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SYMPOSIUM

As the Pendulum Swings—Medical Products Class Actions Litigation in Canada: Recent Developments

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Abstract

During the relatively short history of class proceedings in Canada, developers and manufacturers of medical devices and pharmaceuticals ("medical products"), including medical products designed for patients with diabetes, have found themselves at the receiving end of a significant number of class action claims. As a result, medical products litigation has become the battleground for some of the most significant developments in Canadian class actions law. This article provides a broad overview of some of the most significant developments. The authors pay particular attention to developments regarding the test for class action certification and consider whether high-profile dismissals of certification motions represent a trend toward raising the threshold for plaintiffs seeking to obtain certification of a proposed class action. The authors also consider a decision arising out of a lengthy class action common issues trial in which the medical device company was victorious. In the authors' view, the class action pendulum in Canada, particularly as it relates to medical products claims, remains in motion. It behooves all affected players to keep their eye on this ball with rapt attention to see where it may move next.

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Introduction

During the relatively short history of class proceedings in Canada, developers and manufacturers of medical devices and pharmaceuticals ("medical products") have found themselves at the receiving end of a significant number of class action claims. To date, the main battleground with respect to these claims has been the certification motion, a preliminary step in which the court assesses whether a given claim should proceed as a class action. Overall, the certification case law weighs heavily in favor of certifying proposed class proceedings involving medical products. However, a few recent certification decisions signal to both plaintiffs and defendants that, despite the track record to date, certification in medical products cases is not simply a rubber stamp; the allegations and evidence presented in each individual case really are supposed to be reviewed and rigorously analyzed by the court to determine whether a given case meets the test of suitability for class treatment.

Of the medical products cases that have been certified in Canada, only one has advanced all the way to trial: Andersen v. St. Jude. In contrast, a substantial number of the others have settled after certification, while the remainder have stalled through the postcertification litigation process. The court's decision, in which it found no liability on the

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part of St. Jude, highlights the enormous complexity and cost of a common issues class action trial, the importance of expert evidence in a medical products lawsuit, and the risk assumed by both parties in deciding to proceed to trial.

Query whether these successes for the defense, in aggregate, constitute a trend and reflect a reverse swinging of the judicial pendulum back toward the center of the certification arc between plaintiffs and defendants.

This article will discuss these developments in Canada and comprises four parts. Part I will provide an overview of Canada's class action regimes. Part II will discuss class action claims involving medical products designed for patients with diabetes. Part III will describe the process of bringing a medical products class action claim to trial, with a particular focus on the certification process and some court decisions dismissing certification motions. Part IV will summarize the medical device common issues trial decision in Andersen v. St. Jude and identify some key messages from that trial decision.

Part I: Product Liability Class Actions in Ontario: A Brief History

Class proceedings in some provinces in Canada are still a relatively recent phenomenon. Quebec was the first province to enact class proceedings legislation in 1978. Since that time, the number of Canadian jurisdictions that have class proceedings legislation has expanded to all but one province (Prince Edward Island); in addition, the three territories—Nunavut, Yukon, and the Northwest Territories—do not yet have class action legislation (see: British Columbia – Class Proceedings Act, RSBC 1996, c 50; Alberta – Class Proceedings Act, SA 2003, c C-16.5; Saskatchewan – The Class Actions Act, SS 2001, c C-12.01; Manitoba – The Class Proceedings Act, CCSM c. C130; Ontario – Class Proceedings Act, 1992, SO 1992, c 6; Quebec – An Act Respecting the Class Action, RSQ, c R-2.1; New Brunswick – Class Proceedings Act, RSNB 2011, c 125; Nova Scotia – Class Proceedings Act, SNS 2007, c 28; and Newfoundland & and Labrador – Class Actions Act, SNL 2001, c C-18.1.)

Class action legislation is fairly similar across all of the provinces, as is the case law that interprets and applies that legislation. For simplicity, this paper will focus primarily on the province of Ontario, Canada's largest and most populous province, which enacted its class action legislation, the Class Proceedings Act, in 1992 (Ontario Class Proceedings Act, 1992, SO 1992, c 6).

