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PATENTABILITY OF DOSAGE REGIMENS:
TOWARDS AN EASING OF REQUIREMENTS IN CANADA

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Paris, October 28, 2021 - In *contrast to that of the United States, Canadian patent law excludes therapeutic methods from patentability on the grounds that physicians should not be hampered in their practice of medicine. However, as in many countries that also have this exclusion, it is possible to protect the use of a compound or a composition for therapeutic purposes in Canada, provided that an appropriate claim format is used.*

When the first patent applications claiming a new dosage regimen were filed, the question arose as to whether or not such subject-matter could be considered patentable without rendering the patentability exclusion of therapeutic methods meaningless.

In Canada, following several decisions of the Federal Court, a Patent Notice was published by the Canadian Intellectual Property Office (CIPO) in 2015 specifying that a claim relating to a dosage regimen should not be automatically considered as relating to a therapeutic method excluded from patentability. In such a case, the Examiner should determine if the implementation of the invention requires the intervention of a physician and is therefore likely to limit the practice of his/her professional expertise.

According to a Practice Notice of the CIPO, adjustments within a dose range are considered to fall within a physician's expertise when not all doses in the range will work for all subjects in the treatment group. In contrast, features which restrict treatment to a fixed dosage, to a particular patient subpopulation, or to a particular administration site, are not considered to be limiting to a physician's practice. A claim comprising these features would therefore be patentable in Canada.

Two decisions issued by the Patent Appeal Board (PAB) this year have further allowed claims with the following features:

- "*for at least 1 week in a daily dose of 10 µg to 80 µg per square meter patient body surface area and wherein the daily dose is for administration over at least 6h" (Re Amgen Research (Munich) GmbH (2021 CACP 2)*, and
- *"use in dosage form corresponding to initial dose of 8 mg / kg and a plurality of subsequent doses in an amount that is 6 mg / kg, wherein the doses are separated in time for each other by three weeks" (Re Genentech, Inc. (2021 CACP 8).*

This suggests that:

- the definition of doses according to a patient parameter (weight/body surface area) should be accepted because a simple conversion does not require medical skills, and
- dose ranges may be acceptable in certain cases, when each dose of the claimed range is appropriate for all patients (as argued by the applicant in *Re Amgen Research (Munich) GmbH (2021 CACP 2)*.

In both of these decisions, the granted claims also included a minimum number of administrations or a minimum duration of treatment, but no maximum number of administrations or maximum duration of treatment, suggesting that a claim may be acceptable without defining a precise value for the duration of treatment or the number of administrations.

These decisions will most certainly encourage applicants to attempt to protect their dosage regimen-related inventions in Canada in cases where they can demonstrate that the implementation of such inventions does not require medical follow-up and/or expertise.

Our teams are at your disposal to provide you with further information on this subject and with the most appropriate advice regarding the best strategy to protect your inventions relating to dosage regimens, especially in Canada.

Coming soon on the same subject: the situation in Japan.

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