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Apotex v. Eli Lilly – A Decade-Long Battle Over an Ancient English Statute Comes to an End

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The English *Statute of Monopolies*,[1] introduced in 1624, was enacted to limit monarch abuses in awarding monopolies over a variety of economic activities. Almost 400 years later, Apotex began relying on the statute to claim damages against innovator pharmaceutical companies in circumstances where Apotex was delayed in receiving marketing authorization due to the innovator bringing an application under the *Patented Medicines (Notice of Compliance) Regulations* (“***PM(NOC) Regulations***”), and where the patent in issue was found invalid. Somewhat remarkably, over the past decade since Apotex started making these claims, no action has gone to trial. Apotex had successfully resisted several motions to strike these allegations on the basis that the claims were novel. Nevertheless, in *Apotex v. Eli Lilly*, 2021 ONSC 1588, the Ontario Superior Court decided on a summary judgment motion that the pre-confederation English statute, along with the similar Ontario *Statute of Monopolies*[2] and the common law, are all not applicable in the determination of damages under Canada’s patented drug regime.

The PM(NOC) Regime

Introduced in 1993, the *PM(NOC) Regulations* permit innovator drug companies to list patents on a Patent Register that meet certain criteria. Companies wanting to launch a generic product before the expiry of listed patents must serve a Notice of Allegation (“**NOA**”) on the innovator that details why the listed patent would not be infringed by the generic, is invalid, or is improperly listed on the Patent Register. Service of an NOA gives to the innovator the right to bring an action for patent infringement against the generic, triggering a freezing event whereby the Minister of Health is prohibited from issuing regulatory authorization to a generic company for a 24-month period (unless the prohibition proceeding was disposed of earlier). If a generic company is ultimately successful in the action, it may seek damages for delayed market entry pursuant to section 8 of the *PM(NOC) Regulations*.

For the past decade, Apotex had alleged in several actions against innovator companies that if a patent kept Apotex out of the market by operation of the *PM(NOC) Regulations*, and that patent was subsequently found invalid and void *ab initio*, then Apotex should be entitled to damages under the English *Statute of Monopolies*, its Ontario equivalent, and the common law. Until now, that issue had not been decided.

[1] *An Act concerning Monopolies and Dispensation with Penal Laws, and the Forfeitures thereof*, 1624, 21 Jac. I, c.3 (the English *Statute of Monopolies*).
[2] *An Act concerning Monopolies, and Dispensation with penal laws, etc.*, R.S.O. 1897, c. 323 (the Ontario *Statute of Monopolies*).

The *Olanzapine* Decision

In *Apotex Inc. v. Eli Lilly Canada Inc.*, 2021 ONSC 1588 (“***Olanzapine***”), Apotex claimed damages against Eli Lilly for being delayed market entry with respect to olanzapine, an anti-schizophrenic drug. While Lilly’s patent was upheld in a prohibition proceeding against Apotex, the patent was later declared invalid in another proceeding against a different generic company. Despite the subsequent invalidation, Apotex was precluded from seeking damages pursuant to section 8 of the *PM(NOC) Regulations* since it was unsuccessful in Lilly’s prohibition application. As an alternative, Apotex commenced the Ontario action claiming damages against Lilly, including treble damages under both *Statutes of Monopolies,* for the delayed market entry by reason of an invalid patent.

Lilly brought a summary judgment motion shortly before trial. In granting Lilly’s summary judgment motion and dismissing the action, the Court found that Apotex was kept out of the market due to the lawful operation of the *PM(NOC) Regulations*. By invoking the *PM(NOC) Regulations*, Lilly relied on an existing patent that was presumed to be valid. Lilly was simply using the established regulatory scheme established to address patent disputes involving pharmaceutical drugs. Relying on a number of judicial precedents, the Court concluded that patent law in Canada is “wholly statutory”, with the *Patent Act* and the *PM(NOC) Regulations* providing “a complete code” to govern the issuance and use of patents, and the remedies available when patents have been infringed or found invalid. The Court also specifically observed that the *Patent Act* does not provide a right of damages against a patentee that unsuccessfully asserts a patent against a person. The Court thus held that absent a “stand alone cause of action” or a claim “totally independent of the regulatory regime,” the *Patent Act* and the *PM(NOC) Regulations* constitute a complete code which precludes causes of action arising from the operation of that code. Accordingly, the Court found that Apotex’s action should be dismissed as the actions alleged to have caused harm to Apotex were authorized by law and flowed from the operation of law.

Apotex argued that it had been “hindered, grieved, disturbed and disquieted by occasion of [Lilly’s Patent]” that was void *ab initio*, and sought “treble damages”. The Court found that when the English *Statute of Monopolies* was enacted almost 400 years ago, it specified that the prohibition on monopolies did not apply to patents for new inventions (nor did the Ontario *Statute of Monopolies*). Instead, it restricted other monopolies for trade in certain goods, trade routes, and to operate in particular industries, in return for payment to the Crown. The Court noted that Apotex’s argument that it was harmed by Lilly’s Patent was inconsistent with its position that Lilly’s Patent never existed. If Lilly’s Patent is void *ab initio*, then it is deemed to have never been granted a prohibited licence, patent, or monopoly under the *Statutes of Monopolies* under which Apotex could be granted damages. Lastly, to hold a patent owner retroactively liable for damages beyond those provided for in the *Patent Act* and *PM(NOC) Regulations* if a patent is found invalid would upset the patent bargain and undermine the objectives of the *Patent Act*. Thus, the Court found that Apotex’s monopolies claim had no merit and did not raise a genuine issue for trial. The Court also summarily dismissed Apotex’s claims for damages under section 7 of the *Trademarks Act* and for conspiracy.

The *Sildenafil* Decision

Four days after the *Olanzapine* decision, the Superior Court released an endorsement in a parallel action: *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2021 ONSC 1860 (**"*Sildenafil*"**). In that action, Apotex sought damages under the *Statutes of Monopolies* similar to those in the *Olanzapine* action, but this time against Pfizer and its patent relating to sildenafil. Pfizer had sought to adjourn an upcoming trial date to instead schedule a summary judgment motion against Apotex to dismiss its action. The decision was under reserve when the *Olanzapine* decision was released.

Relying on the *Olanzapine* decision, the Court in the *Sildenafil* action vacated the upcoming trial dates, allowing Pfizer to proceed with its summary judgment motion instead. As noted by the Court: "[i]nviting a 20-day trial to re-visit questions of law already decided against the plaintiff by this court does not strike me as apt based on the foregoing doctrinal, resource allocation, efficiency, and affordability concerns".

While a procedural one, the *Sildenafil* decision foreshadows that the *Olanzapine* decision—if upheld—will have broad application with respect to numerous pending cases that Apotex has brought making similar claims. Indeed, the Court in *Sildenafil* noted that if the *Olanzapine* decision is upheld "as one of pure legal analysis", then a trial in the underlying *Sildenafil* action "is probably unnecessary".

These cases, and in particular, the *Olanzapine* decision, suggest that the only remedy available to a generic company that is delayed market entry due to operation of the *PM(NOC) Regulations* is damages through section 8 of those regulations. While Apotex has appealed,[3] the decision starts to bring welcomed clarity to an issue left unresolved in many actions for a decade.

[3] Ontario Court of Appeal Docket C69320.