PATENT ON THE USE OF PELARGONIUMS FOR THE TREATMENT OF HIV AND ITS ASSOCIATED DISEASES (EP 1 651 244 B1)

WHAT IS THIS PATENT ABOUT?

Schwabe Pharmaceuticals was granted a patent right over the use of the *Pelargonium* to treat HIV and its associated diseases on 29 August 2007 by the EPO.

WHO IS CHALLENGING THIS PATENT?

The ACB has been supported in challenging this patent by Funeka Nkqayi, a representative from the Alice community in the Eastern Cape, South Africa.

WHAT ARE THE GROUNDS OF OBJECTION?

1 As with the previous patent objection, this patent also violates public order or morality, since it violates the ethical and legal norms of the CBD. This is so as since to date, we have not found any evidence that Schwabe so far has complied with the requirements of PIC, MAT and BS of the CBD which South Africa and Germany have both ratified.

2 The patent for the treatment of HIV and HIV related diseases includes the treatment for numerous ailments such as TB, respiratory tract infections, sexually transmitted diseases, and all other related viral, bacterial and parasitic infections and inflammations. Since the traditional communities have been treating all of these secondary infections prior to the existence of HIV, it is only natural that they have continued to do so after the start of the HIV pandemic. There are numerous historical accounts and publications testifying to the use of the two *Pelargonium* species by traditional communities for secondary infections. Therefore, this patent contains no novelty that warrants the granting of this patent.

3 In looking at all prior publications of the use of the two *Pelargonium* species, and comparing it to the patent claims, there is nothing to suggest that a person skilled in the trade would have concluded that this patent includes an inventive step. We contend that the scientific community is not able to conclude that the patent is non-obvious.

4 There has been insufficient disclosure of the patent application to support its claims. The European patent law requires that the patent claim in its entirety should be disclosed, such that it is sufficient for person skilled in the trade to duplicate the claims, without the necessity for further undue experimentation. In this instance, the claims have been vague and too broad and there is lack of evidence regarding pre-clinical trials and testing.

Umckaloabo and Umcka are already marketed by Schwabe, and are medications to treat common coughs and colds. Not only does Umckaloabo have an alcohol and water base, but it is also sold and marketed for having immune boosting properties and being efficacious for infection and inflammation of the respiratory tract. The efficacy of Umckaloabo in the treatment of various ailments has been tested extensively at the German Medical Institute (Bundesinstitut für Arzneimittel und Medizinprodukte). We have asked for full disclosure of the Medical Institute's findings in order to determine whether it duplicates its claims, substantiates the patent claims, and if so, to what extent.

WHAT IS THE STATUS OF OTHER PELARGONIUM PATENT APPLICATIONS BY SCHWABE?

Patent on the use of Pelargoniums for the treatment of stomach and intestinal Infections (EP1878434 A1)

On 16 January 2008, Schwabe applied for another patent at the EPO titled "Use of extracts from *Pelargonium sidoides* and/or *Pelargonium reniforme* for manufacturing preparations and preparations containing these extracts" (EP1878434 A1). This patent is pending at the EPO. It claims a monopoly over the use of *Pelargonium* extracts in the treatment of various stomach and intestinal ailments, caused by beta-lactamase resistant bacterial or *Helicobacter pylori* infections and associated diseases. Such associated diseases include peptic ulcers, gastritis and duodenitis. However, there is already a vast number of publications that record the use of Pelargoniums by South African communities for the treatment of various viral, bacterial, parasitic infections, including various stomach and intestinal ailments.

Patent on the use of Pelargoniums for the treatment of behavioural changes associated with illnesses (EP 1 684 775 B1).

On 26 March 2008, EPO granted the patent application by Schwabe, which claims novel use for the Pelargoniums for treating behavioural changes as a result of long term illnesses.

It is highly likely that both the ACB and the Berne Declaration will challenge this patent.

This is the most aggressively sought after of all the patents. The patent has been granted by the German Patent Office and has been filed in 12 other countries including South Africa, Australia, Brazil, Canada, China, Korea, Japan, Mexico, New Zealand, Philippines, Russia, and the United States.

This patent claims novel use of the Pelargoniums for behavioural changes associated with illnesses, as well as the method of preparing the extracts by way of alcohol and water extraction. The patent claims monopoly over the use of Pelargoniums for symptoms associated with illnesses, stress, and trauma such as depression, listlessness, fatigue, sleep disorder, anxiety, weak concentration, indifferentism, chronic post viral fatigue symptoms, stress induced symptoms (post-viral / chronic fatigue symptoms).

If the patent is granted by the South African patent office, it would have grave implications for traditional healers, herbalists, and local communities. These people will not be able to make, use, sell the Pelargoniums for the same use as described in the patent. This becomes highly problematic not only for the healers, but for the public, since over 70% of South African relies on traditional medicines for their basic healthcare. This patent for the use of Pelargoniums for behavioural changes will be the most relevant for South Africans, since Schwabe has applied for this patent in South Africa.

WHAT HAPPENS WHEN PATENTS ARE FILED AT THE SOUTH AFRICAN PATENT OFFICE?

Patent applications are made to the Patent Office at the Companies and Intellectual Property Registration Office (CIPRO). The Patent office is also in charge of applications for the enforcement of international patents in South Africa. In terms of the current Patent Act 57 of 1978, the Registrar is obliged to accept and approve each and every patent application if these comply with the procedures of the Act. A patent application can only be refused if the patent is offensive, immoral or frivolous.

This permissive approach is exacerbated by the fact there is no requirement for examination officers to verify the existence of prior art, PIC or benefit sharing agreements. The onus to disclose all previous publication rests solely on the applicant who must also vouch for the novelty of the patent.

Once granted, a patent is effective from the date of publication or priority date (i.e. date of provisional patent application), and is published in a patent journal for public inspection. Since patent publications have to be accessed physically, or through a patent lawyer, there is no way for the public to have easy access to information about new patent applications. Objections by members of the public can only be done after publication and granting of a patent. Challenging a patent after it has already been granted is substantially more difficult, onerous and expensive than if citizens had a clear right to challenge patents from the outset: when patent applications are lodged and before any decision is taken. Thus, as a result of the ease with which patents are granted in South Africa, as well as the costly exercise involved in revoking a patent, indigenous communities have limited leeway to prevent a patent from infringing their rights.

WHAT IS THE EFFECT OF THE PATENT OBJECTION?

Although the patents have been challenged, until the EPO makes a finding on the validity of the patents, the status quo on the validity and enforceability of the disputed patent remains unchanged under the European Patent Law. This means that the exclusive monopoly rights granted to Schwabe remain intact and fully enforceable. The objection process which may involve an appeal could take anything from 3-10 years to reach its final conclusion.

Nevertheless, there has been considerable amount of international coverage of the patent challenges immediately prior to the ninth meeting of the Conference of the Parties (COP) to the CBD held in Bonn during May 2008. Concomitantly, public awareness has been considerably raised in Europe, especially in Germany, where Schwabe is based.

WHAT ARE THE DEMANDS OF THE SOUTH AFRICAN LOCAL COMMUNITY?

The Alice community in the Eastern Cape, South Africa are demanding that the two *Pelargonium* species and their associated TK be freed from the stranglehold of patent rights held by a single corporation. In this regard, they are demanding that Schwabe do the right thing and withdraw all the patents and desist from lodging more patents.

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