

Federal Court



Cour fédérale

NOTICE TO THE PARTIES AND THE PROFESSION

**GUIDELINES FOR ACTIONS UNDER THE
AMENDED PMNOC REGULATIONS**

September 21, 2017

These Practice Guidelines apply to actions commenced pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, as amended in 2017 (NOC proceedings). They supersede the *Case Management Guidelines for NOC Applications* dated May 2016.

Counsel and parties are advised to refer to the relevant Parts of the *Federal Courts Rules* (the Rules) as well as to any other relevant guidelines or notices to the profession, including *Case Management: Increased Proportionality in Complex Litigation before the Federal Court* and *Trial Management Guidelines*, which are available on the Federal Court website at: http://cas-cdc-www02.cas-satj.gc.ca/portal/page/portal/fc_cf_en/Notices.

I - Introduction

Proceedings may be brought under the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133), as amended in 2017 (the *Regulations*), enacted pursuant to subsection 55.2(4) of the *Patent Act* RSC 1985, C.P.4. Such proceedings were previously known as “NOC” applications.

The purpose of a NOC proceeding is for the Court to determine whether a proposed generic version of a drug of a “first person” (generally a brand or innovator company) as defined in the *Regulations* and already approved by the Minister for sale in Canada would infringe a patent listed on the patent register in respect of that drug. Only patents or certificates of supplementary protection¹ containing a claim for the medicinal ingredient, a claim for the use of the medicinal ingredient, a claim for a formulation containing the medicinal ingredient, or a claim for the dosage form, are at issue. However, all claims of a listed patent may form part of the proceeding. Thus, where a listed patent includes claims to a process, such additional claims will need to be addressed by the second

¹ The Regulations have also been amended to permit the listing of CSPs on the patent register and to litigate CSPs in s. 6 actions in appropriate circumstances. The Guidelines apply to CSPs that may be the subject of a s. 6 action.

person in the Notice of Allegation (NOA) and may be part of the proceeding. However, patents solely directed to the processes for making the drug cannot be listed, and will not be involved.

The process is initiated by a NOA (section 5 of the *Regulations*) served by a second person on the first person in respect of any new drug submission or a supplement to a new drug submission on a patent list submitted to the Minister of Health.

The eligibility of a patent to be on a patent list is governed by sections 4 and 4.1 of the *Regulations*.

In the past, the first person was required to initiate court proceedings within 45 days from the date of service of the Notice of Allegation. Such proceedings were governed by court rules related to **applications** (Part 5 of the *Federal Courts Rules*) and were commenced by way of Notice of Application. Due to amendments to the *Regulations* in 2017, proceedings must now be brought by way of **action** in accordance with section 6 of the *Regulations* and are governed by Part 4 of the *Federal Courts Rules*. The rules set out in Parts 1, 2, 3, 7, 8, 9, 10, 11 and 12 are also applicable, except to the extent they have been modified, as described below.

No other action may be brought against the second person for infringement of a patent or certificate of supplementary protection that is the subject of a notice of allegation, unless the first person or owner of the patent did not, within the 45 day period set out in subsection 6(1) of the *Regulations*, have a reasonable basis for bringing an action under that subsection.

If an interlocutory decision made by the case management judge or trial judge is appealed, the appeal must be made directly to the Federal Court of Appeal (FCA) within 10 days of the order being made, and leave must be granted by the FCA before the matter will be heard. Motions for leave are governed by Rules 352 to 356.

The Court may make any order in respect of costs, including on a solicitor-and-client basis, in accordance with the Rules (subsection 6.12). Pursuant to subsection 7(8) of the *Regulations*, as long as the Court has not made a declaration referred to in subsection 6(1), it may shorten or extend the 24-month period referred to in paragraph 7(1)(d) if it finds that a party has not acted diligently in carrying out its obligations under the *Regulations* or has not reasonably cooperated in expediting the action.

To avoid placing disproportionate burdens on the parties and the Court, and to expedite the case for trial, an action brought under subsection 6(1) of the *Regulations* shall automatically be a specially managed proceeding in accordance with Rules 383, 383.1 and 385 of the *Rules*: subsection 6.1(1)).

II – Initial Steps to Be Taken

The following guidance is provided regarding the manner in which NOC proceedings will be managed, in the absence of exceptional circumstances.

