



The Pelargonium Patent Challenges

Very few patents have been filed on the medicinal use of pelargonium. However, four patents have been granted to German-based Schwabe Pharmaceuticals and three more have been filed by the same company based on two pelargonium species – *Pelargonium sidoides* and *Pelargonium reniforme* – making Schwabe the most important actor in this field. Schwabe specialises in phytomedicines and produces, inter alia, alcohol extracts from the roots of the pelargoniums in syrup form, under the brand name Umckaloabo. Umckaloabo is successfully sold in Europe as a natural medicine for the treatment of respiratory tract infections such as bronchitis and common coughs and colds.

The four pelargonium patents granted to Schwabe are being challenged upon the instruction of the Alice Community by the African Center for Biosafety (ACB) together with the Berne Declaration (for Patents A, C and D) and with Funeka Nkayi, a member of the Alice Community in South Africa (for Patents B and C). Legal support for all four challenges is provided by Prof. Fritz Dolder of Switzerland. All patents granted are seen as an illegitimate and illegal monopolisation of a genetic resource from Southern Africa and traditional knowledge of the communities in the Eastern Cape Province of South Africa.

Patent EP 1 429 795

A) METHOD FOR PRODUCING EXTRACTS OF PELARGONIUM SIDOIDES AND/OR PELARGONIUM RENIFORME

Publication date: 23.6.2004

Granted: 13.6.2007

Appeal filed: 10.3.2008

Public hearing: 25./26.1.2010

What is the main claim?

A procedure (percolation and mazeraton) for the production of an excerpt from pelargonium with an aqueous-ethanol solvent (10-92% ethanol).

The invention claimed is a very common extraction method in the phytomedicine sector. Water/ethanol is a main solvent for extraction of the active ingredients and other properties of interest. This broad patent gives Schwabe Pharmaceuticals, over the next 20 years, the exclusive right in the countries that are parties to the European Patent Convention (EPC) to make, sell, or import/export the active ingredients of the pelargonium root that have been extracted by water and alcohol .

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 member from the Alice

Community, Milile Rwexu, and a biologist from South Africa, Dr William Stafford. In this objection, the European Patent Office (EPO) is asked to fully revoke the patent.

The main grounds of the objection can be summarised as follows:

a) Pursuant to Articles 1, 8(j), 15 and 16 Convention on Biological Diversity (CBD) prior informed consent has to be obtained from the traditional knowledge holders and the provider countries prior to accessing genetic resources and its associated traditional knowledge. Additionally, Schwabe is required to share the commercial and other benefits with the providers of the resources and the traditional knowledge on mutually agreed terms.

Since there is no evidence that Schwabe has complied with any of these rules, the patent is in contradiction with Article 53 of the European Patent Convention, which bans patents that are *contra bonos mores* or contrary to public order.

b) As the patent allows Schwabe to control the entire trade with the main product (extracts, tinctures) of two pelargonium species (*P. sidoides* and *P. reniforme*), the patent has the same effect as a patent covering a plant variety.

Hence, the patent on the main method of producing extracts from two species of pelargonium is a clever way by Schwabe of circumventing Article 53 of the EPC, which explicitly bans patents on plant varieties.

c) The subject matter of the patent, consisting of a simple method to produce pelargonium root extracts, lacks novelty (Article 54 EPC) and inventive step (Article 56 EPC), since it can be qualified to simply repeat standard textbook processes in phytochemistry and phytomedicine. It also lacks novelty, since it duplicates extraction methods in current practice with the Alice and other communities since time immemorial.

Patent EP 1 651 244

B) USE OF EXTRACTS FROM ROOTS OF PELARGONIUM SIDOIDES AND/OR PELARGONIUM RENIFORME

Publication Date: 3.5.2006

Granted: 29.8.2007

Appeal filed: 19.5.2008

What is the main claim?

Use of extracts from roots of pelargonium for the manufacture of a medicament for the treatment of AIDS and associated infections.

This patent claims exclusive use of *P. sidoides* and *P. reniforme* for treating AIDS and AIDS-related diseases. The AIDS related diseases include a vast number of bacterial, viral, and parasitic infections and inflammations; including tuberculosis (TB), all respiratory tract infections, sexually transmitted diseases, etc. This patent precludes everyone in the European Union and contracting States 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.

The African Centre for Biosafety and Funeka Nkayi, a representative of the Alice Community in South Africa have filed a challenge to this patent in May 2008 supported by affidavits. In this objection the EPO is asked to fully revoke the patent.

The main grounds of the objection can be summarised as follows:

- a) The use of pelargoniums for treatment of HIV and associated diseases lacks novelty (Article 54 EPC), and the subject matter of all claims altogether lack an inventive step (Article 56 EPC). The fact that the traditional medical practitioners of Alice community have been using pelargonium since time immemorial to treat a wide spectrum of viral and bacterial infections and inflammation and, since its discovery in the 1980s, also for AIDS therapy constitutes highly relevant prior art. This traditional knowledge constitutes traditional intellectual property of the Alice Community, has been for time immemorial in the South African public domain, and therefore cannot be monopolised by an individual company.
- b) Pursuant to Articles 1, 8(j) of the CBD, prior informed consent has to be obtained from the traditional knowledge holders prior to accessing traditional knowledge. Consequently, Schwabe was required to share the commercial and other benefits with the holders of the knowledge on mutually agreed terms.
- c) Furthermore, the alleged AIDS therapy is disclosed in the specification of the patent in an extremely summary way and therefore does not comply with the rules requiring sufficient disclosure of the subject matter of the invention (Article 83 EPC).

Patent EP 1 684 775

C) USE OF EXTRACTS FROM THE PELARGONIUM SPECIES

Publication Date: 2.8.2006

Granted: 26.3.2008

Appeal filed: 22.12.2008

What is the main patent claim?

