

January 31, 2018

Via email: <u>Lise.Henrie@cas-satj.gc.ca</u>.

Lise Henrie Executive Director and General Counsel Federal Court of Canada 90 Sparks St. Ottawa, ON K1A 0H9

Dear Ms. Henrie:

## Re: PMNOC Timetable Checklist

We write on behalf of the Canadian Bar Association Intellectual Property Section's (CBA Section) Court Practice Committee to comment on a PMNOC Timetable Checklist proposed by the Federal Court of Canada.

The CBA is a national association of 36,000 lawyers, Québec notaries, law teachers and students, with a mandate to promote improvements in the law and the administration of justice. The CBA Section deals with law and practice relating to all forms of ownership, licensing, transfer and protection of intellectual property and related property rights, including patents and trademarks.

The CBA Section wishes to thank the Court for the time and careful thought and attention it has taken to prepare a PMNOC Timetable Checklist. The CBA Section feels strongly about retaining as much of the document's structure and content as possible, with one broad proviso. We believe the Checklist should serve as a non-binding list of items for counsel and the Court to consider in discussing, settling and implementing a schedule of next steps. Any schedule that flows from this Checklist should maintain some flexibility – particularly in the early days of the new PMNOC Regulations. While the Checklist is helpful, it should not be a replacement for an actual scheduling order. Even when an initial schedule has been agreed, the Checklist should be consulted as an ongoing resource, with departures made when and where appropriate. In brief, there should be leeway for parties to run their cases and be creative, knowing that not all steps can be anticipated and planned thoroughly at first instance.

Our members are concerned about the length of trials. While the Court aims to limit trials to two weeks, the Court has and should continue to have discretion to adjust the length of trial as needed (within the 24-month time period), taking into account among others whether a trial is the first proceeding involving the patents in issue or a follow-on proceeding.

Further, we recommend that two weeks be devoted to evidence and a further two days scheduled for oral argument. A short break between the end of evidence and start of argument will allow counsel to organize written and oral submissions and prepare compendia for the assistance of the Court. The number of days for oral argument may be adjusted if the evidence is extended beyond two weeks.

Under the current structure, a first case management conference (CMC) will take place early on; however, without a full set of pleadings, it will be difficult for parties and the Court to make appropriate long term decisions. We recommend a second CMC take place once the pleadings have closed to ensure that all scheduling factors have been appropriately considered.

As drafted, the Checklist sets out major steps under thematic headings. Users of the Checklist, and any derivative schedule, will find a chronological list easier to work with. We have attempted to minimize redrafting the chart. Rather, where appropriate, we suggest placement changes together with other specific, substantive comments in the attached chart.

Yours truly,

(original letter signed by Tina Head for Jordana Sanft)

Chair, CBA Intellectual Property Section – Court Practices Committee

## Patented Medicines (Notice of Compliance)

## PMNOC Timetable Checklist

Item No.	Description	Yes/ No	Date for Completion/Filing	CBA Section comments
Pleadin	ngs and Related Motions Phase			
1	Service and filing of Statement of Claim and submission of letter to the Registry that (i) identifies the proceeding as a NOC proceeding; (ii) requests that the proceeding be specially managed; and (iii) advises whether the stay has been renounced under paragraph 7(5)(b).	Yes	Date of issuance of Statement of Claim is considered day 1 for the purpose of the 24 month clock. *Pursuant to Rule 203(1) of the <i>Federal Courts Rules</i> [Rules], the Plaintiff has 60 days to serve the Statement of Claim from the date of issuance. Accordingly, the Court needs to encourage service within a shorter timeframe.	<ul> <li>Plaintiff should also identify any other current proceeding before the Federal Court involving the same drug.</li> <li>Plaintiff must deliver the following with the statement of claim: <ul> <li>(a) any information/documents requested in the notice of allegation under section 6(3.1)(a) and 6(3.1)(b);</li> <li>(b) alternatively, a document either explaining the steps being taken to locate the information or documents and a statement that they will be provided when feasible, or setting out the reasons why they are not being provided</li> </ul> </li> </ul>
2	Service and filing of Notice of Intention to Respond, together with an indication of whether the Defendant intends to challenge the validity of any claims in the patent, and whether there will be a counterclaim relating to validity seeking a declaration of invalidity and impeachment	Yes	Within 10 days of service of Statement of Claim	The Checklist should incorporate notice about <i>inter partes</i> testing to avoid dispute about when the notices are to occur
3	Plaintiff to requisition a case management conference and provide a jointly-proposed timetable of all steps leading up to trial (including duration, venue and language of trial) and dates of	Yes	Within 7 days of service of Notice of Intention to Respond	