In 1982, the Ontario Law Reform Commission released a report recommending significant legislative reform to facilitate class proceedings in Ontario. Even at that very early stage, the commission opined that product liability cases would, in its view, be more than appropriate for class action treatment. (The commission pointed out that the new class action legislation would "remove several significant obstacles that face consumers … in their attempt to redress harm resulting from defective products,." Ontario Law Reform Commission, Report on Class Actions, Vol. 1 [Toronto: Ministry of the Attorney General; 1982]). Given the report's findings, few were surprised that, when the Class Proceedings Act was finally introduced in 1992, product liability cases quickly became treated by plaintiffs' counsel, and many judges, as the "quintessential" model for the class action process [Nantais v. Telectronics Proprietary (Canada) Ltd., 1995 OJ No 3069 (QL)]. Courts were quick to point out that cases involving a single purpose product, which is alleged to be defective or dangerous, provides a certain commonality for which a class proceeding is ideally suited [Ontario New Home Warranty Program v. Chevron Chemical Co., (1999), 46 OR (3d) 130 (available on QL)].

Due, in part, to this supportive legal climate, Canadian courts have addressed numerous medical product liability class actions, many of which have been based, at least in part, on recalls or failures to recall where a recall was, allegedly, warranted. Most of these cases have followed on the heels of mass aggregate claims commenced in the United States dealing with similar allegations about the same products.

The First Battleground: The Certification Motion

In Ontario, a class proceeding is commenced by the issuance of a statement of claim, with or without a notice of action. The plaintiff is then required to apply to the court to have the action "certified" as a class proceeding. Certification is

a purely procedural step during which the court decides whether or not a class proceeding is an appropriate and preferable procedure to advance the common issues in the case.

The importance of this stage in the process, even though it does not involve any adjudication on the merits of the case, is not to be underestimated. The fact is, a great many putative class actions are "won" or "lost" at this preliminary stage. "The reality is that the battleground of class proceedings in Ontario is the certification motion" [Fresco v. Canadian Imperial Bank of Commerce, 2010 ONSC 1036 (CanLII)].

In general terms, the certification requirements in Ontario are similar to those in all the provinces, with the exception of Quebec, where the certification requirements are somewhat less restrictive. Pursuant to section 5 of Ontario's Class Proceedings Act, the court *must* grant certification of a proposed class action where

(a) The pleadings or the notice of application discloses a cause of action;

(b) There is an identifiable class of two or more persons that would be represented by the representative plaintiff or defendant;

(c) The claims or defenses of the class members raise common issues;

(d) A class proceeding would be the preferable procedure for the resolution of the common issues; and

(e) There is a representative plaintiff or defendant who

(i) Would fairly and adequately represent the interest of the class,

(ii) Has produced a plan for the proceeding that sets out a workable method of advancing the proceedings on behalf of the class and of notifying class members of the proceeding, and

(iii) Does not have, on the common issues for the class, an interest in conflict with the interest of other class members (Ontario Class Proceedings Act, 1992, SO 1992, c 6).

The language of the statute is mandatory: the court is *required* to grant certification if all five tests are met. Ontario courts have stated that the purpose of a certification motion is to determine how the litigation is to proceed (i.e., whether the claims can appropriately be prosecuted as a class action) and *not* to review the merits of the plaintiff's claim [2038724 Ontario Ltd. v. Quizno's Canada Restaurant Corp., 2008, 89 OR (3d) 252, OJ No 833 (QL)]. As such, rather than focusing on the action's likelihood of success, judges have chosen to apply the certification test in what they perceive to be a purposive and generous manner, so as "to give effect to the important goals of class actions—providing access to justice for litigants; promoting the efficient use of judicial resources; and sanctioning wrongdoers and encouraging them to modify their behaviour" [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)].

