August 16, 2018

VIA EMAIL (jeremy.mclean@canada.ca)
Attention: Jeremy McLean
Canadian Intellectual Property Office
Patent Branch
50 Victoria Street
Place du Portage I
Gatineau, QC
K1A 0C9

RE: MOPOP Chapter 17 Consultation

Dear Mr. McLean:

We are writing to provide feedback on the proposed new section of Chapter 17 of the Manual of Patent Office Practice (MOPOP) relating to patentability of pharmaceutical solid forms. We thank the Canadian Intellectual Property Office (CIPO) for providing us with this opportunity to comment.

AbbVie Inc.

AbbVie is a global, research-based biopharmaceutical company. AbbVie develops and markets advanced therapies that address some of the world's most complex and serious diseases. AbbVie's products are focused on treating conditions such as chronic autoimmune diseases in rheumatology, gastroenterology and dermatology; oncology, including blood cancers; virology, including hepatitis C virus (HCV) and human immunodeficiency virus (HIV); neurological disorders, such as Parkinson's disease and multiple sclerosis; metabolic diseases, including thyroid disease and complications associated with cystic fibrosis; as well as other serious health conditions. AbbVie also has a pipeline of promising new medicines in clinical development across such important medical specialties as immunology, oncology and neurology, with additional targeted investment in cystic fibrosis and women's health.

Executive Summary

The proposed section is a significant departure from established case law and creates an unwarranted barrier to patentability for new solid forms by mandating a new requirement for patentability for new solid forms that does not exist for other technologies. This barrier disproportionately affects patent applicants of patents for pharmaceutical solid forms. It will discourage rather than incentivize the private sector and scientific institutions vis-a-vis innovation relating to pharmaceutical solid forms. This is contrary to fostering the Canadian Government's Innovation Agenda.[1]

[1] Government of Canada, *Innovation and Skills Plan*, online: Government of Canada <http://www.ic.gc.ca/eic/site/062.nsf/eng/home>.

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General Comments

(1) Solid forms should not be held to a different standard than other technologies.

It is unnecessary to create a separate section in MOPOP pertaining to solid pharmaceutical forms. Doing so takes Canadian Patent Law out of harmony with other international jurisdictions. For example, the Manual of Patent Examining Procedure (MPEP) in the United States does not have a separate section pertaining to solid forms. Moreover, there is no separate statutory basis for examining claims to polymorphs or other solid states in Canada and therefore no reason for separate examination guidelines.

If a separate section is added to MOPOP, it should not hold solid forms to a higher standard than required by law nor to a higher standard than other technologies.

Anticipation

(1) There must be both disclosure and enablement in the prior art for a finding of anticipation.

In Section 17.01.01, paragraph 3, the sentence "a polymorph that is already known" should be changed to "a polymorph that is already disclosed and enabled".

The Supreme Court of Canada has clearly stated that there must be both (i) disclosure and (ii) enablement for a finding of anticipation, e.g., of a polymorph, under Section 28.2 of the Canadian *Patent Act*.[2] Mere "knowledge" is insufficient for a finding of anticipation. Accordingly, the guidelines should be amended to correctly state the law.

Obviousness

(1) The preparation of new solid forms is not a routine endeavor.

Section 17.08 of the proposed amendment includes statements regarding the state of the art of solid state chemistry. For example, it describes screening for new solid forms as "routine" and "using general methodologies that utilize basic crystallization techniques which are standard in the field".

As a matter of policy, we do not believe that CIPO should state generic conclusions regarding the state of the art of solid state chemistry. This is a nuanced matter that is appropriately left for Examiners to evaluate on a case-by-case basis as it represents a factually intensive inquiry that will necessarily be different for each invention.

Furthermore, the statements contradict Canadian jurisprudence on this issue. Recent caselaw (2017) recognizes that preparation of new solid forms is "difficult and not direct", "involving an

[2] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61 at para 28.

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extremely large number of studies and tests with no identified or predictable result", and "[not] routine or non-arduous".[3] Given the recognized unpredictable, difficult and indirect nature of the state of the art of preparation of solid state chemistry, the proposed guidelines should be amended to remove generic statements and conclusions regarding the state of the art.

(2) The patentability of a solid form is not dependent on the process by which it is made.

Section 17.08.01 states that "one factor to consider is the process by which the new form is produced. Inventiveness may be acknowledged for a form that can only be produced using an inventive process."

If enacted, the proposed guidelines should be amended to state that the inventiveness of a solid form, <u>like any other product</u>, is not dependent on the inventiveness of the process by which it is made.

(3) A patent claiming a novel solid form is not a selection patent. Thus there is no basis for a requirement to disclose an unexpected benefit.

Section 17.08.01 states that a new solid form will be inventive if the originally filed application <u>discloses</u> that the new solid form provides an "unexpected benefit" or a "significant difference or improvement" over a known small chemical molecule. These features are not pre-requisites to non-obviousness and patentability in Canada for solid forms or any other products, because as described in in Section 15.02.02 of MOPOP, only a "scintilla of invention" is sufficient to support non-obviousness as described. There is no basis for this higher standard in the Canadian *Patent Act* or Canadian jurisprudence.

It is thus an error of law to suggest that an application for a new solid form must disclose an unexpected benefit over the disclosure of the compound *per se* or a known different solid state of the compound. **<u>A patent claiming a novel solid form is not a selection patent</u>**. The disclosure rules of unexpected utility for selection patents should not apply with respect to polymorphs or other solid forms. <u>Indeed, a patent claiming a novel solid form is the opposite of a selection patent in that it is unknown how many solid crystal forms, if any, can exist for any particular compound</u>. Moreover, the distinguishing features of any specific solid form <u>remain unknown and unpredictable</u> until the solid form has been explicitly created and characterized.

The unpredictable nature of polymorph generation has been explicitly recognized in recent Canadian jurisprudence. For example, in *Pfizer* the Federal Court clearly stated:

> A Skilled Person would not know nor could he or she predict that Form I ODV succinate existed nor could they identify or predict what properties it would have,

[3] *Pfizer Canada Inc. v. Teva Canada Limited*, 2017 FC 777 at paras 248 and 279 [Pfizer]; *Bristol-Myers Squibb Canada Co. v. Mylan Pharmaceuticals ULC*, 2012 FC 1142 at paras 119-121.

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> or how if at all, it could be prepared.[4]

Furthermore, *Pfizer* confirms that a polymorph of a known small chemical molecule is not a selection invention:

> The novel crystal Form I ODV succinate is a new composition of matter; it is a three-dimensional arrangement of the atoms and molecules of ODV succinate. It was not found in the genus of any other patent. Therefore this is not a case of a second invention being selected from the prior art genus. Therefore this is not a selection patent.

The Court also indicated that there is no requirement to include a statement of advantage:

> I have previously found that the 668 Patent is not a selection patent. Therefore, and in my respectful view, Teva's arguments [that the 'disclosure of the 668 Patent is insufficient] based as they are on the incorrect premise that the 668 Patent is a selection patent, are not relevant...[5]

Hence, there is no requirement to disclose an unexpected benefit of a specific polymorph over the compound *per se* or a known different solid state of the compound. The proposed guidelines should be revised to reflect this state of the law.

In closing, we thank CIPO for providing us with this opportunity to comment. We support the Canadian Government's Innovation Agenda and believe that the proposed section needs to be re-considered in view of the comments provided in this submission.

Thank you for considering our comments.

Yours truly,

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[4] See *Pfizer*, *supra* note 6 at para 258. See also para 269.

[5] *Ibid* at paras 320-321.

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