INTELLECTUAL PROPERTY INSTITUTE OF CANADA
INSTITUT DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA

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Intellectual Property Institute of Canada's Submission on Proposed Changes to the Manual of Patent Office Practice - Chapter 17 (Section on Pharmaceutical Solid Forms)

Submission to the
Canadian Intellectual Property Office

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INTRODUCTION

The Intellectual Property Institute of Canada (IPIC) is the professional association of patent agents, trade-mark agents and lawyers practicing in all areas of intellectual property law. Our membership totals over 1,700 individuals, consisting of practitioners in law firms and agencies of all sizes, sole practitioners, in-house corporate intellectual property professionals, government personnel, and academics. Our members' clients include virtually all Canadian businesses, universities and other institutions that have an interest in intellectual property (e.g. patents, trade-marks, copyright and industrial designs) in Canada or elsewhere, and also foreign companies who hold intellectual property rights in Canada.

IPIC is pleased to provide comments on proposed changes to the Canadian Intellectual Property Office (CIPO)'s proposed changes to the *Manual of Patent Office Practice* (MOPOP), which would add a new section 17.08 on pharmaceutical solid forms to Chapter 17.

In general, IPIC welcomes the introduction of new section 17.08, which addresses a guidance gap that is not currently in MOPOP. IPIC's proposed revisions to the proposed draft section 17.08 are intended to provide increased clarity to applicants regarding the subject-matter addressed and to address residual guidance gaps not already covered in the draft section.

IPIC's comments and proposed changes are set out in detail in the following pages. We would be pleased to discuss any of the items set out below if helpful.

PROPOSED CHANGES TO THE MANUAL OF PATENT OFFICE PRACTICE CHAPTER 17 (SECTION ON PHARMACEUTICAL SOLID FORMS)

IPIC's comments on the proposed section on pharmaceutical solid forms are set out below, broken out by subsection and addressing items in the order in which the relevant content appears in the draft section.

17.08 PHARMACEUTICAL SOLID FORMS

- In the 1st paragraph: For clarity, we suggest modifying this paragraph as follows:

  > "Many small chemical molecules are able to exist in more than one solid form. A solid form may be generally described as either crystalline or amorphous. The structure of a crystalline solid is dictated by the regular arrangement of the atoms of a molecule within a crystal lattice. The crystalline solid may contain the molecule in free base (or free acid) form or the molecule may exist as a salt. The molecule or salt may crystallize as a hydrate/solvate or co-crystal (see 17.08.06 for further guidance on salts, hydrates/solvates and co-crystals). Conversely, an amorphous solid contains molecules exhibiting a high degree of disorder in the molecular arrangement and, therefore, lacks crystallinity. The amorphous solid may also contain the molecule in free base (or free acid) form or the molecule may exist as a salt."

- In the 4th paragraph: While we agree with the statement that "the basic crystallization techniques have long been part of the common general knowledge of synthetic chemists in all fields of technology", the decision-making process to evaluate which combinations of techniques, solvents and conditions are to be used is not necessarily part of the common general knowledge and may require "considerable effort". This is discussed, for example, in *Pfizer v. Apotex*, 2017 FC 774 at paras [232] and [305], and *Pfizer v. Teva*, 2017 FC 777 at paras [194] and [276]. We suggest that this be made more clear in this paragraph.

17.08.01 CONSIDERATIONS RESPECTING ANTICIPATION AND OBVIOUSNESS

- General: We suggest that, throughout this section, the use of the terms "crystalline form", "solid form" and "polymorph" be made more consistent. For example, in the 5th paragraph, the terms "solid form" and "crystalline form" seem to be used interchangeably. We suggest that the whole section 17.08.01 should be reviewed to ensure that the proper terms are used, in a consistent manner.

- In the 5th paragraph: Two decisions are cited (see footnote 4) to support CIPO's view that "an unexpected beneficial property may represent the scintilla of invention sufficient to support the non-obviousness of the solid form." We have the following concerns about these citations:

- The cited paragraph 50 of 2017 FCA 76 discusses selection patents. However, crystalline form patents are not selection patents, since it is impossible to predict in advance that a particular crystalline form, or polymorph of an already known crystalline form exist. This is also supported in recent Canadian jurisprudence, for example by *Pfizer v. Apotex*, 2017 FC 774 at paras [404], and by *Pfizer v. Teva*, 2017 FC 777 at paras [287] to [293].

- It is also noteworthy that 2017 FCA 76 only has claims directed to a salt, and not to a crystalline form. This reference is therefore, in our view, not applicable to claims directed to crystalline forms.

- In the 5th paragraph: To avoid confusion associated with the word "scintilla" (which is never discussed in MOPOP in association with obviousness), we suggest the following edited sentence:

  "Since beneficial physicochemical properties are generally not predictable, they are generally considered as unexpected. It follows that an unexpected beneficial property may be ~~represent the scintilla of invention~~ sufficient to support the non-obviousness of the solid form."

