British Columbia Court of Appeal overturns certification of pharmaceutical class action

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In a decision released January 22, 2015, the B.C. Court of Appeal unanimously overturned an order certifying a class proceeding against the manufacturers of the weight-loss drug sibutramine. The Court held that the certification judge erred in certifying the class action in the absence of evidence that the question of general causation (i.e. whether sibutramine increases certain risks for all class members) was capable of resolution on a class-wide basis. In doing so, the Court followed guidance from the Supreme Court's 2013 competition class action trilogy on the evidentiary requirements for certification and the gatekeeping role of the certification judge.

Background

In late 2000, Health Canada approved the marketing of Meridia®, a prescription drug containing sibutramine, for use as part of weight-loss regimes. Abbott Laboratories, Ltd. (Abbott) distributed and sold Meridia® in Canada. In late 2009, Abbott's exclusive right to distribute Meridia® ended and Health Canada approved an application by Apotex Inc. (Apotex) to distribute the generic equivalent to Meridia® under the name Apo-Sibutramine.

A clinical trial conducted between January 2003 and March 2009 (the Sibutramine Cardiovascular Outcome Trial, or SCOUT Study) suggested an increased risk of serious cardiovascular events associated with sibutramine use by patients with pre□existing heart problems for which the drug was contraindicated. The drug was voluntarily withdrawn from the Canadian market by Abbott and Apotex in October 2010.

The plaintiffs commenced the British Columbia action in 2011 on behalf of all persons in Canada who used or purchased sibutramine and their family members. The plaintiffs alleged that ingestion of sibutramine causes or contributes to an increased risk of adverse cardiovascular events, such as heart attacks and strokes, increased blood pressure and heart rate, and irregular heartbeat and that the SCOUT study determined that sibutramine increases the risk of cardiovascular events. The plaintiffs asserted causes of action for negligence and failure to warn and for deceptive advertising pursuant to the *Business Practices and Consumer Protection Act*, and the *Competition Act*.

A similar proposed class proceeding was commenced in Quebec. In 2012, the Quebec Superior Court refused to authorize that proceeding as a class action.

The focus of the appeal judgment was whether the plaintiffs had met the requirements of commonality and preferability under section 4(1) of the *Class Proceedings Act*.

With respect to the common issues requirement, the Court of Appeal applied the "some basis in fact" requirement for certification as affirmed in the 2013 Supreme Court trilogy. The Court held that where a plaintiff seeks to address questions of causation on a class-wide basis, the plaintiff must provide evidence of a methodology for proving causation on a class-wide basis. The Court held that while this rule is most clearly evident in indirect purchaser claims made in competition cases, such as the claims considered in the 2013 Supreme Court trilogy, there was no basis in principle to distinguish such claims insofar as this evidentiary requirement is concerned. The Court also relied on a recent decision from the Alberta Court of Appeal, *Andriuk v. Merrill Lunch Canada Inc.*, in which this evidentiary requirement was applied outside the indirect purchaser context.

In applying this test to the plaintiffs' claim, the Court of Appeal noted that the certification judge certified the case on two footings, both of which required an assessment of the general causation question: as a class action brought by those who have suffered injury to recover damages, and as a class action brought by patients prescribed a drug that ought not to have been marketed. The Court held that the claims of those who have suffered cardiac events are grounded in negligence, which requires proof of damages and causation. Such claims would be advanced by a finding of general causation. The Court noted that the claim advanced on behalf of users who have not suffered harm appears to be grounded upon the argument that relative ineffectiveness coupled with some risk ought to have kept sibutramine off the market as a weight-loss drug. The Court held that these claims must also be founded upon some proof of a risk to the population of patients for whom sibutramine was prescribed. The Court concluded that the successful prosecution of the class action in relation to the marketing of a drug with a poor risk-to-benefit ratio hinges upon the evidence that those who ought to have been prescribed the drug were put at risk by its use.

All of the proposed common issues, therefore, were based on the plaintiffs proving that sibutramine caused or contributed to cardiovascular events. The Court found that the evidence before the certification judge was that the question whether sibutramine causes or contributes to heart attacks, strokes, and arrhythmia is incapable of resolution on a class-wide basis. The SCOUT Study only concluded that sibutramine increased the risk of cardiovascular events for those patients with a history of cardiovascular disease for whom sibutramine was contraindicated and who should not have been prescribed the drug. The plaintiffs' own expert admitted that there was no study on whether sibutramine increased the risk of cardiovascular events for those without a history of cardiovascular disease or those who are undiagnosed with the disease. There was thus no evidence of a methodology for establishing that the class as a whole, as opposed to those who were wrongly prescribed sibutramine despite a history of cardiovascular disease, was affected or put at risk by using sibutramine.

The Court distinguished the evidence in this case from other cases such as *Stanway v. Wyeth Canada Inc.*, where there was evidence (such as a large clinical study) that the increased risk of a certain result to the class as a whole could be quantified. The Court noted that the case at hand was not one where the experts disagree on the extent of the risk, but rather a case where the experts are uncertain whether there is a risk to the class as a whole and have not described a methodology for addressing that question.

Accordingly, the Court of Appeal held that the certification judge erred by failing to consider whether the class had adduced some evidence of a method of proving general causation and set aside the certification order.

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[1] The authors are counsel to Apotex Inc. in this proceeding.