



Therapeutic vs Non-Therapeutic use at the EPO

What to consider when drafting patent applications to maximise the potential for use claims

Use claims can be incredibly valuable – they provide an additional layer of protection for novel products and can offer protection when a new use of a known product has been identified. Both therapeutic uses (also referred to as medical uses) and non-therapeutic uses are patentable at the EPO and it is possible to pursue protection for both types of use in a single application. However, it is not possible to have a single use claim that encompasses both a therapeutic and a non-therapeutic use. On the contrary, a separate claim is required for each type of use. This can cause problems when trying to protect the use of a product that has both therapeutic and non-therapeutic aspects. However, as we explain below, there are some steps that can be taken at the drafting stage to minimise and hopefully avoid such problems.

Background

The required separation of therapeutic and non-therapeutic uses derives from Article 53(c) EPC, which excludes methods for treatment of the human or animal body *by therapy* from being patented. However, Article 53(c) EPC does not exclude: (1) non-therapeutic methods (i.e. methods for treatment that are not by therapy); or (2) substances or compositions for use in therapeutic methods. Consequently, non-therapeutic use claims, such as cosmetic use claims, are allowable at the EPO as well as so-called medical use claims.

Medical use claims differ from non-therapeutic use claims in that they are purpose-limited product claims. Medical use claims typically take the format of “*X for use in therapy*” or “*X for use in treating disease Y*”. The term “for use” is mandatory as without it the claim is not limited by the intended use and is construed as a product claim, which is problematic if the product is already known. In addition, medical use claims are only permitted for uses that are purely therapeutic. For instance, a claim directed to “*substance X for use as an antifungal agent*” is not considered as a medical use claim as antifungal agents can be used for treating plants as well as treating fungal infections in humans and animals, i.e. they are not purely therapeutic.

Similarly, non-therapeutic use claims cannot encompass any therapeutic aspect as this would result in the claim encompassing a therapeutic use which is not patentable under Article 53(c) EPC. The format of non-therapeutic claims is less restrictive than medical use claims. For example, non-therapeutic use claims can simply take the format of “*use of X as an anti-wrinkle cream*”. Alternatively, they may take the format of “*cosmetic use of X for purpose Y*” or “*non-therapeutic use of X for purpose Y*”. In some instances, including the term “cosmetic” or “non-therapeutic” at the beginning of the claim may help to establish that the claim does not encompass a therapeutic use, however, this is usually case dependant.



In view of the above, therapeutic uses and non-therapeutic uses must be distinguished from each other in order to be patentable at the EPO.

When are therapeutic and non-therapeutic uses distinguishable?

Whether or not a therapeutic use and non-therapeutic use are distinguishable is often decided on a case-by-case basis and it frequently comes down to what is described in the patent application.

For instance, in T 290/86, a claim directed to the use of a composition for cleaning plaque was determined to encompass both therapeutic aspects and non-therapeutic aspects that were inextricably linked because the patent disclosed that plaque is generally regarded as the dominant etiological factor in periodontal disease and removal of plaque from teeth, or prevention of its accumulation, is known to have a beneficial effect in those conditions. Consequently, the Board held that the claimed use of cleaning plaque will always *inevitably* have a therapeutic effect (at least in the prophylactic sense) as well as a cosmetic effect and that the two effects could not be separated. Therefore, the non-therapeutic use claim was not allowed.

In contrast, in T 144/83, a claim directed to a method of improving bodily appearance comprising administering naltrexone in a dosage effective to reduce appetite and repeating said dosage until a cosmetically beneficial loss of body weight has occurred was determined to encompass a cosmetic use only. In this instance, the Board stated that although in some cases it may be difficult to distinguish between the cosmetic and therapeutic effect (i.e. losing weight and curing obesity), this should not disadvantage an Applicant who, according to the wording of the claims, seeks patent protection for cosmetic treatment but not for the therapeutic treatment as such. Therefore, this cosmetic use claim was allowed.

It is possible to have both a cosmetic use and a therapeutic use claim in a single application. For example, in T 36/83, a claim directed to the use of thenoyl peroxide as a cosmetic product and a claim directed to thenoyl peroxide for use in treating acne were both allowed despite the uses potentially overlapping. In this case, the Board found that the two uses were adequately presented in the description as two separate methods, especially in view of the examples provided, which demonstrated that a purely cosmetic effect could be achieved. Specifically, the examples showed that thenoyl peroxide was capable of cleansing skin that was not affected by acne.

These decisions (along with others) provide some guidance as to when the Boards of Appeal consider therapeutic and non-therapeutic uses to be distinguishable. In particular, if you can differentiate the use based on the patient or consumer using the product then they can be considered separable. On the other hand, if the same patient or consumer uses the product regardless of the intended use it's very unlikely they can be separated and they are more likely to be considered to be inextricably linked. For example, the same person will use a toothpaste regardless of whether it is to remove plaque or prevent gum disease (T 290/86).

In cases where the uses are considered to be inextricably linked, you may be able to claim the therapeutic use using a medical use claim. However, based on current EPO practice, you will need to specify the disease being treated in the application and the product would have to be considered a substance or composition.

Practical considerations when drafting

Ultimately, whether a therapeutic use and a non-therapeutic use are considered distinguishable or not will depend on the information provided in the patent application.



Therefore, it is important to consider the intended use(s) of any product thoroughly when drafting a new patent application. As a minimum, if there is likely to be more than one use then describe these separately in the application. Avoid including a single list of multiple uses especially where there is overlap between cosmetic uses and therapeutic uses. If there is a possibility of the use being considered therapeutic and non-therapeutic then consider defining the patient group or consumer for each. If possible, you may also want to include different examples for each use.

However, if you only want to protect a non-therapeutic use then avoid including statements in the description that the use is therapeutic, for example describing long term advantages such as prevention of disease later in life.

In contrast, if there are therapeutic aspects to the use that you would like to protect then consider how these could be claimed as medical use claims. This will likely require a clear definition of the diseases that can be treated in the application and data that can be used to demonstrate that the intended therapeutic effect has been achieved.

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