Federal Court  Cour fédérale

NOTICE TO THE PARTIES AND THE PROFESSION
CASE MANAGEMENT GUIDELINES FOR NOC APPLICATIONS
May 2016

Proceedings may be brought under the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133) (*Regulations*), enacted pursuant to section 55.2(4) of the *Patent Act* RSC 1985, C.P.4. Such proceedings are commonly known as "NOC" applications.

The purpose of a NOC proceeding is for the Court to determine whether or not the Minister of Health should be prohibited from issuing a Notice of Compliance (NOC) to a "second person" as defined in the *Regulations* (generally a generic company) in respect of that company's application to market a generic version of a drug of a "first person" (generally a brand or innovator company) as defined in the *Regulations* already approved by the Minister for sale in Canada. A prohibition order will not be granted if it appears to the Court that the allegations made by the second person about non-infringement and/or invalidity of the patent(s) listed on the Patent Register are justified. Only patents 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. Patents relating to the processes for making the drug, for instance, are not involved.

The process is initiated by a Notice of Allegation (section 5 of the *Regulation*s) served by a second person on the first person. The first person must initiate court proceedings (almost always in the Federal Court but not necessarily) within 45 days from the date of service of the Notice of Allegation.

The Court proceedings follow the Federal Courts Rules (Rules) related to applications (Rules 300 et seq) and are commenced by a Notice of Application. Evidence is given by way of affidavits and transcripts of any cross-examination.

The following guidance is provided regarding the manner in which NOC proceedings will be managed in the absence of exceptional reasons for departing from this general approach:

- These proceedings are summary in nature. Hearings are typically conducted in 2 or 3 days, and no more than 5 days will be assigned, absent extraordinary circumstances.

- A case management conference (CMC), presided by both the case management judge and the hearing judge (if different than the case management judge), should be held within 30 days after the requisition for hearing has been filed. The case management judge will encourage filing of the requisition for hearing as early as possible to facilitate setting the hearing date. The topics to be canvassed at that time typically will include:
    - The timing for voluntary productions
    - Verification orders
    - The possibility of interlocutory motions (e.g., ss 6(5) and (7) of the *Regulations*; Rule 312 of the *Rules*)
    - Whether any protective orders (and later confidentiality orders under Rule 151 if needed) may be required and what appropriate scope of such orders will be permitted by the Court
    - The timing for service of affidavits and filing proof of service, and whether the application will make a request for the reversal of evidence
    - The date for completion of cross-examinations
    - The target date for the requisition for hearing
    - The timing for filing of application records
    - The requirements for status updates and/or CMCs and CMCs prior to motions being filed
    - The prospect of settlement before the case management judge or judicial officer other than the hearing judge
    - Whether the hearing is to be conducted in English, French, or both;
- Any confidentiality order respecting some or all of the evidence may be re-visited by the Judge hearing the matter;
- Pursuant to Rule 52.4(1) of the *Rules* and Section 7 of the *Canada Evidence Act*, each party is limited to 5 expert witnesses, unless leave to exceed that number is otherwise granted by the Court in exceptional circumstances.
- At the hearing, counsel for the first person will usually lead off and present the entirety of the first person's case, including oral argument. Counsel for the second person will typically follow, again, presenting evidence and argument; the first person may reply;

- The Minister of Health is usually a named Respondent and is served with the relevant documents; however, in practice, the Minister rarely takes any active role in the proceedings;

- The Court must render a decision within 24 months from the date that the Minister received proof of the issuance of any Notice of Application (section 7(1)(e) of the *Regulations*). That time period may be extended, if the parties consent or on motion if the Court finds that the second person has failed, at any time during the proceeding, to reasonably cooperate in expediting the application. That time period may also be shortened, if the parties consent or on motion if the Court finds that the first person has failed, at any time during the proceeding, to reasonably cooperate in expediting the application.

