May 10, 2017

By Email

Canadian Intellectual Property Office
Patent Branch
50 Victoria Street
Place du Portage I
Gatineau, QC
K1A 0C9

Attention: Josée Pharand

Dear Madam:

RE: Consultation on the new Manual of Patent Office Practice Chapter 17 section on medical kits

This letter and attachments are in response to the call for comments in relation to the above draft Office Practice Notice. We appreciate the opportunity to comment.

FICPI (Fédération Internationale des Conseils en Propriété Intellectuelle) has a total membership of over 5000 intellectual property attorneys in private practice in over 86 countries around the world.

FICPI Canada is a self-governing national association of FICPI representing the interests of Canadian patent and trade-mark professionals. Our membership includes senior professionals at most major Canadian intellectual property firms who are responsible for filing the vast majority of patent and trade-mark applications that are submitted to CIPO each year. Our members' clients represent all types and sizes of businesses, including multinational corporations, small and medium size enterprises, and individuals.

We have reviewed with interest the consultation document.

We have few comments and are in general agreement with the contents of the document. Our comments are provided with reference to the Section numbers.

Section 17.03.04a – Claims of indefinite scope or lacking clarity

In view of the fact that terminology used by applicants from various regions of the world may vary while in substance carry similar meaning, we suggest that a sentence be introduced to state that amendments to terminology used in the claims in order to satisfy Subsection 27(4) of the *Patent Act* will generally not be viewed by CIPO as constituting new matter if the substance thereof is reasonably inferable from the specification as-filed.

Section 17.03.04b – Other patentability requirements

In the penultimate paragraph reference is made to PN2015-01 and "a dosing schedule encompassing a range" is given as an example of non-statutory subject matter. We suggest removing the example between parentheses because is some cases "a dosing schedule encompassing a range" may be statutory.

Case in point, Commissioner's decision No. 1418 of March 20, 2017, where it is noted at paragraph 19:

[19] However, PN 2015-01 also recognizes that there may be instances where essential elements serve to instruct a medical professional "how" to treat a patient but are not considered to prevent, interfere with or require the professional skill of a physician. For example, essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen or to a patient sub-population are not considered to comprise a limitation of a physician's professional skill or judgment.

The independent claims at issue were indicated at paragraph 19.

[29] Independent claims 1 and 7 read as follows:

1. Use of calcitonin 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.

7. A pharmaceutical composition comprising calcitonin 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 use in the treatment of a disorder responsive to the action of calcitonin, wherein said composition is for oral administration to a human host from about 5 minutes to 2 hours prior to a meal.

The above claims were found to be directed to statutory subject matter even if the feature of administration "from about 5 minutes to 2 hours prior to a meal" was found to be an essential element. See paragraphs 38 and 71.

[38] Likewise, we expressed the view in the Panel Letter (page 9) that the physician's skill and judgment are not expected to be exercised within the scope of the claims once the physician has decided to prescribe the oral CT formulation shortly before a meal in accordance with the claims on file. With respect to the essential element of timing the administration of the oral CT formulation, we considered that the POSITA would appreciate that any time during the recited time window would overcome the negligible plasma levels observed when administering an oral formulation of CT with a meal, so that no physician judgement is required in selecting a time within this range. (...)

[71] In our view, the subject matter defined by the claims on file falls within the definition of an invention as set out in section 2 of the Patent Act but is obvious, contrary to section 28.3 of the Patent Act.

Section 17.03.04c – Instructions

In the last paragraph, sentence beginning with "In contrast, where only the instructions provide...", we suggest to clarify by amending to "In contrast, when the preamble of the claim does not recite a particular use and where only the instructions provide...".

We thank you for considering our view on this matter and remain, as always, available for discussion. Please do not hesitate to contact the undersigned if you have any question, wish to discuss this matter further or would like to set-up a meeting.

Respectfully submitted,

John W. Knox,
President FICPI-CANADA