Part II: Class Actions Involving Medical Products for Treating Diabetes

A handful of the medical product class action cases in Canada have involved drugs and products designed specifically for patients with diabetes. For example, Serhan (Trustee of) v. Johnson & Johnson, involved claims regarding Johnson & Johnson's SureStep System, which was designed for use by diabetes patients to monitor their blood glucose levels [Serhan (Trustee of) v. Johnson & Johnson, 2004, 49 CPC (5th) 283, 11 ETR (3d) 226 (SCJ) (Serhan), aff'd (2006) 85 O.R. (3d) 665 (Ont Div Ct)]. The SureStep System was released in the U.S. and Canadian markets despite several alleged defects, of which the defendants admitted they were aware. First, it was alleged that there were errors in the monitor's software that resulted in the meter giving incorrect readings. Second, it was alleged that if users failed to completely insert their test strips into the meter, the SureStep could potentially give a lower-than-accurate blood glucose reading. The defendants corrected the design errors and undertook a voluntary recall of the affected products. There was no evidence of any injury in Canada arising from either of the design issues.

A class action lawsuit was commenced in 2001 in Ontario claiming damages for negligence, negligent and fraudulent misrepresentation, breach of the Competition Act (Competition Act, RSC 1985, c C-34), and conspiracy relating to the manufacture, sale, and distribution of the SureStep meters and strips against the defendants on behalf of users of the device in all Canadian provinces except for British Columbia and Quebec. The case was certified, in part, with the cause of action being waiver of tort. The action was eventually settled in 2011 for a total payment of $4 million [Serhan (Trustee of) v. Johnson & Johnson, 2004, 49 CPC (5th) 283, 11 ETR (3d) 226 (SCJ) (Serhan), aff'd (2006) 85 O.R. (3d) 665 (Ont Div Ct)].

In 2007, a proposed class proceeding entitled Wall Estate v. Glaxosmithkline was commenced on behalf of persons resident in Canada who were allegedly negatively affected by Avandia, a prescription drug used to treat type 2 diabetes [Wall Estate v. Glaxosmithkline Inc., 2010, SJ No 625 (QL)]. The claim alleges, among other things, that the defendants, who developed, manufactured, and sold the drug, failed to warn the public of the risks associated with taking Avandia, including an increased risk of heart failure and death. The issue of whether this proposed class action will be certified by the court has not yet been determined, and no decision has been made on the merits of the plaintiffs' claims.

In December 2011, a proposed class action was brought against Takeda Pharmaceutical Company Limited and related defendants with regard to their product, ACTOS. ACTOS, which the Takeda defendants had researched, developed, and distributed, was being prescribed to patients suffering from type 2 diabetes. The plaintiffs allege, among other things, that ACTOS is defective and inherently dangerous in that it caused, materially contributed to, and materially increased the risks of bladder cancer and bone fractures and that the defendants failed to adequately warn patients about these risks (Casseres v. Takeda Pharmaceuticals et al, CV-11-442584; the statement of claim in this matter was issued on December 21, 2011 and we are not aware of any reported decisions in respect of this case). The case is still pending class certification, and no decision has been made on the merits of the plaintiffs' claims.

Beyond these diabetes-related cases, medical products class action claims have been commenced in Canada in respect of virtually all types of pharmaceuticals and medical devices, including antipsychotic medication, diet drugs, pacemakers, defibrillators, and myriad other forms of medical implants.

Part III: The Potential of Certification: Are Canadian Courts Beginning to Raise the Bar for Certification?

In the past, the Ontario cases that had interpreted and applied the requirements for certification, particularly in the context of medical products claims, had set what appeared to be an exceedingly low bar or threshold to be met for each element of the certification test. This trend made it very challenging for defendants in class proceedings to defeat certification [see, for example, the certification decisions in: Jones v. Zimmer GMBH, 2011, BCSC 1198 (CanLII); Lefrancois v. Guidant Corporation, 2008, CanLII 15770 (ON SC), leave to appeal to the Ont Div Ct refused, 2009, CanLII 76, 245 OAC 213 (ON SCDC); Schick v. Boehringer Ingelheim (Canada) Ltd., 2011, ONSC 1942 (CanLII); Lambert v. Guidant Corporation, 2009, CanLII 23379 (ON SC), leave to appeal to the Ont Div Ct refused, 2009, CanLII 58583 (ON SCDC); and Schroder v. DJO Canada Inc., 2010, SKQB 125 (CanLII), aff'd 2011 SKCA 106 (CanLII)].

However, a few decisions suggest that Ontario courts may now be questioning that liberal approach to certification and might now be more inclined to scrutinize more discriminately each proposed class action case to determine whether it really is reasonable and fair to allow it to proceed as a class action.