The main patent claim is the use of extracts from pelargonium species for the manufacture of a medicament for the prophylaxis or treatment of disease-related behavioural changes, the post-viral asthenia syndrome and/or stress-induced chronic pathological conditions. Patent claim number four includes a whole list of behavioural changes included in the patent: weakness, fatigue, anergy, social isolation, sleep disorders, anxiety etc..

The African Centre for Biosafety, Funeka Nkayi, a representative of the Alice Community in South Africa and the Berne Declaration have filed a challenge to this patent in December 2008 supported by affidavits. In this objection, the EPO is asked to fully revoke the patent.

The main grounds for the objection can be summarized as follows:

- a) The use of pelargonium for the treatment of behavior changes caused by illness lacks novelty (Article 54 EPC). The fact that the medical practitioners of Alice Community have been using pelargonium since time immemorial to treat behavior changes caused by illness has been substantiated by six witnesses testifying under oath. This prior art has long been an integral part of common medical knowledge in the relevant regions of Southern Africa. The most important claim of the Schwabe patent thus lacks novelty.
- b) The patent altogether lacks an inventive step (Article 56 EPC). To the average expert looking at the sources from South African folk medicine and other submitted documents it is immediately evident that pelargonium extracts were used to treat behavior changes caused by

illness quite independently of the treatment of respiratory (or other) medical conditions. The patent thus lacks an inventive step.

c) The patent is contrary to the public order (Article 53(a) EPC). According to Articles 1, 8(j), 15 and 16 CBD genetic resources and related traditional knowledge may not be seized without the prior informed consent of the owners of such traditional knowledge and the countries where such resources are found. Moreover, Schwabe is obligated to share all commercial and other benefits with the owners of resources and traditional knowledge pursuant to prior agreement.

Given the lack of evidence that Schwabe complied with even one of these requirements, the patent is in violation of Article 53 EPC prohibiting patents that are contrary to public order or morality.

d) The substance of the patent is not disclosed in a manner sufficiently clear and complete (Article 83 EPC). The patent specification contains no evidence that pelargonium extracts successfully treat, by means of prevention or therapy, all indications mentioned in the patent claim. For instance, the description lacks all evidence of a successful therapy for behavior changes associated with injuries, traumata, tumors, inflammatory response, or autoimmune diseases: These claims appear to be pure speculation intended to provide the patent owner with a safe area which, judging by the experiments disclosed, this alleged invention does not deserve. Also, the crude preliminary observations on a few mice in a light-dark-box do not qualify as sufficient and serious evidence for the clinical effectiveness of pelargonium extracts as a prophylactic and therapy for human behavior changes caused by illness.

Patent EP 1 763 520

D) USE OF TRISUBSTITUTED BENZOPYRANONES

Publication Date: 30.6.2005

Granted: 17.12.2008

Appeal filed: 11.09.2009

What is the main patent claim?

The invention relates to trisubstituted benzopyranones (extracted from pelargonium plants), and their physiological acceptable salts. The invention relates furthermore to plant extracts, drugs, dietary foods and pharmaceutical preparations containing these compounds. The compounds are used for the treatment or prophylaxis of disease states, accompanied by oxidative stress and/or inflammatory responses (e.g. Diabetes mellitus type I and/or II, neurological diseases as Alzheimer disease or Parkinson, tumor illnesses, rheumatoid arthritis, asthma, psoriasis, Neurodermitis, as well as infections by bacteria and viruses (e.g. Influenza, AIDS, viral hepatitis)).

The main grounds for the objection can be summarized as follows:

a) The patent is contrary to the public order (Article 53(a) EPC). South African communities' traditional knowledge about the medicinal use of pelargonium extracts gave the patent holder a considerable starting advantage for further research. Nevertheless, contrary to the CBD, the patent holder failed to ask the holders of the traditional knowledge for their prior informed consent and to share the benefits in a fair and equitable manner.

b) Use and product claims bring about an increasing monopolization of plants of the *genus pelargonium* and thus the monopolization of a limited number of plant species in contradiction to Article 53(b).

c) Based on published scientific data the patent lacks novelty (Article 54 EPC) and an inventive step (Article 56 EPC).

d) Successful prophylaxis and/or therapy for the long list of illnesses claimed in the patent would require an undue burden of experimentation. The doctrine of the contested patent therefore appears to be mostly speculative and fails to meet the requirements of Article 83.

More Pelargonium Patents

Schwabe has already submitted applications for more pelargonium patents in recent months:

- **Method for producing solutions of pelargonium extracts stable during storage** (EP 1 982 731, published 23.10.2008). The patent is still under examination.
- **Use of extracts from *Pelargonium sidoides* and/or *Pelargonium reniforme* for manufacturing preparations and preparations containing these extracts** (EP 1 878 434, 16.1.2008). The patent claims the use of an extract from *Pelargonium sidoides* and/or *Pelargonium reniforme* for producing a preparation for the treatment or prophylaxis of beta-lactamase-resistant bacterial- or *Helicobacter pylori* infections and their associated diseases (stomach ulcer). The patent is still under examination.
- **Dry extracts of *Pelargonium sidoides* and *Pelargonium reniforme*** (WO2008125239, 23.10.2008). The invention relates to production methods for obtaining dry extracts from Pelargonium with a better solubility. The patent has not entered the European phase now.

This shows how aggressively the Schwabe company is seeking to monopolize the market for pelargonium-based natural medicines by means of patents on procedures and applications, regardless of the fact that all uses of pelargonium are based on traditional knowledge and genetic resources from southern Africa. Meanwhile the legitimate heirs of this tradition get nothing. The profits are going to a company from the North.

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