

COURT FILE NO.: 294/09

DATE: 20090928

**ONTARIO
SUPERIOR COURT OF JUSTICE**

DIVISIONAL COURT

B E T W E E N:

ADRIEN LEFRANCOIS, SALLY ANNE)	
GEORGIU, GEORGE GEORGIU,)	
CYNTHIA ANN QUENNEVILLE, ROBERT)	<i>James M. Newland, Rebecca Case and</i>
QUENNEVILLE, SHANTI DEVI PANDEY,)	<i>Louise F. Moher, for the Plaintiffs</i>
MADHURI SINGH, MARGARET ADELLA)	
FITZGEORGE, WILLIAM FITZGEORGE,)	
HERBERT BRUCE HERON and)	
MADELEINE MARIE HERON)	
Plaintiffs)	

- and -

GUIDANT CORPORATION, GUIDANT)	
CANADA CORPORATION, GUIDANT)	<i>John A. Champion, Paul J. Martin and</i>
SALES CORPORATION and CARDIAC)	<i>Brad Moore, for the Defendants</i>
PACEMAKERS INC.)	
Defendants)	

) **HEARD at Toronto:** September 28, 2009

JANET WILSON J.:**The Motion**

[1] This is a motion for leave to appeal brought by the defendants ("Guidant") from the post-certification decision of Cullity J. dated June 11, 2009.

[2] Cullity J. certified this action concerning defects in thirteen defibrillator models as a class proceeding under the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 on April 10, 2008 (the “Certification Decision”).

[3] Guidant brought a motion to amend the certification decision to insert cut-off dates to limit the class with respect to the defibrillator models, based upon mitigation steps they had taken. The parties were able to agree on cut-off dates for all but three of the defibrillator models that are subject to this motion for leave to appeal.

[4] The plaintiffs were not satisfied that the defendants had provided adequate evidence to substantiate that the mitigation steps taken had corrected the defects in the three models in question. Cullity J. agreed with the plaintiffs’ submissions and dismissed the motion to set cut off dates for the three models in question as requested by the defence. Guidant now seeks leave to appeal from Cullity J.’s June 11, 2009 decision dismissing the amendment motion (the “Amendment Decision”).

The Issue

[5] The defendants advance two arguments. First, they argue that the motions judge erred by placing the burden of proof upon the defendants to establish the propriety of the proposed cut-off dates. Second, they argue that the motions judge erred in his conclusion that there was some basis in fact for the plaintiffs’ claim to go forward beyond the cut-off date proposed by the defendants.

[6] The defendants rely on both rules 62.02(4)(a) and (b) of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194.

The Certification Decision

[7] In this class proceeding, the plaintiffs seek general and punitive damages or, in the alternative, a disgorgement of revenue or net income from the defendants, for alleged negligence and conspiracy in the development, marketing and sale of the thirteen models of defibrillators that are subject to the certification order.

[8] The function of defibrillators is described in paragraph 10 of the Certification Decision of Cullity J. dated April 10, 2008:

[10] Defibrillators are battery operated devices that are intended to treat irregular heart rhythms – typically tachycardia in which the heart is beating too fast. Tachycardia can be life-threatening when it originates in the lower ventricles of the heart. Sudden cardiac death in such cases can be prevented by implanted defibrillators which administer an electric shock to the heart when the ventricular rhythmic disorder is detected. Their great benefit when they are operating effectively is to provide the necessary defibrillation, or electric shock, within a matter of seconds.

[9] Cullity J. outlines an overview of this proceeding in paragraphs 14 and 15 of the Certification Decision:

[14] In their pleading, the plaintiffs identify various defects in the defibrillators that, allegedly, can have adverse health consequences for patients in whom they were implanted. The defects were allegedly to vary in their nature and severity from one model to another.

[15] It is alleged that the defendants conspired to conceal the defects; to submit false and misleading information to Health Canada and the Federal Drug Administration (“FDA”) in the United States; to delay rectifying the defects; and

to mislead class members about the safety of the devices. It is pleaded that they were motivated by their own self-interest in certain respects – including a desire to increase revenues, save costs and avoid unfavourable publicity. It is pleaded further that their conduct was unlawful and was directed at the plaintiffs and the other class members.

[10] The three models of defibrillators which are the subject matter of this motion are:

- (i) Ventak Prizm 2DR 1861 (shorting in header failure mode);
- (ii) Contak Renewal H135 (shorting under header failure mode); and
- (iii) Contak Renewal 2H155 (shorting under header failure mode).

[11] The defect identified in the three defibrillator models in issue was the use of polyamide insulation, which had a tendency to crack or leak, making the defibrillator potentially dangerous.

[12] Advisory Notices were published by Health Canada when the defibrillators' defects became known. Doctors whose patients had one of the thirteen models of defibrillator were provided with the Advisory Notice and asked to contact their patients. The Advisory Notice issued by Health Canada for the three models in question established a cut-off date based on the defendants' assertion that the polyamide problems had been rectified.

[13] The defendants characterize this case as an advisory recall case, and seek to limit the class in this proceeding to those who received Health Canada Advisory Notices through their physicians, with the cut-off dates as stipulated by Health Canada. The plaintiffs assert that this is a defect case, and the definition of the class is linked to the identified defect in the defibrillators that may or may not coincide with the time frame covered by the Advisory Notices.

