



May 4, 2026

Via email: PMPRB.Information-Renseignements.CEPMB@pmprb-cepmb.gc.ca

Patented Medicine Prices Review Board
333 Laurier Avenue West
Suite 1400, Box L40
Ottawa, ON K1P 1C1

Dear Review Board:

Re: Consultation on the PMPRB Proposed Practice Directions

We are writing on behalf of the Intellectual Property Law Section of the Canadian Bar Association (CBA Section) in response to the *Consultation on the Patented Medicine Prices Review Board (PMPRB) Proposed Practice Directions* (Practice Directions).¹

We write to applaud the PMPRB for seeking efficiencies but strongly caution against limiting procedural rights in a manner that would prevent Rights Holders from preparing and presenting a fulsome case before the Board.

The CBA is a national association of 40,000 lawyers, Québec notaries, law teachers and students, with a mandate to promote improvements in the law and the administration of justice. The CBA Section serves as the CBA's voice on the intellectual property law and legal practice. It deals with legal issues around ownership, licensing, transfer and protection of intellectual property and related property rights. Its work includes patents, trademarks, copyright, industrial designs, plant breeders' rights and trade secrets.

The CBA Section consulted with its Executive members and a working group and is pleased to submit comments on the Practice Directions.² The PMPRB is tasked under the *Patent Act* to prevent Rights Holders from abusing their patent rights by charging an excessive price for a patented medicine. In the context of this mandate, the PMPRB can oversee hearings on excessive price and other related subject-matter. The proposed Practice Directions aim to address various PMPRB hearing procedures. Overall, the proposed Practice Directions seek to streamline hearing proceedings by favouring determinations made in paper (over live hearings), while also implementing short default timelines and other procedural limits.

¹ PMPRB, [online](#).

² PMPRB, [online](#).

TOPIC 1: Proposed Practice Direction on the Mode of PMPRB Hearings

Mode of hearing

The mode of hearing (paper/in-person/virtual) should be determined by Case Management on an *ad hoc* basis. Hearings will range in complexity and facts and are properly assessed on a case-by-case versus default basis. Historically, the Board has not held many hearings such that volume should not prevent it from maintaining its *ad hoc* approach.³

Live testimony

There should be no paper-mode default applicable to witness/expert cross-examinations. These should be heard in-person (whether live or virtual) to better allow the Board hearing panel to assess issues of witness credibility. In addition, as adverted to below, the arbitrary page limits on expert reports, written evidence, and written argument, put even further restrictions on the ability of the parties to receive a fair hearing. The ability to present evidence and arguments in person will be important in many cases. In terms of best practices, we refer the Board to the Federal Court where live hearings are the default, and virtual and paper proceedings are subject to the consent of the parties.⁴

Hearing length

The default length of hearing being proposed is much shorter than recent hearings, which have spanned approximately 20 days. There should be no “exceptional circumstances” (EC) threshold applicable to obtaining a longer hearing. The EC standard has not been defined in the proposed Practice Directions, but on a plain reading connotes “rare” or “unusual”, which sets too high of a standard. The length of hearing is fact-specific and, like the mode of hearing, is properly assessed on a case-by-case basis.

TOPIC 2: Proposed Practice Direction on Facilitating Document Exchange

Affidavit of Documents

It is worth noting that the PMPRB operates under a statutory scheme requiring mandatory disclosure of information from patentees. Based on this disclosure, Board Staff has the information it needs to form an assessment of excessive pricing. Once a matter has been referred to the Board and a Notice of Hearing has issued, the proceeding falls under the *Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR/2012-247 (PMPRB Rules). Under the PMPRB Rules, any procedural matter is to be dealt with in a manner that ensures the fair and expeditious conduct of a proceeding. The PMPRB Rules are silent as to document exchange, subject to case management procedures to discuss the filing of evidence (Rule 22(c)) and the mode of tendering documents (Rules 6(1)(a), 6(2), 10, and 14). The PMPRB Rules do provide for interlocutory relief, which presumably could relate to demands for documents. In this way, production requests are dealt with on a case-by-case basis. For example, in the *Procysbi* case, the Panel granted Board Staff’s motion for production of documents. The Panel ordered: (i) the Respondent to produce certain requested documents; and (ii) the Parties’ experts to meet and confer to endeavour to come to agreement on the remaining document requests.