- In the 5th paragraph: The decision cited (see footnote 5) to support CIPO's view that "Only benefits disclosed in the originally-filed application will be taken into account during an obviousness assessment" does not appear to fully support the statement which this decision is proffered. The decision relates to a patent claiming the single enantiomer of an already known compound. The obviousness analysis in that decision is in line with the selection invention approach, which is not applicable to crystalline forms as discussed above. (See *Pfizer v. Teva*, 2017 FC 777 at paras [320] to [321]). Further, in *Pfizer v. Apotex*, 2017 FC 774, and *Pfizer v. Teva*, 2017 FC 777, claim construction does not end up including the advantages of the claimed crystalline form in the inventive concept. This follows the judge's assessment that obtaining the claimed crystalline form required "considerable effort", as discussed above, and that the crystalline form in itself was the inventive concept of the claim. We suggest that these two decisions be reviewed by CIPO before finalizing MOPOP section 17.08.01, as several of the judge's conclusions appear to directly contradict CIPO's position on the assessment of obviousness.

- In the 6th paragraph: No discussion is provided for the comparison of several polymorphs that are not found in the prior art. It is common for an application to include a description of all the polymorphs identified in a polymorph screening. The physical-chemical properties of all the polymorphs are also often obtained, and one or two forms is shown to have one or more advantages over the others. We suggest that CIPO clarify its position on the use of such comparisons during an obviousness assessment.

- Second to last paragraph: We suggest amending the last sentence as follows to insert missing word:

  "However, such expected benefits are generally not sufficient, when taken alone to support a finding of non-obviousness".

- Citation 6: Citation 6 is from 1989. This citation is used to support the comment that "the person skilled in the art would generally expect or predict that a crystalline form will have certain benefits over an amorphous form of the same chemical molecule, including easier isolating, purifying, drying and in batch processes, easier handling and formulating." We suggest that a more recent citation be provided.

17.08.02 CONSIDERATIONS RESPECTING UTILITY

- First sentence: We suggest replacing the word "activity" with "utility" in the first sentence for consistency as follows:

  "It is generally understood that the person skilled in the art would reasonably expect that polymorphs of a known small chemical molecule with a previously established utility (e.g., pharmacological or therapeutic utility) would also possess the same ~~activity~~ utility since it is a general effect of the molecule itself."

17.08.03 DEFINING A POLYMORPH IN THE CLAIMS

- General: This section describes how a polymorph should be defined in the claims. We suggest that CIPO address how a reference to a drawing containing, for example, an X-ray powder diffraction (XRPD) spectrum for the polymorph, can be referenced in the claims if it is more efficient to simply refer to the drawing rather than write out all of the peaks in the XRPD spectrum. Some Examiners allow claims that refer to a Figure showing an X-ray powder spectrum, while some Examiners issue a rejection pursuant to subsection 27(4) of the *Patent Act*. We suggest that this point be clarified in this section of MOPOP chapter 17.08.

17.08.05 EXAMPLES

- Example 2 addresses a scenario in which the process for producing the claimed polymorph is inventive despite the lack of any advantages of the claimed form over previously-disclosed forms of compound V. This Example could be clarified further with the following modification to the final sentence of the first paragraph of Example 2:

  "The process used to prepare Form III is not disclosed in D1, and nor would it be self-evident to the skilled person to prepare antiretroviral compound V according to such a process."

- General: Scenarios A and B of Example 1 and Example 2 appear to be in line with CIPO's proposed guidelines. However, such straightforward Examples hardly ever arise in real-life patent applications. The most common scenario usually involves the following:

    - A claim directed to a novel crystalline Form I of Molecule A;
    - A prior art document that discloses a synthetic route to obtain Molecule A, but the only characterization data disclosed in the prior art document are solution NMR, solution IR and elemental analysis. No solid-state data is present in the prior art document for Molecule A;
    - As such, there is no way of actually knowing what solid form (an amorphous form, a crystalline form, a hydrate, a solvate etc.) was actually obtained in the prior art document.
    - In such case, what would be CIPO's position with respect to the obviousness analysis for a claim directed to Form I of Molecule A?

  We suggest that at least one additional example with two different scenarios be added to clarify this point.

17.08.06 CONSIDERATIONS RELATING TO PARTICULAR SOLID FORMS

- 17.08.06a Salts: In paragraph 2, we suggest removing the expression "like polymorphs", at the beginning of the paragraph. Indeed, polymorph screening usually requires way more planning and can be more arduous and prolonged than salt screening.

- 17.08.06c Co-crystals: We suggest adding a statement specifying that assessing novelty and obviousness of a co-crystal is done with regard to the same criteria as crystalline forms, since co-crystals are in effect a crystalline form of the two compounds that are bound together.

Thank you for the opportunity to provide input on the proposed changes to the *Manual of Patent Office Practice* (MOPOP). For any questions or follow-up discussions, please contact IPIC's Executive Director Adam Kingsley.

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