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Patentability of Dosage Regimes in Canada: Lessons Learned From the Patent Appeal Board

By Pia-Lauren Reece, PhD

In Canada, methods of medical treatment and surgery are not patentable subject-matter. Medical "use" claims (e.g. use of X to treat Y), however, are directed to patentable subject-matter. The Supreme Court of Canada has cautioned that problems may arise if medical use claims attempt to "fence in" an area of medical treatment by indicating "how and when" (e.g., by indicating a dosage range or treatment regime) a pharmaceutical composition is to be used. These cautionary statements were received by the lower courts. For example, in *AbbVie Biotechnology Ltd. v. Canada (Attorney General)*, 2014 FC 1251 (*AbbVie*), it was determined that "fixed" dosages, that do not require any application of professional judgment, are directed to patentable subject-matter in Canada.

In response to the above, the Patent Office issued PN2015-01, which stated that in respect of dosage regimes and the requirement of professional skills:

Where an **essential element only serves to instruct a medical professional "how" to treat a patient** rather than "what" to use to treat the patient, **it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", the claimed use will be considered to encompass a method of medical treatment** that does not comply with section 2 of the *Patent Act*.

Essential elements that point to a limitation of a physician's professional skill or judgment **include those that provide details of a dosing schedule encompassing a range and those that represent a range of potential dosages** that a patient may receive (as distinct from a range of dosage forms). In contrast, **essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen**, a patient sub-population or to a particular administration site are **not considered to point to a limitation of a physician's professional skill or judgment**. (emphasis added)

This Practice Notice, in addition to the *AbbVie* decision, prompted Applicants to ensure that medical use claims were directed to fixed doses (see, e.g. Canadian Patent No. 2504868, CD 1409) and in some cases, additionally to patient sub-populations (see, e.g. Canadian Patent No. 2588966, CD 1495), to ensure that claims were deemed allowable when the claims were before the Patent Appeal Board in Canada.

Following *Yves Choueifaty v. Attorney General of Canada*, 2020 FC 837 (*Choueifaty*), the Patent Office issued PN2020-04, which further defined the scope of professional skill and judgment as it relates to dosages or dosing regimens:

[I]n cases where at least one of the essential elements of the actual invention limits the claimed use to a dosage...and/or a dosage regimen, **regardless of whether these are fixed and/or cover a range**, this fact alone is **not determinative of whether the claim is patentable subject-matter**. It is **also necessary to consider whether the exercise of professional skill and judgment of a medical professional is part of the actual invention**. For example, professional skill and judgment may be involved **if a medical professional is expected to monitor or make adjustments to the treatment, or make a selection of a dosage from a claimed range (i.e., in cases where not all dosages in the range will work for all subjects within the treatment group)**. In such cases, the subject-matter defined by the claim would encompass a method of medical treatment and would not be patentable subject-matter. (emphasis added)

This is very much in line with *AbbVie*, where it was similarly explained that even if claims involve a fixed dosage and schedule, if "there is evidence to contradict that claimed dosage," such as where adjustments

are needed that require a physician to exercise their skill and judgment, then the claims are not directed to patentable subject-matter (see, paragraph 114 of *AbbVie*).

In other words, when assessing the patentability of medical use claims, a fixed dosage and schedule is "a good signal or starting point," but whether or not the medical use claims are directed to patentable subject-matter requires that the specification does not provide evidence indicating that the dosage regime and schedule are not exactly as claimed (i.e. "contradictory evidence" to the claimed dosage). In these cases, professional skill and judgment are required, and the claims are considered to be directed to non-patentable subject-matter.

Since *Choueifaty* and PN2020-04, four cases have been before the Patent Appeal Board in Canada to date. While they all involve fixed dosage regimes, the Patent Appeal Board further determined whether professional skill and judgment were required through the determination of any contradictory evidence to the claimed dosage.

Each of the four cases were found to be allowable, shedding a positive light on the patentability of dosage regimes in Canada. Of note, the Board agreed that professional skill or judgment is not required when:

- decisions to start and stop treatment are not considered to be within the scope of the claims (see, Genentech, Inc. (Re) 2021 CACP 8);
- determination of a dose amount for a particular patient is a matter of (simple) arithmetic for an ordinary worker using calculations that are standard in the field (see, Nektar Therapeutics (Re) 2021 CACP 13 and Alexion Pharmaceuticals, Inc. (Re) 2021 CACP 41);
- determination of a dose amount requires merely converting to a specific dose based on a patient's body surface area (see, Amgen Research (Munich) GmbH (Re) 2021 CACP 2);
- the dose is fixed at an amount in mg/kg, even if the patient's weight changes, requiring re-calculation (see, Alexion Pharmaceuticals, Inc. (Re) 2021 CACP 41);
- evidence indicates that any dosage falling within the claimed range would be appropriate for all those to whom it is administered; and, based on the examples, the selection from within the range does not appear to depend on any patient-specific factors (see, Amgen Research (Munich) GmbH (Re) 2021 CACP 2);
- there is nothing contrary in the specification that teaches that a physician would need to make any adjustments to the dose amount, any adjustments to the dosing frequency or to select a different dose for treatment (see, Nektar Therapeutics (Re) 2021 CACP 13; Alexion Pharmaceuticals, Inc. (Re) 2021 CACP 41, and Genentech, Inc. (Re) 2021 CACP 8); and/or
- there is no evidence that monitoring of the patient is required (see, Genentech, Inc. (Re) 2021 CACP 8 and Nektar Therapeutics (Re) 2021 CACP 13).

Thus, while patenting dosage regimes in Canada is possible, especially when the medical use is directed to fixed doses and schedules, these Patent Appeal cases remind us that when drafting the specification in support of the claims, it is important to avoid including any evidence that may contradict the claimed dosage (e.g. requirement for monitoring patient responses, requirement for changes to the dose amount and/or frequency, or indications that the dose may not work in all individuals being treated). By keeping this in mind, the claimed dosage regimens should not require, restrict, prevent, interfere with or otherwise engage the exercise of professional skill and judgment, and therefore, should be directed to patentable subject-matter in Canada.

Author

Pia-Lauren Reece, PhD
Patent Agent | Associate
T 416.865.3061
preece@airdmcburney.com

Brookfield Place, 181 Bay Street, Suite 1800, Toronto, Canada M5J 2T9
T: 416.863.1500 | Fax: 416.863.1515

AIRD McBURNEY