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Welcome to the Canadian pharmaceutical patent dance

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Authors: J. Bradley White, Nathaniel Lipkus

For nearly 25 years, Canada's *Patented Medicines (Notice of Compliance) Regulations* have been the cornerstone of pharmaceutical patent litigation in Canada. Loosely modeled on the US *Hatch-Waxman Act*, the Regulations sought to balance effective patent enforcement over new and innovative drugs with the timely market entry of lower-priced generic alternatives.

However, after many years of extensive litigation under the Regulations, the Canadian system has come under increasing criticism both domestically and internationally. Originally conceived as a summary and efficient proceeding, based on a paper record involving affidavits and out-of-court cross-examinations rather than a full trial, litigation under the Regulations is now anything but. Given the increasing factual and legal complexity of cases, judges find themselves faced with dozens of volumes of expert evidence, without the aid of live witnesses to provide assistance in resolving the disputed issues. Both parties litigate without the benefit of formal discovery or subpoena power, meaning that key documents and testimony may often be missing from the evidentiary record.

The system is often criticised for not finally resolving the issues between the parties. Although intended to streamline initial litigation under the Regulations, the Regulations permit losing parties to commence a second proceeding over the very same patents over which they lost. This is often characterised as causing "double-jeopardy", viewed as particularly troublesome to international companies litigating in multiple jurisdictions. And the quid pro quo of permitting follow-on litigation was the lack of appeal available to unsuccessful patentees from the case at first instance under the Regulations.

All this is finally set to change. On September 7 2017, the Canadian government finalised amendments to the Regulations that will fundamentally alter Canada's patent linkage system. The amendments will change the nature of proceedings from summary applications to patent trials by way of actions, involving full rights of appeal, live witnesses and final judgments on disputed patent issues. The amendments were the result of a Canadian commitment in the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) and came into force as part of CETA implementation on September 21 2017.

The amended Regulations are intended to re-establish a balance between effective patent enforcement and timely entry of generic and biosimilar versions of branded products. The balance is unique in the world and will re-situate Canada as a leading jurisdiction for pharmaceutical and biotechnology patent litigation. This article discusses key changes to the Regulations of interest to life sciences companies doing business in Canada.

North America's new rocket docket

One challenge in moving from summary applications to full trials will be ensuring that all cases are adjudicated within a 24-month deadline, which remains unchanged from the

deadline under the current system. During a government consultation period, the brand-name pharmaceutical industry attempted to extend the 24-month deadline to 30 months but was unsuccessful.

Canada's Federal Court is readying itself for litigation under the new Regulations. As set out below, in an effort to move cases ahead quickly, litigants will undertake significant and frontloaded documentary discovery obligations. Oral discovery will proceed in the normal course. At trial, although all witnesses will be subject to cross-examination, to minimise trial time, much of a party's evidence in chief will be tendered by way of written affidavit in advance of trial, rather than live at the trial itself.

When serving its initial pleading, the Notice of Allegation (NOA), the generic or biosimilar applicant will be required to include all documents it relied upon to support allegations of invalidity, and a copy of the relevant portions of its regulatory submission. Patentees will be faced with similarly significant document production obligations. When requested by the generic company, patentees will be required to disclose inventor contact information and invention documents relevant to an allegation, as well as laboratory notebooks. Disclosing parties may impose reasonable confidentiality obligations, reviewable by the court.

Discovery in patent litigation in Canada is narrower than in the United States. Typically, one corporate witness is examined for each party, in the nature of a 30(b)(6) witness discovery in the United States. Inventors may also be examined, although their answers are not binding on the patentee. Depositions of third parties or other party witnesses are not permitted as of right, although it is possible to obtain third-party discovery based on demonstrated necessity.

The Federal Court is aiming for pharmaceutical litigation trials to last a maximum of two weeks and to take place within 21 months of commencement of a proceeding.

No more double jeopardy, but market certainty is not guaranteed

By replacing summary proceedings with full actions under the *Patent Act*, judicial decisions will result in a final determination of patent infringement and validity for patents litigated to a conclusion.

Decisions will be appealable by both parties. Patentees are required to assert listed patents in response to a NOA if they had a reasonable basis to launch an action, or else forfeit their right to do so. However, there are several scenarios under which a generic or biosimilar applicant may seek market certainty under the regulations yet still be put in a position to launch at risk. For example:

- A patentee may waive their right to a 24-month stay, thereby forcing a generic or biosimilar applicant to consider launching their product before disposition of the litigation;
- A patentee may have unlisted patents that they wait to assert until after a generic or biosimilar entrant has launched; or
- New facts may come to light upon market entry that ground a distinct claim for patent infringement that was not reasonably available or is not addressed by the earlier litigation.

