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The first steps taken at the Canadian pharmaceutical patent dance

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In September 2017, the Canadian government implemented extensive and fundamental changes to Canada's patent linkage system. The amendments to the *Patented Medicines (Notice of Compliance) Regulations* (PMNOC Regulations) aligned the existing patent linkage system with Canada's obligations under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA).

As outlined in our article one year ago, *Welcome to the Canadian Pharmaceutical Patent Dance*, prior to the 2017 amendments, the PMNOC Regulations attracted domestic and international criticism. Litigation under the previous regulations was supposed to be by way of a summary and efficient proceeding, based upon a paper record and out-of-court cross-examinations. Over time, however, and given the stakes, proceedings became unwieldy, costly and resource-intensive, with judges forced to adjudicate highly complex patent cases based on dozens of volumes of conflicting expert evidence and without the benefit of live testimony.

One of the central criticisms of the previous PMNOC litigation process was that, unlike in the United States for example, the litigation did not finally resolve disputed infringement and invalidity issues. The previous regime was a dual track system with both summary proceedings under the PMNOC Regulations and also potentially separate patent infringement or invalidity (called impeachment) litigation under the Canadian Patent Act dealing with the same underlying issues. Decisions under the PMNOC Regulations were not final judgments on the issues of patent infringement and validity. Moreover, if regulatory approval was issued to the generic litigant while a patentee's appeal of a PMNOC loss was pending, that appeal would become moot. This had the effect of creating a situation where a party that lost a PMNOC proceeding – whether brand or generic – could then commence a separate action on the same issues on which they had lost.

CETA required Canada to implement a system providing "equivalent and effective rights of appeal" for litigants subject to a patent linkage system (i.e. Canada). However, in view of the concerns identified above, the 2017 amendments to the PMNOC Regulations went further, with the aim of streamlining the process by eliminating the dual track system. The 2017 amendments provide for only a single action under the PMNOC Regulations, with equal rights of appeal for patentee and generic companies, live testimony at trial, and binding judgments on infringement and validity. The amendments also introduced new rules relating to scheduling, document production, confidentiality, and the scope of damages.

As the first cases to be litigated under the new PMNOC Regulations move towards trial in late 2019, we are seeing pharmaceutical litigants take their first steps at the new Canadian pharmaceutical patent dance. In this article, we provide some early insights into the Regulations.

Time to trial – from waltz to quickstep

Last year we predicted that one of the consequences of the amendments would be to create North America's newest "Rocket Docket", with complex actions being compressed into a 24-month timeframe.

The Federal Court, which has jurisdiction to hear PMNOC actions, has taken a very hands-on approach to managing the 24-month timeline. Each PMNOC action is a "specially managed" proceeding, with a case management judge assigned to help expedite the process. The case management judge may fix specific times for the completion of any interim step in the process, order a status review or pre-trial conferences, or provide any direction for the quick resolution of a matter. The Court maintains the discretion to extend the deadline past 24 months, but early indication is that the Court will make best efforts to adjudicate matters within the 24 months.

For example, in *Genentech, Inc. et al v Amgen Canada Inc*, involving four patents associated with the drug Herceptin®, even in the face of significant pre-trial motions, the case management judge would not entertain arguments that the 24-month period was inadequate to deal with the issues in the case. She rejected outright the proposition that the timeline was either "accelerated" or unfair in the context of the plaintiff having to deal with a motion to dismiss under tight time constraints. In this case and in parallel litigation involving Celltrion, for which our firm is counsel, the Court has insisted on holding trials within 21 months of commencement of the proceeding, and limited the trial to 10 days to address all patent claims and all infringement and invalidity issues arising in relation to four asserted patents. By comparison, in proceedings brought shortly before the amendments to the old PMNOC Regulations and also involving Celltrion, where no live testimony was involved, the Court set aside 15 days for a hearing on four asserted patents. Genentech's proceeding against Amgen has now discontinued, but trial in the Genentech-Celltrion proceedings is scheduled for September 2019 and will be the first trial under the new system.

The Court is clearly using the opportunity presented by the new amendments to direct compressed timelines. This development was entirely expected, given the strain that previous litigation was placing on resources. It is also clear that in order to meet these objectives, the Court is expecting, and actively encouraging, an even higher level of cooperation between counsel. Its *Guidelines for Actions Under the Amended PMNOC Regulations*, which contain a comprehensive overview of how the litigation time should be allocated, were released the same day the amendments came into force. According to these Guidelines, the Court expects all PMNOC trials to be completed within two weeks or 10 business days. One way that they have proposed to compress trials is to urge parties to provide evidence in chief by way of written affidavit, with witnesses to be cross-examined at trial. The Court is also urging parties to exchange early claim constructions, discovery plans and requests to admit facts, with a view to limiting the issues in dispute at an early stage. Time will tell whether these early interventions will have the intended effect.

