CHAPTER 9

INTELLECTUAL PROPERTY PROTECTION FOR MEDICINAL AND AROMATIC PLANTS

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Abstract. The use of plants for medicinal and aromatic purposes is not new. However, the interest in the commercial exploitation and legal protection of those plants is quite recent. The current contribution reviews current models for the legal protection of medicinal and aromatic plants.
Keywords: patents; plant breeder's rights; wild plants; cultivated plants; isolated chemical substances; methods of isolation, cultivation or preparation

CONCEPTS

Medicinal and aromatic plants

Medicinal and aromatic plants (MAPs) are plants which are primarily used for medical or aromatic purposes in pharmacy and perfumery (European Community Biodiversity Clearing-House Mechanism 2005). Medicinal plants in particular are often the original material of herbal medicines. Herbal medicines are plant-derived materials or products with therapeutic or other human-health benefits which contain either raw or processed ingredients from one or more plants. Under this definition, there are three kinds of herbal medicines: raw plant materials, processed plant materials and medicinal herbal products. The definition does not apply where the active component has been identified, and either isolated or synthesized as a chemical component of a drug product (WHO 1998). The current paper will focus on the legal protection regimes for plants and the isolated active ingredients, as well as on the methods for developing certain plants and isolating chemical compounds.

MAPs can appear in different settings. They be found in nature (wild MAPs) or developed through plant breeding (cultivated MAPs). Conventional plant breeding is based on controlled pollination and selection. Conventional methods of plant

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breeding have been remarkably successful in generating improved varieties. Most of the improvement has been in yield and has occurred through the breeding of lines which are resistant to pests and diseases, which can tolerate stressful environments and which are larger or have heavier croppers, apart from improvements in the intrinsic quality of the crop, such as taste, protein content, etc.

Modern plant breeding applies molecular-biological techniques, including recombinant-DNA techniques, to introduce new hereditary characteristics into plants. Exogenous DNA is directly transferred into the plant cell by use of cloning vectors derived from bacterial plasmids (notably those derived from the Ti-plasmid of the plant pathogen *Agrobacterium tumefaciens*) or based on plant viruses. The long-range targets of biotechnology as applied to plant breeding are exactly the same as in conventional breeding, but the major advantage of recombinant methods as compared to conventional breeding is that in this way characteristics can be introduced more quickly and that totally new characteristics, which do not exist in any member of the same plant family, or even in any plant, can be inserted. The present contribution examines the legal protection regimes for both wild and cultivated MAPs.

The search for or development of MAPs may encompass two different components: a tangible element, the use of biological material, and an intangible component, the appropriation of traditional or indigenous knowledge. The present paper only examines protection regimes offering accommodation for the use of the tangible component, the plants themselves or the isolated chemical compounds, and will not explore the various delicate issues with regard to the related traditional knowledge.

Protection

The term protection is to be understood in the sense of intellectual property (IP) protection. In this sense, MAPs can be protected by way of patents or plant breeder's right. The term protection does not refer to the concept of protection in environmental law, or to the concept of preservation or conservation.

PLANT BREEDER'S RIGHTS PROTECTION

Cultivated, traditionally bred, MAPs

Cultivated, traditionally bred, MAPs can be protected by way of plant breeder's rights. Many countries offer special legal protection for the products of plant breeding on the basis of the International Convention for the Protection of New Varieties of Plants. This Convention was initially signed in 1961 by several countries and created a Union for the Protection of New Varieties of Plants, commonly known under its French abbreviation UPOV (Union pour la Protection des Obtentions Végétales). The initial 1961 Convention was markedly changed in 1991 (see www.upov.org).

Definition
A plant breeder's right is a legal title granting its holder the exclusive right, and to authorize others, (1) to produce reproductive material of his plant variety for the purpose of sale, and (2) to sell this material within a particular territory and for a given period (cf. article 5 1961 UPOV Convention; article 1 (v) and article 14 1991 UPOV Convention).

Types
For the time being, it is possible to obtain plant breeder's rights protection in Europe by separate application to each of the national Plant Variety Rights Offices within Europe. Almost every country in the world has its own plant variety system as well as a Plant Variety Office to grant certificates. However, the disadvantage of a national certificate is that it only offers protection in one country. Therefore, it is much more interesting to opt for a plant breeder's right that is valid throughout the European Community and which is governed by the Community Plant Variety Office at Angers (http://www.cpvo.eu.int). Most national plant breeder's acts are modelled along the UPOV Convention from 1961 or 1991. The Community plant breeder's system greatly mirrors the UPOV Convention from 1991 (European Commission 1994).

