August 17, 2018

Mr. Jeremy McLean
A/ Program Manager
Canadian Intellectual Property Office
Patent Branch
50 Victoria Street, Place du Portage I
Gatineau, QC K1A 0C9

By electronic mail only: jeremy.mclean@canada.ca

RE: Consultation on the new Manual of Patent Office Practice Chapter 17 section on pharmaceutical solid forms

Dear Mr. McLean,

On behalf of the membership of Innovative Medicines Canada (**IMC**), I appreciate the opportunity to engage as part of the Canadian Intellectual Property Office (**CIPO**) public consultation on the proposed new Manual of Patent Office Practice (**MOPOP**) Chapter 17 section on pharmaceutical solid forms. IMC is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian health and regulatory systems.

At the outset, we wish to emphasize that Canada's intellectual property (**IP**) regime is a key driving force behind the generation of IP and, by extension, innovation in the biopharmaceutical sector. Developing complex treatments to fight such illnesses as diabetes, heart disease or cancer is extremely expensive, time consuming and risky. Strong and predictable IP is especially important given that, although a patent lasts for 20 years in Canada, it takes on average 10 years or more for a new medicine or vaccine to go through all the requisite trial and approval stages – often leaving companies on average less than 10 years to recover their investment. These objectives are congruent with CIPO's mission statement to "contribute to Canada's innovation and economic success" by, among other things, "providing greater certainty in the marketplace through high-quality and timely IP rights"[1].

It is within this context that we wish to raise several concerns with the proposed changes to the MOPOP. In particular, and compared to current examination practices, the proposed guidelines set heightened requirements with respect to non-obviousness and utility of certain inventions relating to crystalline forms

[1] Canadian Intellectual Property Office, "About Us", http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00025.html#mission.

of small molecules. We also believe that the proposals are inconsistent not only with Canadian legislation and case law, but also with the practices of other countries and Canada's international treaty obligations.

Heightened Requirements for Non-Obviousness

According to s. 17.08.01 of the proposed guidelines, a crystalline form (e.g., a polymorph) of a small molecule will be considered non-obvious (inventive) if:

- the form can only be produced using an inventive process (generally beyond the mere application of common general knowledge and routine experimentation); or
- the form provides an unexpected benefit, such as a beneficial physicochemical property, attributable to the form itself.

While we agree that these are helpful indicia of non-obviousness, to elevate these indicia to definitive tests for the inventiveness of crystalline forms is inconsistent with Canada's patent legislation and case law.

Canada's *Patent Act*, which – pursuant to s. 28.3 – requires that an invention must not be obvious to a person skilled in the art in relation to the science and information available at the claim date. There is no legal requirement for an application for a new solid form to disclose an unexpected benefit over a known small chemical molecule or forms thereof.

In addition, CIPO's assertion that the unexpected beneficial property must be explicitly or implicitly disclosed in the originally filed application goes beyond the case law in terms of what historically has been required to be explained in the patent application. The CIPO proposal inappropriately directs a patent examiner to read both the claims and the disclosure to identify potential unexpected benefits rather than the claims alone, even in an absence of ambiguity in the claims. As has been recently noted by the Supreme Court of Canada:

> *Generally, an analysis regarding issues of validity, such as novelty or non-obviousness, focuses on the claims alone, and only considers the disclosure where there is ambiguity in the claims (Sanofi-Synthelabo). This is in accordance with this Court's direction that claims construction precedes all considerations of validity [...].*[2]

We refer you to the key decision in the law of obviousness as handed down by the Supreme Court of Canada in *Apotex Inc v Sanofi Synthelabo Inc*[3], and as recently restated in pharmaceutical case law respecting the obviousness and utility of claims covering a specific polymorphic form[4]. These decisions provide guidance on the validity of polymorphic form patents, including in relation to questions of obviousness, confirming the test for obviousness as set out in *Beloit* – that being whether the skilled person would "in the light of the

[2] *AstraZeneca Canada Inc. v. Apotex Inc*, 2017 SCC 36 [*AstraZeneca*] at 31.
[3] 2008 SCC 61.
[4] *Pfizer Canada Inc v Apotex Inc*, 2017 FC 774 [*Pfizer*]; *Pfizer Canada Inc v Teva Canada Limited*, 2017 FC 777.

state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent."[5]

Heightened Requirements for Utility

IMC is concerned with CIPO's proposed guideline that, where the subject-matter of the invention as claimed has a utility that is different from other known form(s) of the same small molecule, the utility must be established by demonstration and cannot rely on sound prediction (at proposed s. 17.08.02). While we agree that generally the properties of new crystalline forms will be unexpected, we see no reason why the evaluation of whether a physicochemical property can be soundly predicted should not be done on a case by case basis, consistent with the treatment of inventions in other technological areas.

