

Pharma in brief - Canada

Motion to strike new claims dismissed despite earlier award of section 8 damages

Case:	<i>Apotex Inc. v. Schering Corporation</i> (Court File No. CV-11-429541)
Drug:	ALTACE® (ramipril)
Nature of case:	Motion to strike claims under the under the <i>Trade-marks Act</i> , R.S.C. 1985, c. T-13 (Trade-marks Act), the Ontario Monopolies Act (<i>An Act concerning Monopolies and Dispensation with Penal Laws, etc.</i> , R.S.O. 1897, c. 323) and the U.K. Monopolies Act (<i>An Act concerning Monopolies and Dispensation with Penal Laws and the Forfeitures thereof</i> , 1624, 21 Jac. 1, c. 3 (together, Monopolies Acts)).
Successful party:	Apotex Inc.
Date of decision:	27 May, 2016

Summary

Sanofi-Aventis, Sanofi-Aventis Deutschland GmbH, and Sanofi-Aventis Canada Inc. (**Sanofi**) market the drug ramipril in Canada under the name ALTACE. Sanofi sells ALTACE under licence from Schering Corp. (**Schering**, and together with Sanofi, the **Defendants**), which owns various patents relating to ramipril, including the one at issue in this case, Canadian Patent No. 1,341,206 (**206 Patent**). Apotex Inc. (**Apotex**) has sold generic ramipril since January 2007. Apotex entered the market after succeeding in applications before the Federal Court (the **Applications**) under the *Patented Medicines (Notice of Compliance) Regulations* (**Regulations**). Apotex was subsequently awarded damages under section 8 of the *Regulations*.

In 2009, after the Defendants brought a separate action for infringement of the 206 Patent, Apotex succeeded in its counterclaim, and the Court declared the 206 Patent invalid.

Despite having received compensation under s. 8 of the *Regulations*, Apotex brought an action in the Ontario Superior Court claiming further monetary remedies resulting from novel causes of action. Specifically, it claims that by listing a patent on the Patent Register that was later declared void, the Defendants are liable under the *Monopolies Acts* and *Trade-marks Act*.

The Defendants moved to strike Apotex's claims. The motion was dismissed: Justice Dunphy held that the law surrounding these novel issues is insufficiently settled to make it plain and obvious that Apotex's claims would fail.

Not plain and obvious that a section 8 damages award bars other remedies

The Defendants argued that the *Regulations* are a "complete code". According to the Defendants, Apotex, which has already received the full remedy contemplated under the *Regulations*, is precluded from making further claims for relief arising outside the *Regulations*. Dunphy J. reviewed the jurisprudence on this issue. Despite a recent decision of the British Columbia Court of Appeal confirming that the *Regulations* are a "complete code" ([Low v. Pfizer Canada Inc., 2015 BCCA 506](#)), he held that the law is insufficiently settled to decide the issue at the pleadings stage.

The Defendants also asserted that the matter of compensation is *res judicata*, as it was already decided in the section 8 action. Dunphy J. also refused to strike these claims, noting that the causes of action have different triggers: the section 8 claims arise from the Defendants' decision to commence prohibition applications, whereas the *Trade-marks Act* claims are triggered by the decision to list a patent on the Patent Register. Accordingly, Dunphy J. believed the determination of the issue was better left for trial.

Monopolies Acts claims not plainly deficient

The Defendants argued that the *Monopolies Acts* claims should be struck on several bases, including that the *U.K. Monopolies Act* was mostly repealed by the *Ontario Monopolies Act*, and that the *Ontario Monopolies Act* is unconstitutional. Dunphy J., citing on his decision in [Apotex Inc. v. Eli Lilly and Company et al., 2015 ONSC 5396](#), again held that the law is not sufficiently settled to strike these claims.

Push to Trial

Despite Dunphy J's reluctance to strike Apotex's novel claims at the pleadings stage, he expressed an intent to move the action more quickly toward a resolution on the merits so that Apotex's novel claims can be determined, thereby providing much needed legal certainty.

Link:

[Apotex Inc. v. Schering Corporation, 2016 ONSC 3407](#)

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