In Martin v. Astrazeneca Pharmaceuticals PLC [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)], a decision released in May 2012, the Ontario Superior Court refused to certify a class action relating to the antipsychotic drug, Seroquel, and the side-effect health risks it is alleged to cause. Remarkably, this 2012 decision was the first Ontario Superior Court decision refusing to certify a proposed class action involving a pharmaceutical product.

Seroquel is an antipsychotic medication approved by Health Canada for use in the treatment of schizophrenia, the acute management of manic episodes, bipolar disorder, and depression associated with bipolar I and II disorder.

The drug was also being prescribed for certain off-label uses, including treatment of anxiety, sleep disorders, and dementia. The plaintiffs made a broad range of allegations against Astrazeneca, including that the drug caused significant health risks to those who used it and that the defendants had failed to warn class members of these risks, which included, for example, significant weight gain, problems with balance, elevated blood sugars, hyperglycemia, loss of energy, numbness in the extremities, pancreatitis, and blindness. The plaintiffs also alleged, among other things, that the defendants had been negligent in the design, manufacture, and distribution of the drug and that the defendants had conspired to conceal information from Health Canada and to promote the drug for certain off-label uses for which it had not been approved. The proposed class was "all persons in Canada who were prescribed, and who consumed, Seroquel" [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)].

In denying certification, Justice Horkins commenced with a recitation of the well-established legal principle that, on a certification motion, the evidentiary burden on plaintiffs is low: all that the plaintiffs are required to do is to adduce evidence that shows "some basis in fact" to meet the requirements of s. 5(1) (b) to (e) of the test for certification as a class action [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)]. Justice Horkins also noted that a defendant is entitled to deliver evidence in rebuttal, but the standard of proof on the defendant is inversely heavy: the defendant must show that there is no basis in the evidence for the facts asserted by the plaintiffs [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)]. Nevertheless, and notwithstanding the extensive evidence filed on the motion by both the plaintiffs and the defendants, Justice Horkins found that plaintiffs had failed to satisfy every element of the certification test.

In this respect, the Court ruled as follows:

1. The plaintiffs' pleading (i.e., the statement of claim) was "seriously deficient" and failed to disclose a cause of action.

2. The plaintiffs failed to provide a sufficient evidentiary basis to establish that a class of two or more persons exists, and the proposed class definition was overbroad (it should have, at a minimum, been bounded by a start date when Seroquel was first introduced in Canada).

3. None of the common issues proposed by the plaintiffs were issues common to the class, the resolution of which would significantly advance the proceeding. This included the "general causation" question of whether Seroquel can cause weight gain and diabetes. The court held that, even if this common issue was resolved in favor of the plaintiffs, the plaintiffs did not provide any evidence to show that a methodology exists whereby general population data (or some other approach) could be used to assess this issue in common and arrive at an answer that would be of any use to the class. Each plaintiff would still have to prove that Seroquel caused his or her weight gain and/or diabetes.

4. Given that there was no single common issue that would significantly advance the litigation for the class, the court felt there was no reason to conclude that a class action would be a fair, efficient, and manageable method for advancing the claim.

5. The proposed representative plaintiffs were not suitable candidates to represent the proposed class because they were not adequately informed about the action and did not have a real interest in the action [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)].

Justice Horkins's extensive, methodical, and detailed analysis of the claim in relation to the criteria for certification has the potential, if followed by other judges, to enliven the level of scrutiny applied to future certification motions involving medical products. The message sent to litigants by the ruling is clear: certification should not be assumed, even in product liability cases. Whether a given case is certified by the court will not turn on whether claims involving similar issues have previously been certified by the court. Rather, certification will depend on the evidence filed by the parties and the adequacy of the presentation of the plaintiffs' case as it relates to the five criteria for certification set out earlier [Martin v. Astrazeneca Pharmaceuticals PLC, 2012, OJ No 2033 (QL)].