- Once a statement of claim is filed pursuant to subsection 6(1) of the *Regulations*, the matter shall be referred immediately by the Registry to the Chief Justice for the appointment of a case management judge and a trial judge.
- The statement of claim shall be accompanied by a letter stating that the action is a NOC proceeding, and requesting that the proceeding be specially managed pursuant to Regulation 6.10(1) in accordance with Rules 383, 383.1 and 385, and identifying any other current proceeding before the Court involving the same drug. The letter should also indicate if the stay has been renounced under paragraph 7(5)(b).
- Within 10 days of service of the statement of claim, the second person shall serve and file a **Notice of Intention to Respond**. The second person shall also indicate in the form whether it intends to defend by challenging the validity of any of claims of the patent(s) asserted by the first person and further whether it intends to serve and file a counterclaim relating to the validity of any of claims of the patent(s). Where invalidity is intended to be asserted, the second person shall also indicate in the form whether it intends to serve and file a counterclaim seeking a declaration of invalidity and impeachment or whether it will defend on the basis of invalidity only.
- Following service of the Notice of Intention to Respond, the parties are expected to reasonably cooperate and agree on expediting pre-trial procedures pursuant to section 6.09 of the *Regulations*, including with respect to the scheduling of the various steps leading up to trial, the order of evidence at trial, and the presentation of evidence at trial in a manner that could streamline the hearing, including the possibility of presenting testimony in the form of affidavits or declarations.
- Within 7 days of service of the Notice of Intention to Respond, the first person shall requisition a case management conference by letter, setting out:
 - a) a joint proposed timetable to govern the steps leading to the trial, including the estimated duration, proposed venue and language of the trial; and
 - b) dates of mutual availability of counsel for the parties for a trial to be completed no later than 21 months from the date of commencement of the action.
- The Court will expect parties to complete trials within two weeks, unless the Court determines that additional time is required.

- The proposed timetable shall incorporate deadlines for making voluntary productions, serving the parties' affidavits of documents, requesting particulars, exchanging claims charts, completing of examinations for discovery, and exchanging notices to admit. In the event that counsel cannot agree on a timetable, separate submissions should be made in advance of the case management conference.
- The letter shall also identify any motions that may be contemplated by the parties, including any motions relating to protective or confidentiality orders, production pursuant to subsections 6.04(1) and 6.04(2) of the *Regulations*, and for relief pursuant to subsections 6.07 or 6.08.
- Given the active role of the Court in case management, no pre-trial conferences shall be held in NOC proceedings.

III - Case Management Conference

- A case management conference will be held as soon as practicable, and in any event, no later than 28 days after the issuance of the statement of claim, to schedule all steps in the action in a timely and reasonable fashion and to deal with any matters of a procedural nature which should be addressed at an early stage of the proceedings. The prospects for settlement should also be addressed at that time.
- It is expected that any matter that may affect the orderly and expedient conduct of a NOC proceeding will be brought to the immediate attention of the case management judge. Counsel should ensure that they will be reasonably available for case management conferences, to complete discoveries on a timely basis and for an expedited trial.
- Counsel will be expected to have conferred among themselves before requesting any case management conference or bringing any motion. The case management judge may require that a case management conference be held before any motion is brought.
- Early claim construction can result in a reduction of the claims being asserted at the trial, or even lead to settlement of the entire proceeding. Therefore, the parties will be required to exchange claims charts in a format prescribed by the Court. A case management conference should be requisitioned with a view to limiting claim construction issues.
- At the request of, and at a time specified by, the trial judge, the parties shall provide a tutorial session in a form to be agreed to by the parties or on direction of the Court.
- Unless otherwise ordered or directed by the case management judge:

- a) the parties shall provide timely advance notice to the party to be examined of their respective discovery plans, including requests for the production of additional documents and possible lines of questioning;
 - b) the parties shall provide timely production of documents in advance of the examination;
 - c) the parties shall consider the use of requests to admit facts prior to taking discovery so as to shorten discovery where possible.
- It is expected that interlocutory procedures including any appeals shall be completed sufficiently in advance of the deadlines agreed to by counsel or fixed by the Court.
 - The parties may seek interlocutory relief, including an extension of scheduling deadlines, by letter if on consent or unopposed, subject to the sole discretion of the case management or trial judge.

IV - Trial Management Conference

- A trial management conference shall be requisitioned by the parties pursuant to Rule 270 of the Rules forthwith upon the trial dates being fixed to deal with matters relating to the conduct of the trial.
- For trial, the parties will be expected to adduce their evidence-in-chief by way of affidavit, subject to variation by the case management judge or the trial judge prior to trial. All such affidavits will have to be served and filed in accordance with the schedule fixed by the Court and, unless a prior order is made, the witness should be available for cross-examination at the trial. If any fact evidence is decided to be adduced by viva voce testimony then an outline of the areas of testimony of any facts witnesses who are expected to appear at the trial will also need to be submitted in advance of trial in accordance with the schedule fixed by the Court, with such witnesses being made available for cross-examination at trial. Where it is agreed by the parties that certain fact evidence may be introduced without cross-examination, parties are encouraged to adduce stipulations of such evidence to streamline the necessity for trial testimony.
- Demonstrative evidence sought to be used should be exchanged by the parties at least 30 days prior to the trial. Objections to any demonstrative evidence must be raised with the Court at least 20 days prior to the trial. No additional demonstrative evidence will be allowed at the trial.

- At least 30 days prior to the trial, a further trial management conference should be held to discuss, among other things, the identification of the patents and/or claims that remain in issue and any specific claim construction disputes that still exist.

“Paul S. Crampton”
Chief Justice