Under the PMPRB Rules, there is no documentary discovery. However, as noted in the proposed Practice Directions, there are disclosure obligations—namely to produce all documents that will be relied on. Under the Practice Directions, this will change—and change significantly. The proposal is a departure from past Board practice and is aligned with a documentary disclosure standard broader than that required in Federal Court. Under paragraph 3(a) a party would be obligated to identify any

³ PMPRB, Annual Report 2024, [online](#) at “summary” (Since 1993, the Board has issued 31 hearing notices, 14 of which were settled prior to hearing, with 17 subject to full hearings. Of the full hearings held, ten concerned allegations of excessive price, and seven related to allegations of failure-to-file).

⁴ Federal Court, 2025-06-20, Amended-Consolidated-General-Practice-Guidelines., e.g., paras 45-75, [online](#)

“documents that are relevant to any matter in issue that are or were in the possession, power or control of the party”. Relevance is not defined. In Federal Court, relevance is defined to be documents upon which a party intends to rely, or documents that tend to adversely affect the party’s case or support another party’s case (*Federal Courts Rules*, Rule 222)—not every document that is or was in a party’s possession, power, or control.

Moreover, relevance is typically assessed considering the pleadings—in this case the Notice of Hearing, the Notice of Application, the Response, and the Reply. Were broad discovery rights to be provided, this would encourage parties to plead broadly, possibly to include areas beyond the scope of the Board’s mandate and the statutory disclosure requirement.

The proposed disclosure standard is unclear and overbroad. If this approach were to be adopted, this standard is far too onerous for an administrative proceeding that is to be conducted expeditiously. Parties should be limited to producing those documents they will rely upon and leave other documents to case management and interlocutory motion practice.

Confidentiality

Under the PMPRB Rules, if a party files a document with the Board that contains confidential information, it must ensure that “CONFIDENTIAL/CONFIDENTIEL” appears prominently on the cover and pages of the document which contain confidential information: PMPRB Rule, 14(6). Under the current proposal, a party who has been served with an affidavit of documents and who opposes a claim for confidentiality of another party may bring a motion to the Board to inspect the document and determine the validity of the claim.

In the *Procysbi* case, there were numerous requests for confidentiality filed by the parties over the course of the proceeding. This was laborious, time-consuming, and expensive. To address confidentiality more efficiently, the Board should adopt a template Confidentiality/Protective Order, like that used in Federal Court.

TOPIC 3: Proposed Practice Direction on Standardizing Motions

The CBA Section recognizes the limited guidance in the PMPRB Rules with respect to motions and appreciates the additional guidance proposed in this Practice Direction.

Parties to Confer

Requiring parties to meet and confer in an attempt to resolve motion issues is a welcome direction from the PMPRB. The CBA Section recommends that the Practice Direction require the moving party to provide the responding party with a draft notice of motion identifying the relief sought and the principal grounds for the purpose of facilitating meaningful discussion and potential resolution at a meet and confer.

Timing

The proposed timelines for motions, particularly the five-business day deadline for responding materials and two days for a reply, are exceptionally compressed and will be difficult to meet in many cases. This is particularly true where a motion requires affidavits or addresses complex legal issues. By comparison, the *Federal Courts Rules* require a responding motion record in writing in the Federal Court of Appeal to be served within 10 days of service of the moving motion record (Rule 365(1)(b), Rule 369). The timelines, as currently proposed, will routinely necessitate requests for extensions, undermining the efficiency goals of the Practice Direction and increasing both administrative and adjudicative burdens.

The CBA Section recommends the adoption of default timelines that are longer, but still appropriately tight. We propose a 10-business day deadline for responding motion records following service of the notice of motion, and a 5-business day deadline for filing a motion reply. Moreover, consistent with

regular court practice, extending these timeframes should not require satisfying an EC standard (which problematic standard is discussed above). Rather, the Board should encourage and allow motion scheduling requests to be made by letter on consent of the parties. These proposed deadlines and procedures would better balance expediency with a fair opportunity to respond and reduce the need for extension requests.

TOPIC 4: Proposed Practice Direction on Electronic Filing and Page Limits

The CBA Section supports the adoption of electronic filing as the default format for submissions in this Practice Direction. However, the CBA Section notes that the proposed page limits, in several respects, are unduly restrictive when considered in light of the nature of proceedings before the PMPRB.