Subject matter
The UPOV Convention offers protection for plant varieties. The original 1961 UPOV Convention defined plant variety as "any cultivar, clone, line, stock or hybrid which was capable of cultivation and which satisfied the conditions of stability and homogeneity" (art. 2 (2) 1961 UPOV Convention), so attempting to define the term variety by listing a number of types of varieties, rather than giving a general description. A more general definition was introduced in the 1991 UPOV Convention, describing variety as "a plant grouping within a single botanical taxon of the lowest known rank which grouping can be defined by features characterizing a given genotype or combination of genotypes, and is distinguished from any other plant grouping by the expression of at least one of the said characteristics" (art. 2 (i) 1991 UPOV Convention).

It is important to notice that the UPOV Convention does not offer protection for breeding methods.

Conditions
For varieties to be protectable, they must be distinct, uniform, stable and (commercially) novel (art. 6 1961 UPOV Convention). These four classic criteria were all taken over in the 1991 UPOV Convention (art. 5 (1) 1991 UPOV Convention).

- The variety applied for must be clearly distinguishable by one or more important morphological, physiological or other characteristics, from any other variety whose existence is a matter of common knowledge at the time of application (art. 6 (1) (a) 1961 UPOV Convention; art. 7 1991 UPOV Convention).

Morphological characteristics include such aspects as leaf shape, flower colour, or general form. Physiological characteristics could include disease resistance, winter hardiness and the like.

- The variety must be sufficiently uniform or homogeneous with regard to the particular features of its sexual reproduction or vegetative propagation (art. 6 (1) (c) 1961 UPOV Convention; art. 8 1991 UPOV Convention). With asexually propagated species like the potato, or with species like the garden pea that are fully self-fertilized, uniformity poses no great problem. But with wholly or partly cross-pollinated species, plants of the variety will exhibit diversity in character. The requirement of sufficient uniformity limits the divergences.
- The variety must be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation, or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle (see art. 6 (1) (d) 1961 UPOV Convention; art. 9 1991 UPOV Convention). Stability can be particularly difficult to achieve with sexually reproduced varieties, where cross-pollination can lead to a shift in type with loss of the important characteristic(s). Nevertheless, the applicant's variety must remain sufficiently true to its description when multiplied through such numbers of generations as is necessary to produce the quantities of seed required by commerce. The minimum standard for stability will vary according to the species and the variety and must be observed under appropriate conditions.
- At the date on which the application is filed, the variety applied for must not have been offered for sale or marketed in the country of application (art. 6 (1) (b) 1961 UPOV Convention; art. 6 1991 UPOV Convention). The meaning of 'novelty' in this article is in fact 'commercial novelty': a variety lacks commercial novelty if it was commercialized by the breeder prior to the filing date.

Examination

The variety applied for is examined by growing reproductive material (e.g. seeds, cuttings) of the variety.

PATENT PROTECTION

Cultivated, genetically modified MAPs

MAPs achieved through modern plant breeding techniques can be protected with a patent.

Definition

A patent is a legal title granting its holder the exclusive right to exploit his invention within a particular territory and for a given period (usually 20 years). The essence of all patent systems is that the owner of the invention receives the exclusive right to

control commercial exploitation of the invention for a limited number of years, in return for disclosing details of the invention in a written published document.

Types

For the time being, it is possible to obtain patent protection in Europe by separate application to each of the national Patent Offices within Europe (the so-called National Route). Almost every country in the world has its own patent system as well as a Patent Office or equivalent bureaucracy to screen patent applications and to decide whether patents should be awarded. As was the case for plant breeder's rights, the disadvantage of a national patent is that it only offers protection in one country, and hence it is mostly a European patent that is opted for at the European Patent Office (EPO) (the so-called European Route). On the basis of a single application and examination procedure one can protect an invention in up to 31 European countries (see http://www.european-patent-office.org/epo/members.htm), all contracting states which have ratified the European Patent Convention (EPC) of 1973 (EPO 2005).

The term 'European patent', however, is misleading from two points of view. It is not a single patent that is valid for the whole of Europe: the application and granting procedures are uniform, after which the patent is broken up into a 'bundle' of national patents which are further subject to national legislation and, more particularly, to national regulations with regard to nullity and infringement. Nor is it a patent granted by the EC: European patents have nothing to do with the EC apart from the fact that all EC Member States have also signed the EPC. It is on the basis of the European Patent Convention that the European Patent Office was brought into being, for dealing with European patent applications. It might be repeated that the European Patent Office is not an EC institution either.

Subject matter

The EPC excludes from its field of application plant varieties or essentially biological processes for the production of plants or animals (Article 53.b EPC). This exclusion does not apply to microbiological processes or the products thereof (Article 53.b EPC), and not to plants provided that the technical feasibility of the invention is not confined to a particular plant variety (Rule 23c. b Implementing Regulations EPC). The main reason for the exclusion of plant varieties from patent protection under the EPC was that a plant-tailored protection system already existed, namely the UPOV system.

