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**By Electronic Submission**

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Canadian Intellectual Property Office  
Patent Branch  
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**RE: Consultation on Revised Manual of Patent Office Practice Ch. 12,  
Written Submission of the Canadian Patent Utility Coalition**

Dear Ms. Pharand:

The Canadian Patent Utility Coalition (“CPUC”) appreciates this opportunity to submit comments to the Canadian Intellectual Property Office (“CIPO”) in response to CIPO's consultation request on a proposed revision to Chapter 12, entitled Subject-Matter and Utility, of the Manual of Patent Office Practice (“MOPOP”). CPUC is a coalition of 21 Canadian, European, Japanese and U.S. innovative companies concerned about Canada’s Promise Doctrine.

CPUC offers the following comments relating to patent utility issues. In particular, CPUC offers comments to: (1) propose specific changes to implement the recent landmark patent utility decision by the Supreme Court of Canada; (2) encourage implementation of these changes as soon as possible in order to provide greater certainty and predictability to patent

holders; and (3) urge caution in the examination of patent utility in the aftermath of this decision, specifically regarding disclosure requirements.<sup>1</sup>

As an initial matter, CPUC commends CIPO for its effort in revising Chapter 12. The proposed changes have resulted in a revised version of Chapter 12 that offers greater clarity for examiners and patent owners. The proposed changes streamline Chapter 12 by eliminating or consolidating various portions, and adding examples and clarifications.

### **Implementation of *AstraZeneca Canada Inc. v. Apotex Inc.***

Since 2005, Canadian courts have applied a new and heightened test for assessing the utility of patented inventions—the Promise Doctrine. During this time period, Canada revoked 25 patents related to commercially significant pharmaceutical products, including numerous groundbreaking therapies. Canada’s Promise Doctrine represented a sharp departure from Canada’s utility law and created significant uncertainty for innovators.

Shortly after CIPO opened the consultation period on the proposed revision, the Supreme Court of Canada rejected the Promise Doctrine in a unanimous decision, *AstraZeneca Canada Inc. v. Apotex Inc.*<sup>2</sup> The decision concluded that the Promise Doctrine is not the correct approach for determining whether a patent has sufficient utility.<sup>3</sup> The Court found that the Promise Doctrine is “unsound” and “incongruent with both the words and the scheme of the Patent Act,” and “is not good law.”<sup>4</sup>

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<sup>1</sup> These comments intentionally are limited and narrow in focus to these issues. CPUC members may, individually or as members of another organization, have additional comments on the proposed changes.

<sup>2</sup> *AstraZeneca Canada Inc. v. Apotex Inc.*, [2017] SCC 36.

<sup>3</sup> *Id.* ¶ 2.

<sup>4</sup> *Id.* ¶¶ 36, 51 (emphasis removed).

The Supreme Court found that the Promise Doctrine runs counter to: (1) “the scheme of the [Patent] Act by conflating [sections] 2 and 27(3);” and (2) “the words of the Act by requiring that where multiple promised uses are expressed, they all must be satisfied for the patent to meet the utility requirement in [section] 2.”<sup>5</sup> As to the former, the Court clarified that “[t]here is a difference between the requirement in [section] 2 that an invention be ‘useful’ and the requirement to disclose an invention’s ‘operation or use’ as per [section] 27(3);” noting that “the former is a ‘condition precedent to an invention’ and the latter a ‘disclosure requirement, independent of the first.’”<sup>6</sup> The Promise Doctrine therefore improperly “import[ed] [section] 27(3) into [section] 2.”<sup>7</sup>

The decision also firmly rejected the notion that the Supreme Court’s opinion in *Consolboard Inc. v. MacMillan Bloedel (Sask) Ltd.*, provided the legal basis for the Promise Doctrine, noting that while the decision “uses the word ‘promise’ it does not refer to, nor does it embody, the Promise Doctrine.”<sup>8</sup> Instead, the Court demonstrated that the Promise Doctrine’s roots were found in England’s “now extinct” false promise doctrine, as opposed to any origins in Canadian law.<sup>9</sup>

In rejecting the Promise Doctrine, the Court set forth “The Correct Approach to Utility,” a two-step analysis to determine whether a patent demonstrates sufficient utility.<sup>10</sup> First, courts

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<sup>5</sup> *Id.* ¶¶ 38, 47.