	mutual availability for trial no later than 21 months from the date of commencement of proceeding			
4	Case management conference with Case Management Judge and Trial Judge	Yes	No later than 28 days from the date of issuance of Statement of Claim	
5	Motion to dismiss and/or strike pursuant to section 6.08 of the <i>Patented</i> <i>Medicines (Notice of Compliance)</i> <i>Regulations</i> [Regs] or Rule 221		*Should be tied to the CMC being held	
6	Motion for particulars		*Should be tied to the CMC being held	
7	Service and filing of Statement of Defence or Defence and Counterclaim	Yes	Within 30/40/60 days of service of Statement of Claim	
8	Service and filing of Reply or Reply and Defence to Counterclaim	Yes	Reply within10 days of service of Statement of Defence	
			Reply and Defence to Counterclaim within 30 days of service of Statement of Defence and Counterclaim	
9	Service and filing of Reply to Defence to Counterclaim	Yes	Within 10 days of service of Defence to Counterclaim	
10	Motion to amend any pleading			
11	Service and filing of any amended pleadings		*To be completed at the earliest date any such amendments are deemed necessary	
Docum	nentary Discovery and Related Motions Ph	ase		
12	Motion for confidentiality order under Rule 151/152 and/or section 6.06 of the Regs			If contemplated, should be discussed at first CMC

13	Motion pursuant to subsection 6.07(1) of the Regs for declaration that a patent or certificate of supplementary protection is ineligible for inclusion on the register			If contemplated, should be discussed at first CMC
14	Motion for joinder pursuant to section 6.02 of Regs			If contemplated, should be discussed at first CMC
15	Service of claims construction chart	Yes	*To be determined in consultation with the CMJ/Trial Judge	Should schedule separate CMC to discuss this. The timing and content of claim construction charts should remain flexible. Preliminary charts should not be ordered before pleadings have closed and before counsel have had the opportunity to confer.
16	Service of response to claims construction chart	Yes	*To be determined in consultation with the CMJ/Trial Judge	Should schedule separate CMC to discuss this.
17	To advise whether the parties are interested in a fully electronic trial	Yes		
18	Finalization of discovery plan	Yes	*The Court should set a target date, with flexibility, to be determined by CMJ (perhaps 90-120 days after service of Statement of Claim).	A discovery plan is best delivered following a counsel conference after pleadings have closed. Discovery plans should have a two-step approach (step 1 - plan for production and step 2 - plan for oral examination)
			Statement of Claim)	
19	Exchange of affidavits of documents and schedule 1 productions	Yes	*The Court should set a target date, with flexibility, to be determined by CMJ	
20	Motion to set aside or vary confidentiality rules under subsection 6.03(4) of Regs			If contemplated, should be discussed at first CMC

21	Motion for production of portions of the ANDS pursuant to subsections 6.04(1) of the Regs			If contemplated, should be discussed at first CMC
22	Motion for production of invention documents pursuant to subsection 6.04(2) of the Regs			If contemplated, should be discussed at first CMC
23	Motion for production of generic samples			If contemplated, should be discussed at first CMC. See the note above on <i>inter partes</i> testing.
24	Finalization of protective agreement		*If needed, a target date should be set at the CMC	
25	Motion for protective order		*If needed, a target date should be set at the CMC	
26	Motion for further and better affidavit of documents			
27	Motion for production from a non-party			
Dispu	te Resolution Phase			
28	Parties to advise whether they are interested in participating in a dispute resolution process at this stage or at a later stage in the proceeding	Yes	*First instance at the initial CMC *To be raised during any subsequent CMC	
29	Dispute resolution conference			
Exami	inations for Discovery and Related Motion	s Phase		
30	Delivery of request to admit facts			Parties should be encouraged to use requests to admit to streamline discovery
31	Delivery of response to request to admit facts			

32	Examinations for discovery	Yes		
33	Delivery of answers to undertakings	Yes		Parties should be encouraged to use shortened timelines for production of undertakings
34	Motions related to examinations for discovery			
35	Delivery of answers ordered on motion			
36	Motion to examine a non-party			
37	If required, follow-up examinations for discovery		*This should be exceptional and not the norm	
38	Delivery of answers to undertakings from follow-up examinations			
39	Motion related to follow-up examinations for discovery		*Consider removing this, to discourage parties from two rounds of discovery	The CBA IP Section agrees.
40	Delivery of answers ordered on motion Related to follow-up examination for discovery		*Consider removing this, to discourage parties from two rounds of discovery	The CBA IP Section agrees.
41	Motion for a preliminary determination of a question of law in relation to claims construction or other issue		*To be completed as early as possible following retention of experts	
Expert	Evidence and Related Motions Phase			
42	Service of infringement expert report(s)	Yes		Aim for service at least 4 months before trial
43	Service of invalidity expert report(s)	Yes		Aim for service at least 4 months before trial
44	Service of responding infringement expert report(s)	Yes		Aim for service at least 2 months before trial
45	Service of responding invalidity expert report(s)	Yes		Aim for service at least 2 months before trial

