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Via email: john.pecman@cb-bc.gc.ca

Mr. John Pecman
Commissioner of Competition
Competition Bureau
50 Victoria Street
Gatineau, QC K1A 0C9

Dear Commissioner Pecman:

Re: White Paper on Pharmaceutical Patent Litigation Settlements

The National Competition Law Section of the Canadian Bar Association (CBA Section) appreciates the opportunity to comment on the Competition Bureau's paper, "Patent Litigation Settlement Agreements: A Canadian Perspective" (the White Paper).

The stated goal of the White Paper is to provide "some background on Canada's regulatory system governing generic entry, its competition legislation, and the Bureau's preliminary views as to how the Canadian competition law could apply to [pharmaceutical patent litigation] settlements" (Settlements). The White Paper may have been intended to provoke discussion about "the appropriate enforcement approach to [S]ettlements in the Canadian context" in the lead-up to a second and more substantive update (the Stage 2 Update) of the Bureau's *Intellectual Property Enforcement Guidelines* (IPEGs). However, the CBA Section believes that the White Paper has pre-empted a thorough and thoughtful debate about a number of key issues relevant to a determination of the "appropriate enforcement approach", including the applicability of section 45 of the *Competition Act* to Settlements and the need for a Settlement notification system.

In these circumstances, the purpose of this letter is to set out the CBA Section's strongly held views:

i) A Settlement should not be subject to challenge under section 45 of the Act unless it is a sham, a "naked restraint", or includes illegal conduct unrelated to the litigation or "beyond the scope of the patent"; and

ii) In the lead-up to the Stage 2 Update, and in any subsequent recommendations it may make for legislative changes that would impact Settlements in Canada, the Bureau should encourage and undertake a broad consultation regarding the many issues discussed in the White Paper, and it should develop informed guidance and recommendations that reflect the particular circumstances and unique features of the Canadian health care system.

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Section 45 of the Competition Act Should Not Apply to Settlements

In our view, the most troubling aspect of the White Paper is the Bureau's position that Settlements may, in some cases, be subject to challenge under section 45 of the Act. This position is questionable from both a legal and policy perspective, and if adopted could have serious negative consequences for the Canadian pharmaceutical industry.

While the White Paper states that the Bureau's general approach to assessing competitor collaborations, including Settlements that may delay generic entry, is reflected in the Bureau's *Competitor Collaboration Guidelines* (the CCGs)[1], it also appears to expand the potential applicability of section 45 to all Settlements. For example, the White Paper states:

> If a settlement is between competitors and includes conduct with respect to markets or products that are not the focus of the patent litigation or the conduct is beyond the scope of the patent, such as fixing a generic entry date beyond the term of the patent, the Commissioner would likely pursue the settlement under section 45 if the conduct is of a type prohibited under subsection 45(1).... Similarly, if the Bureau finds direct or circumstantial evidence that indicates that a settlement is a vehicle for a "naked restraint" on competition that is not implemented in furtherance of a legitimate collaboration or was motivated by factors beyond the issues associated with the litigation, the Commissioner would also likely pursue the settlement under section 45.

However, the Bureau also states:

> For settlements where neither of these two conditions are met, the Commissioner will use his enforcement discretion to decide whether to pursue the matter under section 45 or Part VIII of the Act. Considerations that may inform the Commissioner in the exercise of his enforcement discretion include, in general terms: the type and value of consideration flowing from the brand to the generic for an agreed upon generic entry date; the amount of time until generic entry; and any other available evidence.

It is not surprising that the Commissioner would reserve the right to challenge under section 45 the first category of Settlements discussed above. But the suggestion that the Commissioner might proceed on a criminal track in other circumstances – particularly those involving an assessment of *subjective* factors, such as the amount of consideration flowing to the generic – is troubling and would introduce significant uncertainty into the settlement process. The spectre of criminal prosecution would threaten to significantly weaken patent rights, which in turn could chill incentives to invest in welfare-enhancing innovation. It would also undermine the accepted public policy objective of promoting settlements over protracted, costly and unnecessary litigation,[2] and could dissuade generic pharmaceutical manufacturers from challenging patents on branded products in the first place.

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1 White Paper, at Section V. The CCGs, in turn, state that serious criminal sanctions under section 45 of the Competition Act are appropriately "reserved for agreements between competitors … that constitute 'naked restraints' on competition".

