Pharmaceutical and Biotechnology Litigation in the Federal Court of Canada

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General outline of the system

Canada has a linkage system similar to the Hatch-Waxman system in the United States. This system is governed by the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*). Those that practice in this area often call these proceedings: NOC Proceedings. The *NOC Regulations* apply to both pharmaceutical and biotechnology products.

In order to obtain regulatory approval for a new drug in Canada, a New Drug Submission (NDS) must be filed. If the drug is approved, a Notice of Compliance (NOC) is granted by Health Canada. Generic companies can file an Abbreviated New Drug Submission (ANDS) to obtain approval, showing bioequivalence to the innovative product (among other things). For a biosimilar, a biosimilar NDS is required. The biosimilar NDS will have a reduced data package, however, the nature of the data needed will be determined on a case-by-case basis in conjunction with Health Canada.

A company selling a drug with regulatory approval by way of an NOC from an NDS can list certain types of patents on the Patent Register (which is similar to the Orange Book). If a second company wishes to enter the market with a direct or indirect comparison to the NDS of the innovator, they must address the patents listed on the Patent Register. This is done either by agreeing to await expiry of the listed patents, or by sending a Notice of Allegation (NOA) and detailed statement setting out the reasons the patent is not infringed and/or is invalid.

Once an NOA is served, the innovator must use the *NOC Regulations* to litigate the issues raised in the NOA, unless there is no reasonable basis to bring an action at that time. The proceeding must be started in the Federal Court within 45 days of service of the NOA.

The generic or biosimilar filer is typically referred to as the Second Person. The innovator company selling the drug in Canada is typically referred to as the First Person. The patentee must be joined as a party to any proceeding that is started.

Due to the Federal Court hearing the majority of IP cases, its judges generally have far more experience with IP issues compared to provincial Court judges. Federal Court judges have varied backgrounds, some of which are technical.

The patent register

Patents and Certificates of Supplemental Protection (CSPs) are eligible for listing on the Patent Register if they contain a claim to the:

- Medicinal ingredient;
- Formulation containing the medicinal ingredient;
- Dosage form; or
- Use of the medicinal ingredient; and
- The subject matter of the claim has been approved by Health Canada.

The notice of allegation

The NOA must contain a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug. It also must contain a statement of the legal and factual basis for the allegation(s) of non-infringement and/or invalidity made.

Additionally, the following documents must accompany the NOA:

- Certificate by the Minister of Health of the date of filing of the ANDS or biosimilar NDS;
- Address for service;
- Names and contact information for solicitors of record;
- Searchable electronic copy of any portions of the ANDS or biosimilar NDS that are relevant to determining infringement; and
- Electronic copies of any documents used to allege the patent(s) at issue are invalid.

The NOA can request the name and contact information for any inventor who might have information relevant to the invalidity allegations. The NOA can also request any laboratory notebooks, research reports or other documents relevant to determine whether a property, advantage or use asserted to be part of the invention by the Second Person to be part of the invention, had been established as of the filing date of the patent.

If the First Person is not the patentee, as is usually the case, they must forward the NOA to the patentee within five days of being served, and notify the Second Person without delay.

Pleadings

In response to an NOA, the First Person can choose to start a proceeding by issuing a Statement of Claim. Pleadings then proceed as normal. If inventor information and/or laboratory notebooks etc. are requested, they must be served with the Statement of Claim or a reason provided as to why they can only be produced later.

Pleadings set out the cause(s) of action and the relief sought, as well as any defences or counterclaims. The Statement of Claim and Statement of Defence are the main pleadings together with any Counterclaim and Defence to Counterclaim. Parties can file a Reply, but the Reply cannot raise a new cause of action. Pleadings tend to be substantive in nature, and must set out all of the material facts upon which a party relies for each allegation. Law does not need to be pled, nor does evidence. Pleadings in Canada tend to be longer and more detailed than in the United States. The pleadings form the boundaries of both discovery and the issues at trial. Thus, sufficient detail is needed to ensure that a party knows the case they have to meet and can discover other parties in relation to that case.

The First Person cannot join a patent or CSP to the proceeding that was not the subject of the NOA that gave rise to the proceeding. However, the First Person can allege infringement of all claims in the patent or CSP that was listed on the Patent Register, even if not all claims are eligible for listing.

Case management

Case management is automatically assigned in an NOC Proceeding, typically within days after such a proceeding is started. The Prothonotary (also known as a Case Management Judge) manages timelines to get to trial and hears most interlocutory motions. One of the benefits of case management is that, if the parties are in agreement, a joint letter or consent order can be submitted to the Court, rather than full motion records, thus expediting and simplifying many of the steps.