46	Motion for leave to file reply expert evidence			The topic of reply evidence consumed the greatest time in our discussions. <sup>1</sup> We suggest this be raised as an issue for resolution at an early CMC or TMC. There are three ways to proceed:
				(a) those seeking reply can bring a motion for reply, bearing the burden of establishing the need for reply;
				(b) provide for automatic reply, with the ability of a party to note objections to any part of the reply (which will require some mechanism for adjudication);
				(c) simultaneous exchange of reports- in-chief followed by simultaneous exchange of responsive reports.
47	Service of any reply expert evidence			Aim for service at least 1 month before trial
48	Delivery of any notification of objections to expert reports		*Target within 30 days of service of the report at issue	Add in before this step, a deadline for the exchange of expert qualifications.
Trial P	reparation and Related Motions Phase			
	Trial Management conference	Yes	To be commissioned once trial date fixed	To discuss schedule and conduct of trial and expected evidence
49	Service and filing of any evidence-in- chief affidavits	Yes	Schedule to be fixed by CMJ/trial judge	Guidance on fact evidence affidavits would be welcomed and consideration of how in-chief and cross examinations will play out will be needed to help structure fact evidence affidavits. <sup>2</sup>

<sup>&</sup>lt;sup>1</sup> The debate on this point was robust. There are divergent opinions between committee members and within each member's firm. This is an important item on which broad consensus won't be found. Given the need to minimize disputes under the new regime, the need to move quickly, and the lack of an effective appeal, this item should be left for the parties and the Court to work out in the specific circumstances of a particular case.

<sup>&</sup>lt;sup>2</sup> The purpose of moving away from written application to trials was to help the trier watch and learn as the evidence is developed. Counsel putting witnesses forward will likely want to have the witness spend some time in chief, in front of the trier of fact, to touch on the high points of the witness' evidence before being subject to cross-examination. If the only ability to lead evidence in chief is by way of affidavit, the first time the judge will see the witness is on cross, which can be unfair (unless you are the cross-examiner).

50	Service and filing of outline of intended viva voce testimony of fact witnesses	Yes	Schedule to be fixed by CMJ/trial judge	
	Service and filing of any fact stipulations upon which cross-examination is not required	Yes		
51	Motion for letters rogatory			To be served at least 60 days before trial. This is better dealt with in the discovery phase of the action but should be dealt with expeditiously for those witnesses for whom steps will be taken (e.g. inventors not under the control of the patentee).
52	Last day for delivery of answers to undertakings	Yes		This is better dealt with in the discovery phase of the action.
53	Deadline for final amendments to claims construction chart	Yes		
54	To advise whether the parties are interested in having the proceeding added to the trial ready list			Likely not practical
55	Service and filing of trial record	Yes	No later than 30 days before trial	
56	Filing of expert reports in chief	Yes	No later than 30 days before trial	
57	Further trial management conference to address issues such as identification of the patents and/or claims that remain in issue and specific claim construction disputes that still exist	Yes	No later than 30 days before trial	
58	Service of demonstrative evidence notice pursuant to Rule 287	Yes	No later than 30 days before trial	
59	Service and filing of any objections to demonstrative evidence		No later than 20 days before trial	

60	Service of any final request to admit facts or documents			
61	Deadline for responses to final request to admit facts or documents			
62	Service of proposed discovery read-ins	Yes	*To be determined by CMJ/Trial Judge	
63	Filing of agreed statement of facts	Yes	*To be determined by CMJ/Trial Judge	Target 2 weeks before trial
	Filing of joint statement of issues	Yes	*To be determined by CMJ/Trial Judge	Target 2 weeks before trial
64	Filing of joint book of documents	Yes	*To be determined by CMJ/Trial Judge	Target 2 weeks before trial
65	Presentation of joint or individual technical primer to trial judge	Yes	*To be determined by CMJ/Trial Judge	
66	Filing of jointly-prepared schedule setting out the expected order and content of the testimony of each witness	Yes	No later than 10 days before trial	Calendar should be filed setting out the witnesses that are expected to appear on each day, the expected length of their testimony and cross-exam, and the order of the witnesses.
Trial F	Phase			
67	Start of trial	Yes	By 20.5 months from date of issuance of Statement of Claim	The 20.5 month timeline should be viewed as a target. It should be at the discretion of the trial judge to adjust this timeline in complex cases so that the pre-trial steps can be completed effectively. In these circumstances greater assistance of the parties may be required to provide the court with further information prior to trial (i.e. through earlier involvement of the trial judge at the reply evidence phase or through the utilization of a tutorial or early briefing on key motions) so that a shortened timeline between trial and decision can be facilitated.

68	End of trial	Yes	By 21 months from date of issuance of Statement of Claim	
69	Release of judgment	Yes	By 24 months from date of issuance of Statement of Claim	

## **Considerations in Constructing Timetable**

- The Court has 20.5 months to work with from the date of issuance of the Statement of Claim to the commencement of trial.
- The pleadings phase could be longer than anticipated if there is a delay in service of the Statement of Claim or foreign parties are involved, as they have longer to file their Statement of Defence.
- Establish ballpark estimates for each phase of the litigation and then work with counsel to keep each phase within the estimate. For example:
  - Pleadings and related motions 3 months to close of pleadings (which assumes prompt service of Statement of Claim and delivery of Statement of Defence)
  - Documentary discovery and related motions 4-5 months (if 5 months, other phases need to be shortened)

Examinations for discovery and related motions – 7-8 months (if 8 months, other phases need to be shortened)

Expert evidence and related motions - 5 months

Pre-trial steps – 1.5 months