Sana Halwani
416-865-3733
shalwani@litigate.com

July 19, 2017

Procedural Skirmishes and Unintended Effects: The Proposed NOC Regulations

The proposed regulations amending the *Patented Medicines (Notice of Compliance) Regulations* were released on July 14, 2017. These Proposed Regulations are a dramatic change from the existing Regulations, both substantively and procedurally.

It has been 25 years since the NOC Regulations came into force and NOC applications had come to follow a fairly predictable path, with few procedural fireworks. That calm is over. Once the Proposed Regulations come into force, the Court will be addressing procedural skirmishes in every case. Here are three potential disputes that are sure to have case management judges pulling out their hair.

1. Fights about what "reasonable basis" means

Despite the new NOC Regulations regime being actions based, the Proposed Regulations do not do away with Notices of Allegation (NOAs). Apart from theoretically expediting the proceeding, the main purpose of the NOA appears to be to determine whether a first person may bring a subsequent action on any patents listed on the Register in respect of a drug. Under section 6.01: "No action, other than one brought under subsection 6(1), may [later] be brought against the second person … unless the first person or the owner of the patent did not, within the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection."

According to the RIAS, this language is meant to capture situations where, for example, the generic disclosure is false, materially misleading or materially incomplete, or where the product changes subsequent to the NOC proceeding, but is broad enough to raise questions about what a "reasonable basis" means and whether the information provided by the second person with the NOA (discussed below) was sufficient to provide a reasonable basis. But this explanation seems at odds with the language of the Proposed Regulations themselves, which would not – on a plain reading – apply to any situations when a NOC action was previously commenced. Rather, the plain language seems to carve out only situations where no NOC action was commenced on a particular patent

after service of a NOA.

The RIAS also states that “it is expected” that the question of whether a reasonable basis for commencing litigation exists will be addressed in a subsequent proceeding, not in the proceeding brought under the Regulations. It will be interesting to see whether the Court heeds this “expectation”, and whether this provision will spawn a cottage industry of side “no reasonable basis” proceedings.

2. Attempts to consolidate actions despite the prohibition on joinder

Section 6.02 of the Proposed Regulations makes clear that no action may be joined to a given action under subsection 6(1), other than another action relating to the same submission or supplemental submission. So if a generic serves multiple NOAs in respect of the same submission and multiple actions are commenced in response to those NOAs, then those actions can be joined, subject to the Court’s discretion. But the Court cannot join actions involving the same patents and different generic companies. Whether the Court will decide to hear such matters together – if they are on a similar schedule – is another question.

Section 6.02 also makes clear that non-Register patents, which may be infringed by a drug product that is the subject of a submission, cannot be litigated in a NOC action. However, sections 8.1 and 8.2 provide standing to generics and innovators, respectively, to litigate such non-Register patents on a *quia timet* basis in parallel proceedings. Despite the bar on joinder of these cases, we expect to see attempts to practically consolidate such actions with NOC actions, and it is unclear at this point whether case management judges will be sympathetic to such attempts.

3. Derailing timelines with discovery

While the Proposed Regulations recognise the need to expedite the litigation process by defining a subset of the discovery obligations that must take place almost immediately, it will still be a significant (some would say nearly impossible) challenge to run a full discovery process, including document productions, oral discovery, discovery motions, and potentially third party discovery, on a 24-month clock (or more likely a 21 month clock to account for decision drafting time). All with no additional resources being provided to the Federal Court (despite reasonable and well-supported requests).

Even the explicit discovery obligations are likely to have some unintended effects. For example, Subsection 5(3)(c) outlines the production obligations of a second person, and requires

that the following be served along with the NOA: (iii) for infringement, a searchable electronic copy of the portions of the submission or supplement that are relevant and under the control of the second person, and (iv) for invalidity, an electronic copy of any document — along with an electronic copy of it in English or French, if available — on which the person is relying in support of the allegation.

The relevancy standard in (iii) is likely to create “production sufficiency” motions, with both sides arguing about whether undisclosed portions were relevant and whether service of the NOA was therefore effective.

In addition, oddly, given the focus on speeding up discovery at the outset of the proceeding, the Proposed Regulations do not require mandatory production of samples of the generic product, even where infringement is an issue. Parties will only be able to move for samples under the relevant provisions of the Federal Courts Rules, which is sure to cause delays, especially if the second person claims not to have control over samples of its own proposed product. Such delays will be further compounded if either party chooses to do experimental testing on these samples, which will presumably be subject to the Court’s practice guidelines – including notice requirements – on such testing.

The combination of these unknowns and a 24-month clock for actions that commonly take twice that long (if not longer) creates a confluence of events that is sure to generate interesting arguments and unintended consequences for years to come.

Continue reading: http://www.canadagazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/index-eng.php