Additionally, a first-moving generic or biosimilar applicant may choose to seek only an *in personam* rather than *in rem* invalidity remedy, such that a finding of patent invalidity does not remove a listed patent from the Patent Register. In such cases, subsequent entrants may still be required to litigate a previously-litigated patent.

Notice letter is less consequential

Under the old regulations, the NOA defines the scope of the ensuing patent proceeding. Generic companies' arguments in court are restricted to what is included in the NOA. If a generic company's arguments are not supported in the NOA, the NOA is held to be insufficient to support that argument in court.

The amendments give generic companies more latitude in drafting the NOA, since the scope of proceedings would be defined by the pleadings in the action, rather than allegations in the NOA. The amended regulations will retain serving the NOA as the first step in pharmaceutical litigation but will alleviate some of the strict rules that have developed in the jurisprudence regarding the NOA and its sufficiency which have frustrated generic drug manufacturers. Notably, the NOA needs to be detailed only in respect of invalidity allegations, without limiting the issues and arguments that may be raised in the generic companies' defence to an infringement action.

The amendments create a new strategic consideration for generic companies contemplating litigation. Generic companies may wish to elect to not allege invalidity in the NOA and subsequently raise invalidity in response to pleaded infringement allegations. The practical effect of providing inadequate detail of an allegation remains to be determined, although it is anticipated that judges may be willing to extend the 24-month stay preventing generic or biosimilar approval where the generic/biosimilar applicant has delayed in detailing its invalidity position.

Enhanced section 8 damages

If a generic or biosimilar company wins litigation under the Regulations, it may be entitled to damages for losses arising while patent litigation was pending (often referred to as section 8 damages). This compensation which is available under both versions of the regulations is in lieu of a market exclusivity that is provided to a first-mover under the *Hatch-Waxman Act*.

Under the old Regulations, the generic or biosimilar company could only claim damages for the period between the day on which the drug submission would have received an NOC and the day the proceeding concluded in favour of the generic company.

This meant that first-movers could not recover permanent loss of market share resulting from subsequent generic entrants being able to catch up and tie the first-mover to market. The amendments now enable applicants to capture losses arising from delayed market entry that persist after the litigation has ended. As a result, section 8 damages may now better compensate the first-moving generic company for loss of long-term market share.

Game theory over 24-month stay

Under the old Regulations, upon commencement of litigation, patentees benefited from an automatic 24-month stay preventing Health Canada from approving a generic applicant's drug. However, the patentee could not practically relinquish this stay if it was concerned that a generic entrant might win the litigation and sue for section 8 damages. Relinquishing the stay would effectively end the proceeding, which would be deemed moot once Health Canada issued the approval.

Under the new Regulations, the patentee will now have more strategic flexibility. The patentee is now permitted to relinquish the 24-month stay without prejudice in the

underlying infringement action. The stay must be relinquished at the outset of the proceeding. By relinquishing the stay, the patentee avoids potential liability for section 8 damages yet remains able to pursue the patent infringement litigation. At the same time, the generic or biosimilar applicant is put to the decision whether to enter the market at possible risk of patent infringement if they do not succeed in the litigation.

This new strategic flexibility for patentees introduces significant strategic considerations for generic and biosimilar applicants. In the past, companies have obtained significant section 8 damages rewards even without succeeding in earning significant downstream profits in the marketplace. Companies may have had incentive to serve NOAs with a view to litigation rewards rather than market rewards. This non-market incentive will now no longer exist. Under the new Regulations, patentees will have the unilateral ability to eliminate section 8 damages liability by relinquishing the stay.

In considering whether to relinquish the stay, patentees will weigh the risk of section 8 damages based upon the strength of their case and other factors that could affect section 8 damages liability, including a follow-on entrant's willingness to undertake an "at-risk" launch, competitive dynamics, and the impact of lifecycle management strategies on a damages award. Although it may sometimes make sense to relinquish the stay, patentees will not do so lightly due to the anticipated profit reduction and loss of market share from a new market entrant. If the patentee relinquishes the stay and is successful in litigation, it will stand to collect damages for patent infringement arising from the follow-on entrant's at-risk launch.

The dance is about to begin

Canada's new patent dance is about to begin, and all comers – generics and biosimilars – are invited. The amendments come on the heels of other significant IP changes for pharmaceutical companies in Canada – including elimination of the "promise doctrine" from the law of patent utility, extension of patent terms arising from regulatory delays, modernisation of the Patented Medicines Prices Review Board, and evolution of Canada's drug pricing and reimbursement framework more generally. At a time of rapid change, the Regulations will contribute to fundamental shifts in the pharmaceutical patent landscape in Canada. As always, the winners will be those who make the best moves.

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