Ontario Superior Court dismisses Apotex's claims for damages under Statutes of Monopolies

March 15, 2021

In March 2021, the Ontario Superior Court granted summary judgment, in favour of Lilly, dismissing Apotex's claim for treble damages pursuant to the Ontario and English *Statutes of Monopolies* and the *Trademarks Act*.[1]

Background

Lilly obtained a patent covering the compound olanzapine. This patent was listed on the Patent Register in accordance with the *NOC Regulations*. Apotex sent a Notice of Allegation (NOA) pursuant to the *NOC Regulations*, triggering a prohibition proceeding. Lilly was successful in this proceeding both at trial and on appeal. An order was issued, preventing Apotex from entering the market with its generic olanzapine product until the patent expired.

Novopharm also sent a NOA, triggering the *NOC Regulations*. Lilly was unsuccessful in the resulting proceeding and its appeal was dismissed. Novopharm entered the market with its generic olanzapine product. Lilly sued Novopharm for patent infringement, however the Federal Court (FC) declared the patent invalid. The Federal Court of Appeal (FCA) overturned and sent the decision back to the FC for reconsideration. The FC again declared the patent invalid, and the FCA upheld that decision. Lilly was also ordered to pay damages to Novopharm pursuant to s. 8 of the *NOC Regulations* for keeping Novopharm off the market during the initial prohibition proceeding.

Apotex sought reconsideration of the Order that prohibited its entry into the market, due to the invalidity of the patent following the Novopharm infringement action. The Court refused, holding that Apotex had the full opportunity to raise all possible allegations in its NOA, and it could have sued to impeach the patent.

Apotex then started the within action against Lilly, seeking damages at common law and pursuant to the Ontario and English *Statutes of Monopolies* for keeping Apotex out of the market with a patent subsequently found to be invalid, as well as pursuant to the *Trademarks Act* for alleged false and misleading statements by Lilly in reliance on its patent. Lilly brought a summary judgment motion based on the expiry of the limitations

period, and in respect of its allegation that any harm allegedly suffered by Apotex was caused by the operation of the *NOC Regulations* and a court order, and that damages are not recoverable other than pursuant to s. 8 of the *NOC Regulations*.

Summary judgment

The Court held that in this case, both parties are sophisticated and well represented. The factual matrix is not in dispute and both parties are aware of the requirement to put their best foot forward. The 'gating issues' raised by Lilly were held to be well suited to summary judgment.

Limitations Act

Lilly's first basis for seeking summary judgment was that the limitations period had expired before Apotex brought its suit. The Court held that a declaration that the patent was invalid is an essential element of the action, and thus, the *in rem* invalidity declaration is a necessary precondition to bringing the action. Thus, the Court held that the time clock did not begin to run until the second declaration of invalidity by the Federal Court. Although the FC had declared the patent invalid outside of the limitations period the first time, when the FCA overturned that decision, it effectively reset the clock. The Court held that the action is not out of time and should not be dismissed on this basis.

Causation

Lilly's second basis for seeking summary judgment was that the Order in the Apotex prohibition proceeding and the operation of law were the cause of any harm to Apotex.

The Judge cited the SCC's statement that patent law is wholly statutory. Apotex argued that this was an overstatement, citing several common law developments. However, the Court held that these were "judge-made doctrine [which] has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application." (para 98)

The Court held that a feature of the statutory nature of patent law is the limited forms of relief. Before the *NOC Regulations* were promulgated, there was no basis upon which to find a patent holder liable for damages. Furthermore, this potential for damages was limited, and previous attempts by Apotex and others to expand the relief have failed.

