Dear Mr. McLean,

I am writing to provide you with a few observations on the proposed additions to MOPOP Chapter 17 for "Pharmaceutical solid forms", on behalf of my firm. In these, I'm afraid that I have been a bit "monotopic", aware that that IPIC will likely be providing a more comprehensive analysis.

Generally, while the desire for guidelines to achieve more consistent examination is understandable, the proposals have no clear support in the *Patent Act* or in Canadian jurisprudence. Aspects of the proposed guidelines are, with respect, unnecessary and potentially detrimental to examination. For instance, it does not appear that there has been any change in the law to warrant new guidelines on these specific topics. I note that the only recent decision cited in the proposal that actually dealt specifically with a "sold form" *per se* is that of the Federal Court of Appeal in *Bristol-Myers Squibb Canada Co. v Teva Canada Limited*, 2017 FCA 76. That decision concerned a particular salt and was decided on a particular set of facts. It does not support the generalizations contained in the proposal. For instance, the focus on "expected benefits" throughout the proposal seems to render all solid forms *de facto* selections – something for which there is no jurisprudential basis.

Some of the problems I perceive may be down to suboptimal wording. For instance, I am concerned that Sections 17.08.01 and Section 17.08.06 ("Considerations relating to particular solid forms") contain language that is susceptible to misunderstanding and that is potentially prejudicial to examination. The following statements are particularly problematic (with my added emphasis):

17.08.01 (polymorphs):

> It is important to note 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 small chemical molecule, including easier isolating, purifying, drying, and in batch processes, easier handling and formulating.[6] However, such expected* are generally not sufficient, when taken alone, to support a finding of non-obviousness.

17.08.06a (salts):

> It is generally understood that the person skilled in the art would reasonably expect that salts of a known small chemical molecule with a previously established utility (e.g., pharmacological or therapeutic utility) would also possess the same utility despite the incorporation of a counterion in its structure.

17.08.06b (hydrates, solvates and desolvates):

> It is generally understood that the person skilled in the art would reasonably expect that solvates and desolvates of a known small chemical molecule with a previously established utility (e.g., pharmacological or therapeutic utility) would also possess the same utility despite the incorporation of a solvent into the crystal lattice (solvate) or the removal of the solvent from the solvated form (desolvate).

17.08.06c (co-crystals):

> It is generally understood that the person skilled in the art would reasonably expect that co-crystals of a known small chemical molecule with a previously established utility (e.g., pharmacological or therapeutic utility) would also possess the same utility despite the incorporation of a co-crystal former into the crystal lattice.

(*Note that there appears to be a typo here in 17.08.01.)

First, I acknowledge that Sections 17.08.01 and 17.08.02 indicate that claims to particular solid forms may be novel, inventive, and possess utility; and that Example 1 (scenario B) and Example 2 include findings of patentability. It is reassuring that CIPO accepts that this subject matter can be useful and inventive in principle.

However, I have concerns that the above-quoted passages could be interpreted as contradicting this.

In the last three excerpts, for example, I find the language "same utility" to be problematic. If the intention is to acknowledge that new solid forms will likely possess the **scintilla of utility** required to meet statutory requirements, per *AstraZeneca*, based on activity of the parent solid form, then I agree with this. However, this could be stated more clearly.

Otherwise, the language "same utility" is somewhat unclear, and could be interpreted more broadly, e.g., to mean that utility of the new solid form and the parent form will be **exactly identical**. This is certainly not always the case, and I think one has to be very careful to distinguish between the "scintilla" requirement, on the one hand, from the full range of applications in which a new solid form may be used, on the other. For instance, while there may be scenarios in which prior use of drug X treatment of disease Y suggests that a new solid form of drug X may also be used in the same *general field* of application, ***this does mean that their full range of applications is necessarily "the same"***. The new solid form may possess properties, e.g., that lead to **different applications***,* even if the clinical entity treated is the same. For example, the properties of a particular new solid form may make it amenable to delivery via a transdermal patch, where the parent solid form is not.

This is not to suggest that anything more than a "scintilla" of utility is required for the new solid form to meet utility requirements; I simply wish to point out that the use of the terminology "same utility", without qualification, is potentially confusing. Taken to its logical conclusion, the statement that it is "generally understood that the person skilled in the art would reasonably expect " that new solid forms "possess the **same utility**" could be seen to contradict Example 1 Scenario B in which inventiveness is acknowledged.

I suggest that it would be more clear to say that new solid forms may be "expected to meet utility requirements".

I see a similar issue with the statement in 17.08.01 that benefits are "expected" for polymorphs, and "not sufficient" to support inventiveness. Even if different properties/benefits are "expected" in a very general sense, this does not necessarily make their *specific nature* known, predictable, or determinable through routine testing; and such factors can, on their own, support inventiveness. In an analogous situation, the FCA made a distinction between the *known* possibility of separating enantiomers of a racemic mixture (PCR 4099) and the *unknown* nature of the properties of the enantiomers so separately (this was in the so-called 'Sanofi2' decision, 2013 FCA 186). The FCA stated at par. 79 that, "…the person skilled in the art would not think of separating PCR 4099 and testing its enantiomers in order to obtain the benefit of its properties when the existence and nature of those properties were unknown," and at par. 80 " It follows that although the resolution of PCR 4099 was part of the common general knowledge, nothing turns on this as it is the unknown nature of the properties of the enantiomers which explains why the invention was not "obvious to try"". In my view, the term "expect or predict" used with "benefits" requires qualification, and the "not sufficient" language should be removed altogether

since there is no legal or scientific basis for such a general assertion. Example 1 Scenario B rightly indicates that there can be an "*unexpected* beneficial property".

My suggests are as follows:

1. First, I would respectfully suggest that the proposed additions to MOPOP Chapter 17 are unnecessary, and that examiners should be left to apply extent legal principles from jurisprudence to the facts of a particular application, and to draw their own conclusions. The proposals contain generalizations that are unsupported by law, and are therefore unnecessary.

2. If CIPO is nevertheless intent on including something in MOPOP on these subjects, adjustments should be made to address the issued noted above.

    a. I would suggest that the quoted passage from 17.08.01 and the entirety of 17.08.06 be deleted because of the issued noted above.

    b. Failing this, I would recommend deleting the above-quoted passages from 17.08.01, 17.08.06a, 17.08.06b, and 17.08.06c for the same reasons.

    c. Failing this, the language "same utility" should be removed, and the passages amended to clarify that the new solid forms may be "expected to meet utility requirements". Likewise, the passage in 17.08.01 pertaining to benefits of polymorphs being "expected or predicted" should be amended to clarify that the "nature of the properties" of new solid forms may be unknown, and that this could support inventiveness.

I have assembled this rather hastily, so please do let me know if you have any questions.

Thank you for your consideration.

With Best Regards,

Graeme.

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