Further, CIPO's proposed language should be amended to reflect the Supreme Court of Canada's recent decision in *AstraZeneca Canada Inc. v. Apotex Inc*. abolishing the "promise doctrine" in Canada and clarifying once again that "a patentee is not required to disclose the utility of the invention to fulfill the requirements of s. 2 [of the *Patent Act*]"[6]. In this regard, we note the Supreme Court of Canada set out the correct approach to utility in *AstraZeneca v. Apotex*:

> *The [Patent] Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date*[7].

IMC believes that it is unnecessary to create a separate section in the MOPOP pertaining to solid pharmaceutical forms, as there is no indication in either the legislation or case law that different standards of novelty, obviousness or utility apply to this subject matter. Nevertheless, if CIPO proceeds with this new section, changes are necessary to the proposed text to accurately reflect the correct legal test for utility, including, importantly:

- As an applicant is not required to disclose the utility of an invention, we recommend the third paragraph under 17.08.02 beginning "Where the specification is silent as to utility…" be removed.
- As utility must be grounded in the claims and crystalline forms are not precluded from relying on sound prediction, we recommend that the fourth paragraph under 17.08.02 be replaced in its entirety with:

> Where the claims of an application to a crystalline form claim a utility that is different from other known form(s) of the same small chemical molecule, the utility related to the subject-matter must be established by demonstration or sound prediction (see 12.04.02 and 12.04.03).

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[5] *Beloit Canada Ltd v Valmet OY* (1986), 64 N.R. 287, 8 C.P.R. (3d) 289 at 294, as cited by *Pfizer*, *ibid*, at 220.
[6] *AstraZeneca*, *supra* note 2, at 58.
[7] *AstraZeneca*, *supra* note 2, at 56.

Imposing a heightened standard of utility is particularly problematic for pharmaceutical patents because most clinical trial studies on drug efficacy are conducted after the patent application is filed. Innovators cannot undertake the tremendous expense and experimental risks associated with performing human clinical trials without some reasonable assurance of patent protection and – by extension – market exclusivity.

International Alignment and Treaty Obligations

IMC notes that the addition of a separate section to the MOPOP that inappropriately holds pharmaceutical solid forms to a higher standard than other technologies would be inconsistent with Canada's international treaty obligations. Both the TRIPS Agreement and NAFTA specifically require signatories to make patent rights available "without discrimination as to field of technology"[8] . Consequently, more burdensome non-obviousness and utility requirement cannot be imposed on inventions respecting pharmaceutical solid forms as compared to other types of inventions.

Finally, IMC believes that it is unnecessary to create a separate section in MOPOP pertaining to solid pharmaceutical forms. Notably, neither the Manual of Patent Examining Procedure in the United States, nor the Guidelines for Examination in the Europe Patent Office, include separate sections pertaining to pharmaceutical solid forms.

Conclusion

We encourage CIPO and Innovation, Science and Economic Development Canada to continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong IP protection, innovation, and appropriate reward-for-value in Canada's innovative biopharmaceutical industry. However, we are concerned that the proposed guidance represents both a departure from established case law and a barrier to patentability for new pharmaceutical solid forms.

In conclusion, we respectfully recommend that the Commissioner of Patents should not make the proposed amendments to Chapter 17. If the Commissioner decides to move forward with a version of these proposed amendments, we recommend that the abovementioned concerns and recommendations be addressed.

IMC and its members thank you for the opportunity to submit these concerns, and would welcome the opportunity to further elaborate upon these issues or to answer any questions upon request.

Sincerely,

Declan Hamill
Vice President, Legal, Regulatory Affairs & Compliance

[8] NAFTA at article 1709(7); TRIPS at article 70(6).