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A Complete Code: Ontario Court of Appeal Denies Remedies Exist Outside the PMNOC Regime

The Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations) is a complete code. In *Apotex Inc v Eli Lilly Canada Inc*, the Ontario Court of Appeal weighs in on the drawn-out battle between patent owners and generics on whether monetary relief is available outside the parameters of the PMNOC regime. It is not.

Background

This decision is an appeal from the order of Justice Schabas of the Superior Court of Justice dated March 8, 2021. At the core of this appeal is whether the invalidity of a patent owned by Eli Lilly for Olanzapine gives rise to a claim by Apotex for damages for being kept off the market during the proceeding under the PMNOC regime, pursuant to the *Statute of Monopolies*, the *Trademarks Act* and the tort of conspiracy.

In the Court below, the Court accepted Eli Lilly's position on the summary judgment motion and denied Apotex relief for the harm it alleged to have suffered outside of the confines of the *Patent Act* and the PMNOC Regulations.

Issues on Appeal

There were several issues on appeal, namely did the motions judge err by:

- Finding the *Patent Act* and the PMNOC Regulations formed a complete code?
- Finding Apotex's damages are not recoverable because they arose by operation of law?
- Rejecting Apotex's claim under the *Statute of Monopolies* ?
- Concluding that Apotex's *Trademark Act* claims were not available?
- Rejecting Apotex's claim based on civil conspiracy.

There was also an issue as to costs which is not addressed in this blog post.

The Ontario Court of Appeal denied each ground of appeal. The key findings are discussed below.

- **Complete Code**

Section 8 of the PMNOC Regulations provides the sole remedy for a generic manufacturer to seek relief if it has challenged a patent within the PMNOC regime. On the facts of the case, Apotex did not meet the requirements for section 8 damages and no other relief was available.

- **No Liability for Actions Authorized to Take by Law**

Apotex's delay in bringing its generic drug product to market was caused by the statutory stay mechanism provided under the PMNOC Regulations and the Order that Apotex was not entitled to early market access or compensation pursuant to section 8 of the PMNOC Regulations. A patentee, in this case Eli Lilly, is not liable for actions it was authorized to take by law or for alleged harms that were caused by the operation of the patent regime that the generic, in this case Apotex, invoked.

- **The Statute of Monopolies Excludes Liability**

The *Statute of Monopolies* specifically excludes liability for patents for new inventions. At the time the patent was granted to Eli Lilly, it was granted for a new invention. The *Statute of Monopolies* does not distinguish between valid and subsequently invalidated patents. This is in line with the historical purpose of the legislation.

- **Information on the Form IV as to Patent Validity was not a Misrepresentation**

The information that Eli Lilly supplied at the time of listing its patent on the Patent Register, including the brand name of the drug and that it held a valid patent, was not a misrepresentation. It was not an error for the Court below to find that a granted patent is presumed valid as per section 43(2) of the *Patent Act*. As such Eli Lilly did not make a misrepresentation when it completed the Form IV and stated it held a valid patent to be listed on the Patent Register.

- **No Conspiracy**

There was nothing unlawful in Eli Lilly applying for and protecting a registered patent under the *Patent Act* and PMNOC Regulations even though the patent was later held to be invalid. There was also no failure in the factual

finding that there was no evidence to support a claim for conspiracy.

Key Takeaways

There are two key practical takeaways flowing from this decision. The first is that once the PMNOC Regulations have been engaged, the regime is a complete code. A generic manufacturer is entitled to section 8 damages relief for being delayed market entry pursuant to the stay arising under the PMNOC Regulations, if it is successful on a section 6 PMNOC action and meets the criteria for such relief. Failing which, it is precluded from seeking damages. The second is that the general principal that engaging in a lawful activity does not attract liability holds true in the context of the PMNOC regime. Further, although an invalidated patent is considered invalid *ab initio*, the fact that a patent is presumed valid under the *Patent Act* with the grant of a patent, maintains the lawfulness of a patentee's actions regarding that patent if the patent is later invalidated. This adds clarity around the phrase invalid *ab initio* while reinforcing the presumption of validity.