2 As the Supreme Court of Canada has repeatedly recognized, promoting settlements is "sound judicial policy" that "contributes to the effective administration of justice. See, e.g., *Kelvin Energy Ltd v Lee*, [1992] 3 SCR 235 at 259. The Court has also recognized that "there is an overriding public interest in favour of settlement, which promotes the interests of litigants and reduces the strain on an overburdened court system." *Sparling v Southam Inc* (1988), 66 OR (2d) 225 (HCJ) at 230, cited with approval in *Sable Offshore Energy Inc v Ameron International Corp*, 2013 SCC 37 at para 11.

Based on various statements in the White Paper, it appears that the Bureau's concerns are focused, at least in part, on Settlements that involve a payment of some sort. However, as numerous academics and commentators have pointed out, Settlements involving even substantial payments can be explained in many circumstances by factors that are competitively benign or pro-competitive. These include: (i) risk aversion by the patentee; (ii) an unwillingness to endure the high costs and duration of patent litigation; (iii) the limited liquidity of litigants (especially generic drug manufacturers); and (iv) differences in the parties' beliefs about trial outcome (regardless of substantive correctness).[3] Moreover, as the Bureau notes in the White Paper, the availability of section 8 damages in Canada may justify a payment to a generic manufacturer as part of a Settlement.

In our view, Settlements should not be subject to challenge by reason of a payment alone, much less to criminal prosecution. Subjective considerations, such as the size of a Settlement payment or the date of entry, should not be enough to justify criminal inquiry or sanction. Rather, these and other relevant aspects of Settlements (including the business rationale) should be considered as part of an overall assessment of their competitive impact under the civil competitor collaboration provisions in section 90.1 of the Act.

The prospect of a criminal challenge to a Settlement represents a significant (and unexplained) departure from the enforcement approach in the US, where the debate surrounding Settlements has focused exclusively on whether civil antitrust laws should apply and, if so, the appropriate standard of review. The application of criminal law has never been seriously considered in the US.

For these reasons, the CBA Section believes it would be appropriate for the Bureau to clarify that, absent the unique circumstances of the first category of Settlements discussed above, Settlements in Canada will not be challenged by the Bureau under section 45 of the Act.

Bureau Should Undertake Broad Consultation and Discussion Before Finalizing Its Views

Given that the White Paper provides the Bureau's first and only official guidance (preliminary or otherwise) on its potential enforcement approach to Settlements, the CBA Section was disappointed that it was released without the benefit and insight that advance consultation and discussion might have provided. The CBA Section would encourage the Bureau to undertake a broad consultation, and to engage in substantive discussions with the CBA (including the Competition Law and Intellectual Property Sections), the pharmaceutical industry and other stakeholders, before finalizing its views on Settlements as part of the Stage 2 Update.

Certain issues fundamental to an informed approach to Settlements – such as whether a Settlement constitutes "something more" than a mere exercise of an IP right – have yet to be considered in Canada and, accordingly, should be the subject of thorough and thoughtful discussion and debate. The CBA Section believes this would be useful in assisting the Bureau to develop a clear and effective enforcement approach in this important area.

The creation of a Settlement notification system is another issue that requires further discussion and debate. In the CBA Section's view, the Bureau has not adequately explained why a settlement notification regime is warranted, particularly given the Bureau's acknowledgement that the majority of Settlements do not raise competition law issues. The claim that a notification regime is required because the Bureau "doesn't know what it doesn't know" is insufficient justification for creating a potentially burdensome and costly notification regime.

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[3] For example, see Henry N. Butler and Jeffrey Paul Jarosch, "Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation" (2010) 96:1 Iowa L Rev 57 at 94-100.

A Canadian notification regime might also unnecessarily duplicate the existing notification regimes in the US and EU. To the extent that these regimes are intended to create as a disincentive to "anti-competitive" Settlement agreements, they arguably create this disincentive today, given the global nature of the pharmaceutical industry.

Finally, a Canadian notification regime would "single out" the pharmaceutical industry by imposing industry-specific obligations, inconsistent with the "general framework legislation" approach of the Act.

Conclusion

The CBA Section appreciates the opportunity to comment on the White Paper and hopes these comments will assist the Bureau as it considers its enforcement approach to Settlements. The CBA (including the Competition Law and Intellectual Property Sections) look forward to discussing these matters with the Bureau in more detail during the Stage 2 Update consultations.

Yours truly,

(original letter signed by Tamra Thomson for Jay Holsten)

Jay Holsten
Chair, Competition Law Section

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