August 17, 2018

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Canadian Intellectual Property Office
Patent Branch
50 Victoria Street
Place du Portage I
Gatineau, QC
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Re: Consultation on the new Manual of Patent Office Practice (MOPOP) Chapter 17 section on pharmaceutical solid forms

Dear Mr. McLean,

The Pharmaceutical Research and Manufacturers of America ("PhRMA"), European Federation of Pharmaceutical Industries and Associations ("EFPIA"), Japan Pharmaceutical Manufacturers Association ("JPMA"), the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") and INTERPAT (collectively "the Associations")[1] offer the following comments on the proposed changes to Chapter 17 of the MOPOP as it relates to pharmaceutical solid forms, such as polymorphs, salts, hydrates, solvates, desolvates and co-crystals. While we appreciate the desire to provide additional certainty and consistency in the patent examination process, we have significant concerns that the proposed guidance represents a departure from established case law and a barrier to patentability for new pharmaceutical solid forms. Consistent with Canada's obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), crystalline forms should not be held to a higher patentability standard than other technologies. As such, consistent with practice in the United States and Europe, we would propose that the Commissioner of Patents not add this new section on pharmaceutical solid forms to the MOPOP.

I. The Commissioner of Patents Should Not Make the Proposed Amendments to Chapter 17

The Consultation provides no legal grounds for the proposed amendments to Chapter 17 of the MOPOP. On the contrary, as discussed further below in Section II of these comments, there are instances where the proposed amendments appear to be beyond the authority of the Commissioner in that they would create legal tests that do not accurately reflect Canada's *Patent Act* and *Rules* and Canadian jurisprudence.[2] In particular, there is no legal requirement under Canadian law that a polymorph patent application disclose an "unexpected benefit" or a

[1] The Associations represent the world's leading research-based pharmaceutical and biotechnology companies. We support government policies that encourage the discovery and clinical development of innovative medicines for patients around the world.

[2] *Amazon.com Inc., Re*, 2010 FC 1011, at para 47, *rev'd* but not on this point; See *Amazon.com Inc*. *Re*, 2011 FCA 328, at paras 52-54.

"significant difference or improvement" over the known molecule in order to demonstrate inventiveness.

The addition of a separate section to the MOPOP that holds pharmaceutical solid forms to a higher standard than other technologies would be inconsistent with Canada's obligations under TRIPS. Specifically, under Article 27.1 of the TRIPS Agreement, "patents shall be available and patent rights enjoyable without discrimination as to the … field of technology …." Imposing a heightened inventiveness standard solely for pharmaceutical solid forms would impermissibly discriminate against the innovative biopharmaceutical industry, contrary to this obligation.[3]

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

II. Any Proposed Amendments to Chapter 17 of the MOPOP Must be Consistent with Canadian Jurisprudence

Contrary to fostering the federal government's innovation agenda,[4] the proposed revisions to Chapter 17 of the MOPOP would act as a barrier to patentability and innovation. Experience demonstrates that such patentability and innovation barriers significantly impact domestic innovators. For example, a recent industry analysis of India's restrictive biopharmaceutical patentability criteria illustrates the significant impact it has on the ability of Indian companies to capitalize on their innovations in their own market.

While the search for new solid forms may not be uncommon, there is, contrary to some of the language used in proposed Section 17.08, nothing "routine" about researching and developing new pharmaceutical solid forms, *e.g.* polymorphs or single crystalline molecular structures.[5] A polymorph is a single crystalline structure of a molecular compound. Single polymorph forms are often vastly superior – demonstrating better dissolution properties, increased bioabsorption and bioavailablity, improved heat stability, and longer shelf-life.[6] As a result, and as Canadian jurisprudence recognizes, the preparation of new solid forms can be "difficult and not direct", involve "an extremely large number of studies and tests with no identified or predictable result", and "[not] routine or non-arduous".[7] The overall tenor of Section 17.08 does not accurately reflect this jurisprudence.

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[3] To the extent that Articles 27(2) and (3) of TRIPS provide very limited exceptions to patentable inventions, new pharmaceutical solid forms do not fall within one of these exceptions.

[4] See, e.g., the Government of Canada's Innovation and Skills Plan, available at http://www.ic.gc.ca/eic/site/062.nsf/eng/home.

[5] Similarly, statements suggesting that "using general methodologies that utilize basic crystallization techniques … are standard in the field", inappropriately trivialize the complexity that can be involved in developing a polymorph.

[6] Holman, C., "Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination," Indian Law Review, *available at* http://journals.iupui.edu/index.php/inlawrev/article/view/21522/20754.

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

Equally concerning, Section 17.08.01 states that a new solid pharmaceutical form may be considered inventive "if the originally-filed application discloses that the form provides an unexpected benefit (emphasis added)", and that the most persuasive disclosure is one that confirms a "significant difference or improvement" over the known molecule. While these features may be helpful to address 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.

Canadian law does not require an application for a new solid form to disclose an unexpected benefit over a known molecule. While this may be the applicable disclosure standard for a selection patent, it is not relevant when examining a patent application for a polymorph. By definition, a selection patent relates to the selection of a species from a genus, where the genus is a **known universe**. Conversely, the universe of potential polymorphs is **unknown**. A key aspect of crystallography is that one does not know how many crystals, if any, there are of a specific compound, due to the unpredictable nature of polymorph generation.[8] Canadian jurisprudence confirms that a polymorph of a known molecule is not a selection patent.[9] Since there is no genus and no species, there is no requirement to disclose an unexpected benefit over a genus patent.

It is also an error of law to require a "significant" difference or improvement as this is not the threshold for non-obviousness in Canada. Indeed, in Section 15.02.02 of MOPOP (and even in the proposed amendments, e.g., at the end of the sixth paragraph of Section 17.08.01), it is acknowledged that a "scintilla of invention" is sufficient to support non-obviousness. As highlighted above, new solid forms should not be held to a higher, discriminatory standard than other inventions, and there is no basis for this higher standard in the Canadian *Patent Act* or Canadian jurisprudence.

In addition, the proposed amendments appear to go beyond the patent utility test articulated by the Supreme Court of Canada. In *AstraZeneca Canada v. Apotex Inc.*, the Court held:

> To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject matter of the invention as claimed in the patent. Second, courts must ask whether that subject matter is useful – is it capable of a practical purpose (i.e. an actual result). The 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.[10]

Rather than describing the utility requirement as held by the Court – which begins with the claimed invention and asks whether the subject matter is useful – the proposed

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[8] See *Pfizer*, *supra* note 7, at paras. 258, 269.

[9] *Id.*, at paras. 287-292 and 320-321.

[10] *AstraZeneca Canada Inc. v Apotex Inc.*, 2017 SCC 36, at paras. 54 and 55.

amendments state that “in order to establish utility the applicant must be in a position to show that the property associated with the utility” was demonstrated by the filing date. Utility requirements for new solid forms should be analyzed as set forth by the Supreme Court of Canada.

Finally, if the Commissioner decides to move forward with a version of these proposed amendments, one technical revision that should also be made to Section 17.08.01 relates to the phrase in the third paragraph of Section 17.08.01 stating “a polymorph that is already known….” As in the first sentence in this paragraph this language 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 under Section 28.2 of the Canadian *Patent Act.* Mere “knowledge” is insufficient for a finding of anticipation.

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In conclusion, the Associations would strongly recommend that as in the United States and the European Union, the Commissioner of Patents should refrain from establishing separate and heightened examination standards for pharmaceutical solid forms.

Respectfully submitted,

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