<sup>6</sup> *Id.* ¶ 43.

<sup>7</sup> *Id.* ¶ 44.

<sup>8</sup> *Id.* ¶ 43 (citing *Consolboard Inc. v. MacMillan Bloedel (Sask) Ltd.*, (1981) 1 SCR 504, 525, 527).

<sup>9</sup> *Id.* ¶¶ 33–35.

<sup>10</sup> *Id.* ¶¶ 52–54.

must “identify the subject-matter of the invention as claimed” and then ask whether that subject-matter is “capable of a practical purpose (i.e. an actual result).”<sup>11</sup> Under the Act, the Court clarified, no particular “degree or quantum of usefulness” is required, nor must “every potential use be realized—a scintilla of utility will do.”<sup>12</sup> Thus, “[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.”<sup>13</sup>

CPUC agrees with CIPO’s July 4, 2017 Update that modifications to Chapter 12, notably Section 12.04.02, are necessary to implement the Supreme Court’s decision. During the 12-year lifespan of the Promise Doctrine, the doctrine was incorporated into numerous sections of the MOPOP, including Chapter 12. CIPO’s recent efforts to streamline and consolidate the MOPOP, however, have simplified the implementation process. CPUC specifically proposes two changes: (1) the deletion of Section 12.04.02, as well as certain language in Section 12.04 and 12.04.03 referring to “promises;” and (2) the addition of language in 12.04 describing the Supreme Court’s “Correct Approach to Utility.”

In more detail, CPUC proposes the deletion of Section 12.04.02, titled “Promised utility of the invention” in its entirety. This section now is obsolete in light of the Supreme Court’s denunciation of the Promise Doctrine.

CPUC also proposes the following deletions (indicated in ~~strikethrough~~) and additions (indicated in **bold**) to Section 12.04:

Section 2 of the Patent Act requires that an invention be useful. Utility in the sense of the Patent Act can be considered as a requirement for an invention to be operable, controllable and

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<sup>11</sup> *Id.* ¶ 54.

<sup>12</sup> *Id.* ¶ 55.

<sup>13</sup> *Id.*

reproducible such that the objectives of the invention are predictably achieved.

Except where utility is the essence of the invention (e.g. new uses for old compounds), an applicant need not expressly set out the utility of the invention in the application; however if an invention's utility is questioned, utility must be shown to have been demonstrated or soundly predicted (see 12.04.03) as of the application's filing date. **This requirement is intended to prevent the patenting of fanciful, speculative or inoperable inventions. The Patent Act does not prescribe the degree or quantum of usefulness required, or that every potential use, even those described in the claims or description, be realized.** The threshold that must be met to establish utility is ~~generally~~ quite low; a "mere scintilla" of utility will suffice. ~~However, where the specification sets out an explicit promise, utility will be measure against that promise (see 12.04.02).~~ **A single use related to the subject-matter of the claims is sufficient.**

Utility is an essential aspect of an invention, but with the exception of new uses for old compounds, utility does not need to be explicitly defined in the claims. To be directed to a useful embodiment, a claim must define the inventive element or combination of elements necessary to enable the proper operation of the invention for its intended purposes. A feature that is required to allow the invention to work, the presence of which is understood by the person skilled in the art as being implicit, need not be explicitly defined.

The proposed additions provide important clarity based on the Supreme Court's recent decision and are appropriate to set forth the correct test for utility. This guidance from the Supreme Court appropriately emphasizes the minimal utility standard and its stated intention to "prevent the patenting of fanciful, speculative or inoperable inventions."<sup>14</sup>

CPUC also proposes the following deletion to the second paragraph of Section 12.04.03:

~~Demonstrated utility pertains to embodiments of the invention that have been specifically shown to actually work for the ends promised by the applicant.—Where the utility of an invention is to be established by demonstration, the demonstration must have occurred as of the filing date but need not have been included in the description. Information establishing the demonstrated utility as of~~

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<sup>14</sup> *AstraZeneca Canada Inc. v. Apotex Inc.*, ¶ 57.

the filing date may be provided after the filing date by the applicant by way of affidavit.