The Court cited the FCA as holding that while the *Federal Courts Act* provides equitable jurisdiction to the FC, that jurisdiction cannot be used to grant a remedy that s. 8 of the *NOC Regulations* intended to exclude, unless an independent cause of action is alleged.[2] The Court held that while the FCA did not explain what an independent cause of action could be, it "can be inferred that they would involve separate, independent wrongdoing as he went on to say that if the claim for disgorgement arose simply from the dismissal of the prohibition proceedings the action would be unfounded." (para 102). The Court cited support for this proposition in other Ontario courts cases brought by Apotex seeking to broaden the s. 8 provision.[3]

The Court further held that even if Lilly had an improper motive (of which there is no evidence), invoking the *NOC Regulations* would still not be wrong.[4]

In this case, Apotex's claims arise from the patent regime and Lilly's exercise of its rights under the patent. Without a cause of action independent of this regime, the Court held that "the *Patent Act* and the *PM(NOC) Regulations* constitute a "complete code" which precludes causes of action arising from the operation of that code." (para 115)

The Court agreed with Lilly that to allow Apotex' action would drastically upset the statutory regime, and the Court held that it would also undermine it. "Exposing a party to liability for damages simply because it successfully obtained a patent and exercised its rights based on its presumptive validity would remove one of the key benefits of the patent regime, which exists to foster and encourage innovation by protecting inventions for the benefit of the inventor for a limited period of time." (para 116)

The Court held that the fact that the *Patent Act* states that a patent voided by judgment is held to have been of no effect, does not rewrite history, nor does it retroactively create a benefit that the patent holder is liable for acts it had the right to take at the time.

The *Statutes of Monopolies*

The Court discussed the history of the two statutes asserted and the interplay with the *Competition Act*. However, it then held that it was not necessary to address any of these foundational issues in light of the conclusion that the statutes do not support Apotex's position, assuming they are valid and applicable.

A patent for a new invention is not prohibited by the *Statutes of Monopolies*. If the patent is void *ab initio*, it never existed, and Lilly was never granted a monopoly, let alone an unlawful one. The Court held that Apotex cannot have it both ways, by arguing that Lilly never had a patent but Apotex was harmed by the patent. "If one is going to rewrite history, it should at least be done consistently." (para 132)

The Court discussed the patent bargain, whereby an inventor is granted rights in exchange for the disclosure of the invention so that society can benefit from this knowledge. "But to retroactively make a patent holder's actions wrongful and be liable for damages beyond those provided in the Regulations, including treble damages, if the patent is found to be invalid, would upset that bargain and undermine the objectives of the Act." (para 136)

Trademarks Act

Section 7(a) of the *Trademarks Act* relates to false or misleading statements that tend to discredit the business, wares or services of a competitor and result in damage. Apotex led no evidence on this issue other than the Form IV, which listed the patent on the patent register for olanzapine. The Court held that there "is nothing untrue or false in any material respect, let alone disparaging or discrediting of Apotex, in the Form IV." (para 141) The Court held that there was no genuine issue for trial on this cause of action, as it seeks to make Lilly liable for something it had a right to do when it held a presumptively valid patent.

Conspiracy

Apotex also alleged a conspiracy amongst the defendants to monopolize the manufacture and sale of olanzapine and set monopolistic prices. However, the Court held that Apotex led no evidence to support a standalone cause of action, other than what Lilly had the right to do. Thus, there is no genuine issue for trial.

Accordingly the motion for summary judgment was granted, and the action dismissed.

[1] *Apotex Inc. v. Eli Lilly Canada Inc.*, 2021 ONSC 1588

[2] *Apotex v. Eli Lilly*, 2011 FCA 358

[3] *Apotex Inc. v. Abbott Laboratories Ltd.*, 2013 ONSC 356 at para 152; aff'd 2013 ONCA 555 at paras 5-6; and *Apotex Inc. v. Eli Lilly and Company*, 2013 ONSC 5937 at para 8; aff'd 2015 ONCA 305 at paras 35, 53, 57, and 60; leave to appeal refused [2015] SCCA No. 291.

[4] *Harris v. GlaxoSmithKline*, 2010 ONCA 872 at paras 45-47, 50.

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