While none of the cases commenced under the new regulations have begun the trial phase, the time constraint of a 10-day trial may prove to be a challenge. In some cases, for example, multiple drug submissions having varying scope of indications have been filed, and several related actions have been initiated, in relation to multiple patents. Counsel on either side will need to adjust and carefully prioritise their evidence and argument to effectively address all the issues arising at trial in the 10-day timeframe. Outside the PMNOC Regulations, such trials would historically have lasted one or even several months. Litigants have taken note of the Court's new constraints. In the Celltrion cases, though discovery is not yet closed, patent infringement allegations for one of four asserted patents were recently withdrawn.

At the time of writing, there were over 25 PMNOC cases proceeding through the Federal

Court. Thirteen had a trial date set, and all were scheduled to be heard over 10 days, regardless of the number of patents/products at issue. It appears that Canada's Rocket Docket has taken off.

The wallflowers – appropriate parties to a PMNOC proceeding

One early practical issue that has emerged under the amended Regulations is the identification of the appropriate parties in a case. Under the Regulations, only the company selling a reference drug product (called a first person), the patentee, and the generic or biosimilar applicant (called a second person) are permitted parties to a PMNOC proceeding. Since a PMNOC proceeding is an action brought before the generic or biosimilar applicant has entered the market, this rule reasonably restricts the scope of the action.

However, there are several ways in which a third-party may become an important part of a PMNOC proceeding, as illustrated by the *Genentech, Inc et al. v Celltrion Healthcare Co, Ltd* proceedings. In those proceedings, the public pleadings disclose that Celltrion is the manufacturer of a biosimilar version of Herceptin® to be distributed by Teva Canada. Although Teva Canada is not a party to the action, Teva Canada has voluntarily provided discovery to facilitate disposition of the action within the 24-month timeframe. On the other side, an affiliate of the plaintiffs, Roche Basel, is not a party to the action. However, the statement of claim reserves the right to add Roche Basel as a party claiming damages in the event that the biosimilar product is launched while the action remains pending.

If a generic or biosimilar product is launched while a PMNOC proceeding is pending, the parties to the litigation may seek to add additional parties late in the proceeding, and such late impleading of a party could have a significant impact on the case schedule and on that party's rights. It remains to be seen how the Court will address this situation when it emerges.

Freestyle – the new NOA

Under the old Regulations, the Notice of Allegation (NOA), a statement of factual and legal allegations served by the generic applicant on the brand company, defined the entire scope of the patent proceeding. A generic company would be restricted to the arguments advanced in the NOA. Any allegation which was not detailed and supported in the NOA would be found to be insufficient to support the allegation in court. Following the 2017 amendments, the NOA need only be detailed for allegations of patent invalidity, and even then it is open to a generic company to add further prior art or other allegations to the case (though this could conceivably extend the 24-month stay). The result is a degree of flexibility for generic companies when drafting an NOA, as less detail will not limit the arguments that may be raised during litigation. At the same time, generic companies must now address all patent claims, including claims to manufacturing processes, which were irrelevant under the old regulations.

While the importance of the NOA with respect to the scope of litigation has been reduced, it still has some significance. Under both the previous and amended regulations, if a patentee fails to respond to an NOA within 45 days, the generic company will be permitted to market its product(s) in Canada, provided that all health and safety concerns have been met. Additionally, if the patentee fails to respond to the NOA where it had "a reasonable basis for bringing an action", they are now barred from commencing litigation at a later point. So while, a highly detailed NOA may not be required, it may be in the best interests of the generic company to have sufficient detail such that the patentee would be deemed to have a reasonable basis to launch the action should they fail to respond within the 45 days.

Dancing in the dark – confidentiality and early production under the new regulations

Under the old Regulations, when a generic or biosimilar company served its NOA, document production was not required. The amended Regulations now require the production of all documents relied upon to support allegations of invalidity, and document production must now occur when the NOA is served. Similarly, if requested, patentees are now required to disclose documents relevant to allegations about alleged properties of the claimed invention, including laboratory notebooks and inventor contact information.

The new production requirements were also accompanied by new rules regarding the confidentiality of certain types of information. Some of the information that a generic company serves with its NOA is likely to be very commercially sensitive. Section 5(3.5) of the amended Regulations allows the generic company to impose reasonable rules in order to maintain the confidentiality of that information. The rules are binding on all representatives who receive documents produced in accordance with Section 5(3) of the Regulations.

If the patentee finds the rules to be unreasonable, it may bring a motion to the Federal Court to vary or set aside those rules. In *Genentech, Inc and Hoffmann-La Roche Limited v Pfizer Canada Inc*, the biosimilar applicant Pfizer refused to permit the plaintiffs Roche and Genentech to access early production documents unless Roche and Genentech agreed to Pfizer's confidentiality restrictions. Documents were produced on an encrypted USB key, and the decryption password was withheld. Before commencing a patent proceeding, Roche and Genentech brought a motion to compel access to the production according to less restrictive confidentiality rules. The Court held that such a motion can only be brought forward in the context of an existing action. Genentech and Roche had not yet commenced an action in response to the NOA, and the Court consequently found that it did not have jurisdiction to determine a motion in the absence of an underlying action.

