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MORE BANG FOR YOUR BUCK: SECOND MEDICAL USE AND THE EPC 2000

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Second and further medical use claims provide companies and patent lawyers with interesting opportunities, as Caroline Pallard explains.

Under Article 54(5) of the European Patent Convention (EPC) 2000, known substances or compositions are deemed novel provided they are for any specific use in a medical method provided that such use is not comprised in the state of the art (ie, second or further medical use) (this is derived from Article 54[4] EPC 1973).

In 1983, the Enlarged Board of Appeal (G5/83) defined the way to formulate a second or further medical use of a substance or composition for the manufacture of a medicament for any "specified new and inventive therapeutic application", based on Article 54 EPC 1973. Since then, case law decisions have primarily dealt with new diseases or conditions defining such second or further medical use.

In 2010, the Enlarged Board of Appeal (G02/08), redefined the way to formulate a second or further medical use of a substance or composition from Article 54(5) EPC 2000 and emphasised that "any specific use in a therapeutic method" as stated in Article 54(5) EPC 2000 could potentially be considered as a second or further medical use of a substance or composition, provided that such use was not comprised in the state of the art, thereby opening up the possibility to protect "any such specific use in a therapeutic method" as long as it meets all other EPC requirements.

NOVELTY BASED ON PATIENT GROUPS

In 1987, the Board of Appeal held that a distinct group of patients could provide evidence for a second or further medical use provided the group is not arbitrarily chosen: the new group of patients must be distinguished from the former by its physiological or pathological status. An example of this situation was illustrated in T19/86, which held that the therapeutic application of a vaccine against Aujeszky's disease, known for treatment of a particular class of animal (seronegative pigs), to a new and different class of the same animal (seropositive pigs), is a further medical use.

Later, in T108/09, the use of fulvestrant as a third line of treatment for breast cancer patients who had first been treated with tamoxifen and subsequently with an aromatase inhibitor, was considered as a further medical use of fulvestrant. Fulvestrant was already known to be used for treating breast cancer patients. The board held that the tumours of patients first treated with tamoxifen and subsequently with an aromatase inhibitor acquired resistance to first tamoxifen and subsequently to the aromatase inhibitor and that as a result had changed from a biological point of view, defining a new subgroup of disease which could also be seen as a new subgroup of patients.

NOVELTY BASED ON ADMINISTRATION

In 2004 the board, in T1020/03, anticipated G02/08 and held that a distinct administration regimen of a known substance or composition for the treatment of the same disease for the same group of patients could be considered a second or further medical use. In T1020/03, insulin-like growth factor was used for treating chronic renal failure in mammals. A second or further medical use was solely constituted by the specific discontinuous administration pattern of insulin-like growth factor.

A new mode of administration of a known substance for treating a known disease could also considered as a second or further medical use as illustrated in T 51/93, wherein subcutaneous administration of human chorionic gonadotropin (HCG) was the only distinguishing feature compared to the use of HCG administered intramuscularly as known in the prior art.

NOVELTY BASED ON A DIFFERENT TECHNICAL EFFECT

In T290/86 applying G05/83, it was held that a therapeutic use of a known therapeutic compound (the element lanthanum) for a similar therapeutic purpose (preventing tooth decay) was found novel if a new (and inventive) technical effect is taught in the patent. In T290/86, the prior art disclosed as technical effect of lanthanum the reduction of solubility of tooth enamel such as those developed in saliva and in the patent the technical effect was the removal of dental plaque.

In order to be novel, the effect must lead to a new use and not only constitute a mere explanation of the known use. In T254/93, the known composition was retinoic acid combined with corticosteroids used against dermatosis. The alleged new use of this composition was to prevent skin atrophy. The board held that the final effect obtained in this use was known in the prior art when using the known composition for treating dermatosis. The mere explanation of this final effect (preventing skin atrophy) when using a compound (retinoic acid) in a known composition (retinoic acid and corticosteroid) can not confer novelty to a use if the skilled person was already aware of the occurrence of the desired effect.

Such effect may be somehow 'linked' to the effect known in the art. In T1955/09, a substance (peptide) was used for killing bacteria. The prior art used the same substance for neutralising the toxins secreted by the same bacteria. The prior art did not disclose that said substance was able to kill said bacteria. The board held that such antibiotic effect could not be seen as a mere explanation of the final effect as found in T254/93, and held that the prior art teaches a direct effect of the substance on the toxins produced, whereas the patent teaches an indirect effect of the substance on the production of the toxins via their antibiotic action.

The foregoing illustrates that "any specific use in a medical method" as defined in Article 54(5) EPC 2000 seems to offer broad possibilities for defining a further medical use of a known substance. However, it should be borne in mind that such new further medical use must also be considered inventive in view of the prior art in order to constitute a patentable invention.

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ABOUT THE AUTHOR

Caroline Pallard is a European and Dutch patent attorney and a partner at NLO (Nederlandsch Octrooibureau). She joined NLO in 2006 after working at DSM/Gist-brocades in Delft and as a postdoctoral fellow at the Dutch Cancer Institute, where she specialised in immunology and biochemistry. She practises in biotechnology and in particular molecular biology, genomics, biochemistry, haematology and microbiology. Pallard has extensive experience of drafting and prosecuting complex patent applications and supporting licence negotiations and IP due diligences, and she frequently advises biotech start-ups on their IP strategies. Caroline can be contacted at

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