Confidentiality

The Second Person can impose confidentiality restrictions on the First Person and the patentee with respect to the regulatory documents provided. The First Person can similarly impose confidentiality restrictions on the Second Person with respect to the laboratory notebooks and other research documents provided. These unilateral impositions are binding and enforced by the Court unless set aside by motion.

Interlocutory injunctions

In an NOC Proceeding, the generic or biosimilar regulatory approval is linked to the judicial outcome. If an NOC Proceeding is started within 45 days of receipt of a NOA, the generic or biosimilar filer cannot receive regulatory approval for that drug for 24 months, or until a decision issues in their favour, whichever occurs first.

Discovery

Canadian documentary discovery is more limited than in U.S. cases. All relevant documents must be produced. However, the concept of relevance is generally described as all documents that will help or hurt either your case or the other sides, thus underscoring the importance of proper pleadings. All documents that a party plans to rely on at trial must be produced. Documents can be withheld from production if they are privileged. Furthermore, documents should not be unilaterally redacted. Parties will often agree to certain types of redactions and allow counsel to review such redactions

on a “counsel’s eyes only” basis if questions arise surrounding their propriety. On motion, further documents that relate to a “train of inquiry” that would help or hurt the case may be ordered. Proportionality to the size of the case is also relevant to production.

Oral discovery is also much more limited. A single representative of each party is examined for discovery. This person is expected to answer or be able to obtain the answer to questions relevant to the pleadings. Undertakings may be given if the answer is not known at the time. Parties can answer irrelevant questions under objection. The Court is trending toward preferring answers given under objection compared to refusals. However, refusals can be maintained for privilege and for plainly irrelevant fishing expeditions. The discovering party can bring a motion to compel further answers if it feels that refusals were improperly given.

Answers from the discovery of the party’s representative can be read in as evidence at trial by the opposing party. A party cannot use answers from discovery of their own witness.

In addition, any inventor or other assignor can be examined for discovery. Assignor discovery transcripts can only be used to impeach that person if they testify at trial, and cannot be read in as evidence at trial. Other non-parties can only be discovered with leave of the Court.

Markman hearings and summary judgment practice

Canada does not have Markman hearings *per se*. Summary judgment and summary trial motions are not permitted in an NOC Proceeding.

Expert witnesses

Experts are not deposed or cross-examined before trial. A schedule is set for the exchange of expert reports before trial. Parties are encouraged to make any objections to expert reports as early as possible. Often, the parties will also agree to provide expert reports to the trial judge ahead of trial.

Leave of the Court is required to call more than five experts at trial.

At trial, the expert report, once tendered, is taken as read (subject to any outstanding objections). Expert evidence in chief is generally limited, usually to between one and three hours, to highlight portions of the opinion and “warm-up” the expert prior to cross-examination. Cross-examination is done live before the trial judge, and is generally not subject to any time limits.

Trial

As the stay of generic or biosimilar drug approval is 24 months, the Court committed to issuing a decision within that period. Shortly after the Statement of Claim issues, the Court will assign a trial date that is 2 years, less 3 months and 2 weeks in the future. This gives 2 weeks for trial and 3 months for the Court to write its decision.

The decision maker in Federal Court is a judge only, not a jury.

Costs/attorney's fees

A portion of attorney's fees as well as reasonable disbursements (including for all testifying experts) are typically recoverable by the successful party.

Recoverable costs are generally determined by use of a tariff, specifying steps for which costs can be recovered as well as a range of units associated with each step, with the Court determining the appropriate number of units given the circumstances of each individual case. When costs are awarded pursuant to the tariff, recovery is typically around 10 per cent of actual costs.

Recently, however, the Court has tended toward awarding 25-50 per cent actual fees in big IP cases, instead of following the tariff. However, this remains a matter of discretion for the Court.

Costs are awarded at the discretion of the Federal Court, which also hears immigration and admiralty matters, as well as cases against the Federal Government. The Court is currently looking to increase the amounts recoverable under the tariff by adding additional recoverable steps; however, since IP litigants range in size and worth, it is always a balance for the Court when determining costs.

Remedies

The remedy in an NOC Proceeding is an injunction restraining issuance of market approval to the generic or biosimilar filer until the expiry of the patent at issue.

As these proceedings are pre-market entry, there are no damages or profits to seek.

Section 8 proceedings

If the First Person is unsuccessful in or discontinues the proceeding, the *NOC Regulations* provide a new cause of action allowing the generic or biosimilar filer to sue the innovator for compensation in respect of loss suffered from being kept off the market. The Minister of Health certifies a date upon which the Second Person's drug submission would have been approvable but for the operation of the *NOC Regulations*.

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