The above-described additions and deletions would help MOPOP conform with the current state of patent utility law following the Supreme Court’s decision in *AstraZeneca*. CPUC also encourages CIPO to carefully review Chapter 12 to remove any other now inappropriate references to the Promise Doctrine not specifically identified in these comments.

Although these comments are focused on CIPO’s proposed Chapter 12 revisions, we urge CIPO also to revise, as appropriate, other portions of the MOPOP that include discussion of the Promise Doctrine and concepts relating thereto, such as Chapters 9 (Description) and 11 (Claims).

#### **CIPO Should Exercise Caution in Applying Utility Disclosure Requirements**

As noted above, in striking down the Promise Doctrine, the Supreme Court held that the Doctrine improperly imports the disclosure requirements of section 27(3) of the Patent Act into the utility requirement of section 2. As the Court emphasized in its decision, this conflation between distinct sections of the Patent Act was precisely what the Court had “sought to clarify” in *Consolboard*.<sup>15</sup> In that case, and again in *AstraZeneca*, the Court emphasized that section 2 constitutes a “condition precedent to an invention,” while section 27(3) is a “disclosure requirement, *independent of the first*.”<sup>16</sup>

The disclosure requirement for sound prediction, namely that the factual basis for a sound prediction of utility must be disclosed in the patent, appears to stem from the same conflation of utility and disclosure that the Court has now emphatically rejected twice. This requirement also

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<sup>15</sup> *AstraZeneca Canada Inc. v. Apotex Inc.*, ¶ 38.

<sup>16</sup> *Id.*, ¶ 43 (quoting *Consolboard Inc. v. MacMillan Bloedel (Sask) Ltd.*, at 525).

appears to have been undermined by unconditional statements from the Court in *AstraZeneca* that “a patentee is not required to disclose the utility of the invention to fulfill the requirements of [section] 2.”<sup>17</sup>

The Court’s decision in *AstraZeneca* thus has called the disclosure requirement for a sound prediction of utility into serious question. Given the high degree of uncertainty surrounding the scope and proper interpretation of this requirement following *AstraZeneca*, CPUC requests that caution be exercised in the application of this requirement during patent examination. In particular, CPUC urges CIPO to emphasize that patent examination for utility must be, as highlighted by the Supreme Court, “in line with its purpose—to prevent the patenting of fanciful, speculative or inoperable inventions,”<sup>18</sup> regardless of whether utility is demonstrated or soundly predicted.

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<sup>17</sup> *Id.* ¶ 58.

<sup>18</sup> *Id.* ¶ 57.

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CPUC appreciates the ongoing efforts of CIPO to improve MOPOP and to consult with stakeholders as part of this effort. We hope that this submission provides helpful information and proposals regarding the proposed changes to the MOPOP. Given the impact of the MOPOP's guidance on pending and future patent applications, CPUC urges CIPO to implement these changes as quickly as possible. We again thank CIPO for the opportunity to participate in this consultation. Please feel free to contact us should you have any questions about or comments on the information contained in this submission.

Sincerely,

**The Canadian Patent Utility Coalition**

AbbVie Inc.	Amgen
Astellas Pharma US	AstraZeneca
Biogen Idec Inc.	BN ImmunoTherapeutics
Bristol-Myers Squibb	Celgene Corporation
Eisai Incorporated	Eli Lilly and Company
F. Hoffmann-La Roche Ltd	Genentech
Gilead	GlaxoSmithKline USA
Johnson & Johnson	Merck & Company
Novartis US	Oncolytics Biotech Inc.
Pfizer	Sanofi US
Takeda California Inc.	