In most cases, perhaps evidencing the cooperation between counsel referred to above, the parties have managed to reach reasonable agreements regarding the protection of confidential information exchanged before trial. The Federal Court is in a state of flux regarding the manner in which it addresses pre-trial confidentiality. The Court has moved away from protective orders and has insisted that parties reach protective agreements without the Court's involvement, with protective orders to be issued only where absolutely necessary. This confidentiality policy of the Court is currently under appeal.

The dance must go on – high bar set for early patent dismissals

Once the NOA and the supporting documentation are served, the patentee has 45 days in which to commence an action in response to the NOA. Once the action is filed, an automatic 24-month stay – unless expressly waived – prevents the generic company from marketing its product(s) in Canada. As the Court recognised under the old Regulations, in light of the onerous nature of the automatic 24-month stay and substantial resources required to litigate, it is crucial that meritless proceedings are quickly identified and dispatched. Section 6.08 of the amended Regulations allows the generic company (the defendant in the action) to bring a motion to have the patentee's action dismissed on the grounds of being "redundant, scandalous, frivolous, vexatious, or an abuse of process". An action might be frivolous or vexatious if it is clear and indisputable based on the regulatory documents that there is no infringement. The generic company is entitled as of right to bring forward a Section 6.08 motion at any stage of the action, even before discovery is complete. This is in line with the objective of dismissing baseless claims during the preliminary stages of the proceeding.

However, winning a Section 6.08 motion has proved difficult. In the Federal Court's first ruling on a Section 6.08 motion, in *Genentech Inc et al v Amgen Canada Inc*, the Court held that "striking an action [in this context] remains an extraordinary remedy and the threshold on such a motion is high." The generic company would have to show that it is "plain and obvious" that there is no chance that the claim(s) would succeed. The Court also said that due to the change in the Regulations stipulating that the patentee is barred from commencing subsequent litigation if the claim is struck, "a heightened level of caution" should be exercised when considering Section 6.08 motions. Consequently, these motions should only be granted in the clearest of cases. In the case at issue, involving motions to dismiss a proceeding in respect of two patents, the Court determined that disputes over claim construction, as well as certain factual observations (redacted in the public decision), prevented such an early determination. The Court stressed that its role is not to conduct a hearing on the merits, but rather to identify whether there is an *arguable* case, with any doubt favouring the patentee.

Following dismissal of Amgen's motion, in *Hoffmann-La Roche Limited v Pfizer Canada Inc,* Pfizer tried an alternative approach to early dismissal, bringing a motion for summary judgment or summary trial. Pfizer had filed two biosimilar submissions – one with a full label, and one with a skinny label having carved-out indications. The motion pertained to the skinny label. Despite finding that Pfizer brought its motion in a timely manner, the Court denied Pfizer's request, observing that such a summary judgment motion or trial would need to proceed in parallel with the main action and would take the better part of a year to resolve, and proceeding in this manner was unlikely to shorten the case by more than five months. The Court further observed that there would need to be a trial on the full label in any event, and based on conduct to date, the parties appeared unlikely to cooperate as a motion for summary relief moved forward.

Although these are the first – and very likely not the last – skirmishes on early dismissal issues, it is clear that the Court is setting a high threshold on these issues. An expedited proceeding is highly preferable, but it will be very difficult to strike out pleadings under Section 6.08 or obtain summary judgment or trial.

Safety dance – status quo for the 24-month stay

In last year's article, we detailed a new strategic flexibility available to patentees: the ability to waive the previously automatic 24-month stay. As mentioned above, under the old Regulations, as soon as litigation was commenced, patentees benefited from an automatic 24-month stay preventing Health Canada from approving a generic company's product. Relinquishing that stay would end the proceeding.

Under the new Regulations, the patentee can expressly waive the 24-month stay without prejudice at the outset of the action. If the stay is waived at that time, the patentee avoids potential liability for damages during the period of the litigation in case they are unsuccessful. On the other hand, the generic product would immediately be permitted to enter the Canadian market, effectively ending the patentees monopoly. This early market access could expose the generic company to liability in damages for patent infringement, however, if they are unsuccessful in litigation.

Whether any such scenarios will ultimately play out remains to be seen. To date, no plaintiff has waived their right to the 24-month stay.

Dance off – who's got the best moves?

As we approach the first anniversary of these fundamental changes to the pharmaceutical patent litigation process, we have yet to see the full impact of the amendments. Up to this point, we have seen only the first few preliminary decisions in PMNOC actions. As the cases proceed, we will see how the Court continues to deal with the new scheduling realities, the proper scope of discovery, the conduct of PMNOC trials, and damages. The Canadian patent dance is in full swing – we will soon find out what the best steps are, and perhaps more importantly, who is leading.

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