- If there is a Confidentiality Order and if the Reasons include confidential material, the Reasons (but not the Confidentiality Order itself) may be released confidentially to the parties, who may be given a short period of time (such as 10 days) to make submissions as to what passages of the Reasons should remain confidential. The Court may or may not agree, whereupon a public version of the Reasons are released, with the confidential information redacted;

- Early claim construction can result in a reduction of the claims being asserted at the hearing, or even settlement of the entire proceeding. Therefore, pursuant to Rule 107(1) of the *Rules*, at least 90 days prior to the scheduled hearing date, or on another date to be set by the case management judge, on written request by the parties at least 120 days before the hearing date, the parties will submit claims charts in a format that has been previously approved by the case management judge at a case conference. A case conference meeting will follow with a view to limiting claim construction issues, prior to the hearing;

- A Hearing Management Conference, including both the case management and hearing judges (if different), should be conducted approximately two (2) months before the scheduled hearing date, but after the Respondent's memorandum of fact and law has been filed. A further Conference may be held as needed. Topics to be discussed will typically include:

    - The identity of all parties, their solicitors and counsel who will represent them at the hearing;

    - Whether a tutorial session would be of benefit to the Court, in a form to be agreed to by the parties or on direction of the Court;

    - Any remaining motions left to be dealt with before the hearing and when and by whom they will be heard - no evidentiary motions will be entertained at the

hearing except for those dealing with a clear issue of admissibility. Parties may identify portions of evidence objected to by highlighting same or otherwise clearly indicating those portions to the Court.

- Any prospect of settlement or mediation;
- The identification of all evidence to be presented at the hearing - this will include the affidavits of factual witnesses, of expert witnesses and transcripts of cross-examination; all of the above may include exhibits;

- No new demonstrative evidence will be allowed at the hearing. Demonstrative evidence sought to be used should be exchanged by the parties at least 30 days prior to the hearing. Objections to any demonstrative evidence sought to be used must be raised with the Court at least 20 days prior to the hearing. Any audio/visual materials used at the hearing must also be available for the Federal Court of Appeal on any appeal;
- At least 30 days prior to the hearing, a further hearing management conference should be held to discuss, among other things:
  - The identification of what patents and claims remain in issue and any specific claim construction disputes that still exist;
  - Provision of a Statement of Agreed Facts and/or Documents to the Court. Examples of agreed facts to be considered include, but are not limited to:
    i. Background science
    ii. Expert qualifications
    iii. Definitions of the person skilled in the art
    iv. Common general knowledge
    v. Claim construction
    vi. What allegations of non-infringement or invalidity are still live issues;
  - Failure to reasonably agree on facts and documents will result in significant cost consequences to any party the Court decides has been unreasonable or obstructive in reaching agreement;
  - If there is a Confidentiality Order, the parties must advise the Court if that Order needs to be maintained, whether documents should be redacted so as to contain only non-confidential evidence and documents, and whether the hearing to be held in camera;

- At least 15 days prior to the hearing:
    - The parties must serve and file a Compendium in which copies of only the relevant pages from the affidavits, the transcripts of cross-examination, portions of documents, and relevant jurisprudence are reproduced and tabulated to conform to the written Memorandum of Fact and Law. This should also be provided electronically on a USB key or other electronic media (e.g. e-mail) as may be agreed to by the Court and the parties (the whole of the evidence may be on a USB key), at least two days before the hearing. Counsel should also certify that any USB key provided to the Court has been scanned to remove all viruses;
    - While the Court would appreciate delivery of Outlines of Argument and any related Compendium of Argument prior to the commencement of the hearing, they may be served and filed during the hearing of the Application and shall not exceed 30 pages in length, except with leave of Court;
    - The parties must advise the Court if a court reporter is required, as opposed to Digital Audio Recording, and whether a daily transcript will be needed;
- Equal time will be allocated to each of the parties unless otherwise agreed to prior to the hearing;
- Prior to the hearing, parties should also agree upon the hours of hearing;
- Within 15 days following the hearing or judgment being rendered, as will be decided by the hearing judge after consultation with the parties, the parties will submit draft bills of costs to the Court;
- All NOC hearings and trials generally in the Federal Court are in future to be conducted on a fixed-end basis. In other words, all hearings and trials will, save in exceptional circumstances, be required to be completed within the time frame allocated at the time of scheduling the hearing or trial.

« Paul Crampton »
Chief Justice