Matters before the PMPRB often involve complex factual records, technically complex pharmaceutical subject matter, and nuanced legal issues. Overly compressed submissions will tend to incentivize omission rather than efficiency. While the proposed direction permits parties to seek leave to exceed the prescribed limits, requiring advance requests as a matter of course risks adding an additional procedural layer to routine case management. In practice, this may lead to unnecessary correspondence and delay, particularly in cases where it is foreseeable from the outset that standard limits will be insufficient. A more proportionate approach, with higher default limits for certain documents as discussed below, would better align with the realities of proceedings before the PMPRB.

Written Submissions on Merits

Written submissions of no more than 30-pages on the merits and reply submissions of no more than 20-pages are reasonable starting points. In complex matters, 30-pages may be insufficient to properly address nuanced legal arguments, provide careful treatment of the evidentiary record, and engage appropriately with legal authorities. In such cases, page limits should be determined through case management as currently contemplated.

Written Submissions on Motions

Similar considerations for written submissions on merits apply to motions. Complex motions often cannot be meaningfully addressed within a 10-page limit without sacrificing analytical rigour. This overly restrictive page limit runs the risk of requests to case management for most motions, and unnecessary correspondence and delay. The CBA Section recommends that written submissions on motions be permitted up to 30 pages, consistent with Federal Court practice, unless case management directs otherwise. This will reduce the need for routine requests for extensions and the associated administrative burden and delay.

Expert Reports CBA Section submits that a 15-page limit for expert reports is inoperable. Overly compressed expert reports increase the risk of misapprehension, incomplete analysis, and downstream inefficiencies as issues re-emerge on reply or in oral testimony.

Expert reports in technical or scientific matters, such as those frequently before the PMPRB, require space to state conclusions, explain methodology, assumptions, and limitations in a manner that allows the PMPRB and opposing parties to properly assess the evidence. Additionally, the PMPRB Rules, Rule 8(3)(a) mandates the inclusion of an extensive list of information to be included in an expert report. It is not practical for this information to be adequately addressed in 15 pages. Overly condensed expert reports will risk misapprehension of the evidence and may adversely affect the quality of the PMPRB's decision-making.

The CBA Section would expect that virtually every expert report before the PMPRB will require more than 15 pages. The proposal requiring parties to make requests in writing for additional pages of expert reports as a matter of course risks adding an additional procedural layer to routine case management. The CBA Section recommends that there be no imposed limit for expert reports, which is

consistent with Federal Court practice and the *Federal Courts Rules*. The absence of a page limit does not mean an absence of control; relevance, scope, and proportionality will remain subject to case management oversight when appropriate.

TOPIC 5: Proposed Practice Direction on Expediting Failure-to-File (FTF) Proceedings

The CBA Section disagrees that there is any rationale for automatically expediting all FTF hearings by default. The 90-day expedited schedule proposed for these proceedings, whereby parties must file evidence, conduct cross-examinations and make written submissions -- is inoperable and unnecessary in practice for most cases. There is no basis for the Board to suggest that FTF hearings have “different consequences for rights holders” or that they “often do not involve complex legal questions”. The Board’s last FTF hearing, *re: Galderma*, addressed Board jurisdiction over a medicine with prices that had not been filed with the Board for almost seven years. FTF hearings can have serious financial implications for Rights Holders who can be liable for years of unreported sales (possibly also at excessive prices).

- As proposed above under Topic 1, any expedited hearings (FTF or excessive price) should be optional to pursue on the consent of the parties consulting with Case Management. This particular Practice Direction, specific to FTF hearings, should be removed as a result.

TOPIC 6: Proposed Practice Direction on the Use of Artificial Intelligence in Proceedings

The CBA Section agrees that a Practice Direction on the use of artificial intelligence in proceedings is needed. We propose that the PMPRB implement the Federal Court’s Notice to the Parties and Profession on [The Use of Artificial Intelligence in Court Proceedings](#). Alignment with Federal Court practice would promote consistency for parties and reduce uncertainty.

TOPIC 7: Proposed Practice Direction on Virtual Proceedings

The CBA Section recognizes the practicality of virtual witness testimony, virtual cross-examination, and virtual proceedings when appropriate. We propose that the PMPRB implement the general policy on [E-Hearing developed by the Federal Court](#). Alignment with Federal Court practice would promote consistency for parties and reduce uncertainty.

The CBA Section extends its thanks to the PMPRB for considering this submission and urges the PMPRB to carefully consider the proposed feedback and changes outlined above before finalizing the proposed Practice Directions.

Yours truly,

(original letter signed by Julie Terrien for Charlotte McDonald)

Charlotte McDonald
Chair, Intellectual Property Law Section