Medical use claims not involving the professional skill of a physician are patent-eligible in Canada.

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In a previous newsletter [1], we discussed a change in Canadian patent practice in respect of the patent-eligibility of claims relating to medical uses, further to a decision from the Federal Court [2]. Following this decision, the Canadian Intellectual Property Office (CIPO) issued a revised Practice Notice [3] concerning the examination of medical use claims, indicating that claims defining as an inventive feature a fixed dosage or fixed dosing schedule, are patent-eligible. In contrast, claims defining as an inventive feature a dosage range or a dosing schedule that includes a range, are considered to interfere with or require the professional skill of a medical professional and are thus generally rejected by Canadian Examiners.

In a recent decision [4], the Patent Appeal Board (PAB) has determined that claims defining as an inventive feature a dosage regimen that includes a range do not necessarily interfere with the professional skill of a physician and may be acceptable, depending on the circumstances, in contrast to the more strict position taken during examination.

Claim 1 under review in this case reads as follows:

> *Use of calcitonin (CT) in combination with one or more oral delivery agents selected from N-(5-chlorosalicyloyl)-8-aminocaprylic acid, N-(10-[2-hydroxybenzoyl] aminodecanoic acid or N-(8-[2-hydroxybenzoyl]amino) caprylic acid, or a disodium salt, hydrate or solvate thereof for the manufacture of a medicament for the treatment of a disorder responsive to the action of calcitonin, wherein said medicament is for oral administration to a human host from about 5 minutes to 2 hours prior to a meal.*

The goal of the invention is to solve the problem of low bioavailability of calcitonin (CT) that arises when an oral formulation comprising CT is taken with food. The solution proposed is to orally

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administer the pharmaceutical composition comprising CT during a short time window prior to food intake, i.e. from about 5 minutes to 2 hours prior to a meal, as recited in claim 1.

The Examiner rejected the claims under section 2 of the *Patent Act*, alleging that the claims related to a method of medical treatment involving the professional skill of a physician because the essential element only serves to instruct a medical professional "how" to treat a patient, notably the instructions to take the formulation during the period of time from about 5 minutes to 2 hours prior to a meal.

The PAB overturned the Examiner's final decision, asserting that a person of ordinary skill in the art would appreciate that any time during the recited time window would overcome the low bioavailability observed when administering an oral formulation of CT with a meal, and thus a physician's judgment is not required in selecting a particular time within this range. Stated otherwise, once the physician has decided to prescribe the oral CT formulation to be taken shortly before a meal, no exercise of the physician's skill or judgment is required. The PAB thus concluded that the subject matter defined by the claims does not amount to a method of medical treatment, and thus falls within the definition of "invention" under section 2 of the *Patent Act*.

This decision confirms that claims relating to medical uses may constitute patent-eligible subject matter, even when the inventive feature of the claims is somehow based on a dosage or dosing schedule defined in terms of a range, as long as it may be established that practicing the claimed invention does not interfere with or require the professional skill of a physician.

Patent applicants would be well advised to consider this change to Canadian patent practice when seeking patent protection in Canada for these types of inventions.

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1. Recent developments on patent-eligibility of medical use claims in Canada
2. *AbbVie Biotechnology Ltd. v Canada (Attorney General)*, 2014 FC 1251.
3. PN 2015-01, issued March 18, 2015.
4. Commissioner's Decision 1418

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