DOSAGE OR ADMINISTRATION REGIMENS ARE PATENTABLE IN JAPAN, BUT INVENTIVE STEP MAY BE TRICKY!

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Paris, December 23, 2021 - Inventions relating to a new dosage or administration regimen of a compound with a known therapeutic use are not excluded from patentability in Japan. However, it may be difficult to defend their inventive step.

At first glance, the inventive step requirement does not seem to differ from that conventionally applied to other types of inventions in Japan, namely: it is necessary to demonstrate that the invention has an advantageous effect and that this effect is not predictable in view of the prior art.

However, in the case of inventions relating to a new dosage or administration regimen, this demonstration appears to be more complex as not only are both the compound and its particular therapeutic use already known, but modifying the dosage or the administration regimen also seems to be generally assimilated to a simple optimization, considered as a routine procedure for a person skilled in the art.

In particular, the Examination Guidelines of the Japanese Patent Office (JPO) present an example of an invention which, while achieving a slightly superior therapeutic effect, is considered to relate to a simple, routine optimization of a known dosage.

In this example, the invention relates to the administration of a compound at a dosage of 400-450 µg/kg once per day. The prior art taught the administration of the same compound for the same treatment at a dose of 160 µg/kg three times per day. The mere achievement of a slight improvement in the therapeutic effect through the use of a

single daily dose, close to three times the dose previously administered three times per day, is considered to be predictable and therefore insufficient to confer inventive step.

There are, however, cases where the inventive step of an invention relating to a new dosage or administration regimen can be recognized, essentially when the invention deviates, and preferably teaches away, from what was predictable to a skilled person when starting from the prior art. The JPO's Examination Guidelines give two examples of such inventions.

In one of these examples, the invention relates to a compound for the treatment of asthma, which is administered at a dose of 30 to 40 µg/kg once every three months.

The prior art cited against the inventive step disclosed the use of the same compound for the treatment of the same disease, but at a dosage of 1 µg/kg daily. It was further known that the administration regimen of the prior art (low daily dose) led to side effects and a recurrence of symptoms upon cessation of treatment.

The description of the invention mentions, and further experimentally demonstrates, that, contrary to what would have been expected given the side effects associated with a low daily dose and the loss of efficacy when stopping the daily treatment, the invention (administration of the compound at a 30 to 40-fold higher dosage once every three months) leads to improved efficacy over time, including upon cessation of treatment, and to reduced side effects when compared to the administration of a low daily dose. The unpredictable nature of these advantages allows inventive step to be acknowledged.

The second example of an invention that is acknowledged as being inventive relates to the administration of a compound for the treatment of ovarian cancer to a specific site in the brain. Said compound was already known for this use, but its administration had hitherto been carried out intravenously.

The application mentions, and further demonstrates by way of experimental examples, that the advantage of the new route of administration, to a site distal to the targeted cancer, resides in the fact that a significant increase in treatment efficacy occurs,

coupled with the suppression of the hepatotoxicity observed with intravenous administration. Here again, it is the unpredictability of the obtained advantages that justifies the presence of an inventive step.

The above-mentioned examples suggest that inventions relating to a new dosage or administration regimen can be successfully protected in Japan, provided that one can justify their inventive step, which remains the sensitive issue For this purpose, the new dosage or administration regimen should lead to at least one advantage (increased therapeutic efficacy or decreased toxicity, for example) which is significant and which was not foreseeable in light of the prior art (ideally, the advantage is obtained despite a prejudice in the prior art). Achieving a double effect (e.g., increasing efficacy while also decreasing a side effect associated with a known treatment) is generally favorable, as it is often less predictable in view of the prior art.

Our teams are at your disposal to assess, on a case-by-case basis, the best strategy for defending the inventive step of your invention relating to a new dosage and/or administration regimen, particularly in Japan.
Coming soon on the same subject: the situation in China.

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