The differentiation between plant varieties and plants as deployed by the EPO and the EPC is based on the modern biological division of the animal and plant world into groups or taxa: division, subdivision, class, order, family, genus and species, whereby each 'higher' taxon subsumes all 'lower' taxa. The application of these groups to the plant kingdom results in its being classified in a hierarchy with five divisions which, in turn, are divided into subdivisions, classes and orders. Orders are, on the basis of flower structure, further subdivided into families. Families are, in turn, divided into genera and species. An actual example can

perhaps better clarify the contemporary division of the plant kingdom. Let us take the potato:

KINGDOM	Plantae
DIVISION	Tracheophyta
CLASS	Angiospermae
ORDER	Dicotyledonae
FAMILY	Solanaceae (Nightshades)
GENUS	*Solanum* (Nightshade)
SPECIES	*Solanum tuberosum* (potato)
VARIETY	Bintje, Charlotte, Lamia [a], Frieslander [b], Solanda [c], et al.

[a] Preserved by Binst Breeding, Grimbergen, Belgium.
[b] Preserved by Messrs. Cleeren, Alken, Belgium.
[c] Preserved by Aveve, Leuven, Belgium.

In terms of EPC law, no patent protection is possible for the Charlotte variety of potatoes, but it is possible to patent the (transgenic) potato (*Solanum tuberosum* L.). This way of viewing the matter is acceptable given the observation that, with the help of modern modification techniques, induced characteristics can be introduced not only to one particular plant variety, but also to a range of plants.

Apart from plants, the EPC also offers patent protection for chemical substances, which are isolated from MAPs and characterized. The method of isolation, cultivation or preparation of said chemical compounds, is patentable as well.

Summarizing, patent law offers patent protection for a wide range of products, encompassing MAPs and isolated chemical substances, as well as for processes, comprising methods for transformation of MAPs and methods for isolation of the chemical substance embedded in the MAPs.

Conditions

Patents for MAPs, chemical substances isolated from MAPs and/or methods of transformation and isolation can be granted when the plant and/or the related invention meets the patentability requirements of novelty, inventive step and industrial applicability (Article 52 (1) EPC).

- The invention shall be considered to be new if it does not form part of the state of the art. The definition of the state of the art in the EPC amounts to absolute novelty, i.e. the state of the art is held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing (Article 54 EPC).
- The invention shall be considered to be involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Article 56 EPC). The inventive step requirement is intended to prevent exclusive rights forming barriers to normal and routine development. The condition that the invention bear witness to inventiveness would not appear in

practice in the granting of patents for plants to pose any greater obstacle than in the case of other inventions.

- The invention shall be considered to be susceptible to industrial application if it can be made or used in any kind of industry, including agriculture (Article 57 EPC). The requirement that the invention has to be capable of industrial application is no greater hindrance in the case of plants than in the case of other inventions.

Examination

European patent applications may be filed either with the EPO itself (at its headquarters in Munich or at its branch in The Hague), or with national patent offices in the contracting states. The invention will be examined on the basis of a written description.

Wild MAPs

Patent law offers protection for inventions which demonstrate novelty, inventive step and industrial applicability (Article 52 EPC). Patent law does not offer protection for discoveries (Article 52 (2) EPC). Neither does patent law offer protection for products of nature. Wild plants as such are usually considered products of nature and therefore not patentable. However, chemical substances, such as prostratin or conocurvone, which are isolated from wild plants and characterized, are considered patentable subject matter if they meet the standards of novelty, inventive step and industrial applicability. The method of isolation, cultivation or preparation of said chemical compounds, is patentable, on the assumption that the method is novel, inventive and industrially applicable.

CONCLUDING REMARKS

Patent protection is available for genetically modified MAPs, plant cells and seeds assuming that the subject matter meets the standards of novelty, inventive step and industrial applicability. The modification method might be patentable as well. Patent protection is also available for chemical compounds, isolated from MAPs, assuming that the compound is novel, inventive and industrially applicable. The isolation method might be patentable as well. Wild plants as such are not patentable, because they are regarded as products of nature, missing ‘invention’ quality, but the embedded chemical compounds might be patentable, on the assumption that they are novel, inventive and industrially applicable.

No patent protection is available for traditionally bred medical and aromatic plant varieties. For those cultivated plant varieties, though, plant breeder’s rights protection is an option. However, under this legal scheme, no protection is offered for the method of making.

Some thoughtful observers point to a vacuum in current IP law in the field of MAPs. Imagine a case where the wild plant and the therapeutic properties are

known, an effective plant extract is designed, but no molecule has been identified. In the current IP framework, no protection is possible. Most likely, no further efforts will be carried out by big pharma to invest in the plant. Nevertheless, the therapeutic properties can be scientifically substantiated and the safety can be safeguarded through registration procedures. Notwithstanding these facts, big pharma might not wish to take an effort in conducting such research and registration, since there is no exclusiveness at the end of the line to guarantee return on investment. It has been suggested that IP law should take care of this type of effort and provide protection for plant extracts which can scientifically be documented and are safe.

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