Second and third lives for known cancer drugs

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While development of new cancer treatments is ongoing, innovators are also trying to further optimize the use of known cancer drugs. For instance, treating a sub-population of patients with a known drug, even as a third line of treatment, could provide a new and inventive use of a drug. An important aspect to consider is if such uses of known anti-cancer medicines could be protected by a European patent and, if so, how that would be accomplished.

Due to acquired resistance to cancer treatments, it is common for patients to move from a first drug, such as tamoxifen, to a second drug, such as an aromatase inhibitor, as soon as resistance to the first drug occurs. Some even move on to a third drug, such as fulvestrant, when resistance to the second drug occurs. Use of fulvestrant as a third line of treatment is considered a novel cancer therapy even though the drug is already used as a first and second line of cancer treatment.

In general, the European patent system allows for the use of a known substance for further therapy of a disease it already treats. However, protection of this use is only possible if the further therapy has not yet been published and it provides new surprising advantages to the patient.

(Not so) novel?

The idea behind the novelty of fulvestrant as a third line of treatment is that the tumor cells of the patient change during treatment. These cells are not identical to the tumor cells of a patient treated with fulvestrant as a first or second line of treatment because they have become more difficult to treat. Therefore, a new subgroup of cancer patients may be identifiable via reference to the drugs used in their first and second lines of treatment.

In this case, the use of fulvestrant as a third line of cancer treatment is also considered inventive in view of its second line use. As tumor cells treated with two distinct cancer drugs become more malignant, it is uncertain as to whether a drug will be effective in a third line of treatment. A second argument for this case stems from the drug's characteristics: fulvestrant is an estrogen, just like tamoxifen. A skilled person would not have been motivated to use a drug of the same class for further therapy as the one used before, hence a surprising benefit.

Prove your point

Providing experimental data that confirms that tumor cells change between lines of treatment can be a powerful tool: different markers could be expressed, different behaviors could be exhibited in response to external stimuli, etc. If such additional evidence is provided in the patent application or possibly as post-published evidence, you have strong arguments for acquiring the protection of a new use of a cancer drug as a third line of cancer treatment.

As part of the rise of personalized medicines, potential new opportunities exist for obtaining patent protection in Europe for further medical uses of a known drug. These can only be seized successfully if such uses are fully integrated upfront in the company's patent drafting and R&D strategies.

This analysis is based on a the case law decision of the Board Appeal of the European Patent Office (T108/09).