Shortly before Justice Horkins released her decision in Martin, another judge on Ontario's class actions panel—Justice Strathy—released a decision that denied certification in the case of Williams v. Canon Canada Inc. [2011 ONSC 6571 (Canon), aff'd 2012 ONSC 3692 (Ont Div Ct); Fasken Martineau DuMoulin LLP represented the defendants in Canon; the plaintiffs have filed a motion for leave to appeal the Divisional Court's decision to the Ontario Court of Appeal]. While this case did not involve a medical product (rather it alleged a defect in a line of Canon cameras), Justice Strathy's decision is relevant to class actions involving product liability claims of all types because, similar to Justice Horkins's decision, it reinforces the role of the court as a "gatekeeper" on a certification motion, and it reminds the parties that the evidence tendered on a certification motion, including expert evidence, must meet the usual criteria for admissibility; while the courts do not require much in the way of evidence on a certification motion, speculation and unsubstantiated assertions are insufficient to meet the threshold.

Contrary to the perception among some plaintiffs' counsel, certification is not a foregone conclusion in product liability class action proceedings in Canada. A move appears to be afoot toward a more robust application of the test for certification, complete with a disciplined application of evidentiary rules regarding admissibility of expert evidence, even where seemingly similar claims have been certified in the past. This may be the beginning of a trend toward applying the class action certification test in a way that many on the defense side have long thought is the approach that accords with the legislative intent of the class proceedings statutes.

Part IV: Medical Products on Trial

Once a class action is certified, plaintiffs and defendants turn their focus to the possibility of a trial of the common issues. Even though class actions have existed in some provinces in Canada for decades, relatively few cases have proceeded all the way to trial. Most cases have settled before the trial stage is ever reached. As a result, the body of case law precedents of trial adjudications from class action common issues trials is relatively sparse. This is especially true in the context of medical products class actions. As of August 2012, only *one* medical products case had gone to trial in Canada, Andersen v. St. Jude Medical Inc. [Andersen v. St. Jude Medical, 2012 ONSC 3660 (CanLII)].

This case was about the safety of mechanical prosthetic heart valves and annuloplasty rings that were manufactured by the defendant. The prostheses in question were coated with a proprietary mixture called Silzone, which was designed to inhibit the growth of postoperative bacteria. The plaintiffs claimed that Silzone interfered with tissue healing and impaired the body's ability to incorporate the medical devices, thereby causing or contributing to a number of medical complications. St. Jude voluntarily recalled all Silzone-coated products in the year 2000 based on its own testing. The central issue in the case was whether there had been a breach of duty by the defendants, causing injury [Andersen v. St. Jude Medical, 2012 ONSC 3660 (CanLII)].

The plaintiffs were ultimately unsuccessful at trial—the court dismissed their claim in its entirety. However, in terms of its relevance to the Canadian legal landscape, the actual end result of the case is secondary. The primary significance of Andersen is how it exemplifies the enormous complexity and cost of a common issues medical products class action trial. The trial involved some 2293 documents that were introduced as evidence and 138 days of testimony from 40 witnesses, including 23 expert witnesses from 14 different disciplines in science and medicine [Andersen v. St. Jude Medical, 2012 ONSC 3660 (CanLII)].

The Andersen decision also highlights the important role that expert medical evidence plays in medical products class action proceedings. The reliability of the competing expert evidence informed nearly every element of Justice Lax's 202-page ruling, most notably her examination of the issues of causation [Andersen v. St. Jude Medical, 2012 ONSC 3660 (CanLII)]. The rigorous and methodical way in which Justice Lax approached and weighed the expert evidence based on a generally accepted hierarchy within the scientific literature is instructive; it should send a clear signal to litigants about the important role that experts play in pursing or defending a medical products class action claim. Ensuring that the expert evidence that supports one's case is objective, robust, and methodologically sound can mean the difference between success and failure, should the claim go to trial.

Conclusion

Class actions, including those involving claims about medical products, are a relatively new phenomenon in Canada. The number of decided medical product class action cases in Canada, relative to the massive body of mass tort cases in this industry in the United States, is small, but it is growing rapidly. Given the presently unsettled nature of Canadian class action law on several issues in this area, coupled with the prospect that the Andersen decision may embolden more defendants to refuse to settle and force plaintiffs to go to trial on claims where the defendant believes the class claim lacks merit, the class action pendulum remains in motion. It behooves all affected players to keep their eye on this ball with rapt attention to see where it may move next.

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