[14] In December 2005, the defendants stopped using polyamide insulation in the three defibrillators in question and used an alternative product known as PEEK. The plaintiffs argue that the cut-off date should be in December 2005, when the polyamide insulation was replaced with the alternative product, PEEK.

[15] The defendants argue that the appropriate cut-off dates are in April and November 2004, when the defendants had identified and solved the polyamide problems in the three models in question, in accordance with the cut-off dates specified in the Health Canada Advisory Notices.

The Amendment Decision

[16] Before considering specifics of the decision, the role of the motions judge must be placed in context. He has had extensive involvement for over three years, both before certification and after certification, in managing this file. The responding factum outlines the very significant scope of the motions judge's involvement:

Justice Cullity has case managed this action for over three years. In this capacity he has presided over a pleadings motion, six case conferences prior to certification, a motion for production of medical records, an undertakings and refusals motion, and a certification motion held in two parts over a total of six days. Justice Cullity also presided over a further five case conference post-certification with respect to amending the form of Notice and class definition. Finally, he presided over this motion over two motion days.

[17] This intimate involvement with the file, as well as the expertise of the motions court judge in matters of certification requires significant deference by this court.

[18] When the issue of cut-off dates arose, Cullity J. confirms in his reasons that all counsel were properly concerned about sending notices of this proceeding to persons who may not be at risk, causing needless upset and concern to an already vulnerable group.

[19] Counsel therefore attempted to agree to a protocol for interim discoveries limited to the issue raised by the defendants post-certification – that is, the appropriate cut-off dates with respect to the thirteen defibrillator models in question. When that process broke down with respect to the three models still in dispute, Cullity J. proceeded with hearing the argument on the motion.

[20] He applied a flexible approach and allowed further evidence to be filed as to the issue of cut-off dates and declined to follow the rigid rule stipulated in *671122 Ontario Limited v. Sagaz Industries Canada Inc.*, [2001] 2 S.C.R. 983. He noted at paragraph 16 of his reasons that flexibility is essential to precisely define the issues in class proceedings as the action evolves both during and after certification:

[16] It is very common for class definitions and common issues, and the causes of action, to be amended before the hearing of the motion to certify the proceedings and after an original record has been filed. Significant modifications during the course of certification hearing have been accepted and, as in *Pearson v. Inco Ltd.* (2006), 78 O.R. (3d) 641 (C.A.) and *Markson v. MBNA Bank Canada*, [2007] O.J. No. 1684 (C.A.), this has occurred even in the course of appeals after certification has been denied.

[21] Neither counsel challenged the approach taken by Cullity J. to the consideration of further evidence, in order to more precisely define the class of plaintiffs subject to this class proceeding.

Findings of Cullity J.

[22] The motions judge clearly identifies the issue, and concludes that the plaintiffs have provided sufficient evidence to establish that there is an issue to be tried with respect to the appropriate cut-off date for the three models in dispute. He states at paragraphs 30 to 32 of his decision:

[30] It follows that the single point in dispute on this motion is whether there is a sufficient basis in fact for the plaintiffs' position that the defects in the three models of defibrillators were not remedied until the polyamide insulation was replaced with PEEK in December 2005.

[31] In my judgment, there is sufficient evidence to establish that this is an issue to be tried as part of the common issues relating to, among other things, the alleged breaches of Guidant's standard of care. I accept the submission of plaintiffs' counsel that the existence of defects in the devices – and not the contents of Guidant's advisories – provide the required rational connection between an acceptable class definition and the common issues directed at Guidant's liability: *Hollick*, at para. 19.

[32] It is not disputed that the problems with the Ventak Prizm model first came to Guidant's attention no later than February, 2002. The independent committee that subsequently reviewed Guidant's conduct was critical of its failure to report the existence of the problem to the FDA, physicians and other health-care professionals until May 2005. When that was done, the defect was classified by the FDA as a Class I Recall meaning that the malfunction could have serious health consequences for patients and could be fatal.

[23] The motions judge carefully reviewed the evidence filed on behalf of the defendants with respect to mitigation efforts for the polyamide defect, and is bluntly critical of the defendants' incomplete and selective disclosure with respect to mitigation. He states at paragraph 42:

[42] Requests of plaintiffs' counsel for information with respect to the exact dates on which the polyamide insulation was replaced by PEEK have been ignored by Guidant and numerous questions with respect to the efficacy of Guidant's manufacturing changes and its communications with the FDA and Health Canada about them, and the polyamide testing it had performed, were

taken under advisement and have not been answered. No attempt appears to have been made to comply with the plaintiffs' many requests for copies of specific documents relating to these matters. In consequence, much of the available evidence at this stage of the proceeding consists of documentation and information within the possession and exclusive knowledge of Guidant that it has selectively chosen to make available to the plaintiffs and the court. I am far from satisfied that the full story of the effectiveness of the corrective and remedial measures taken by Guidant is in the record. The burden is on the defendants to justify the amendments that would have the effect of excluding patients from the class. In my opinion it has not been discharged.

(Emphasis added)

Test for Leave to Appeal

[24] The test on a motion for leave to appeal is stipulated in rules 62.02(4)(a) and (b) of the *Rules of Civil Procedure* as follows:

- (a) there is a conflicting decision by another judge or court in Ontario or elsewhere on the matter involved in the proposed appeal and it is, in the opinion of the judge hearing the motion, desirable that leave to appeal be granted; or
- (b) there appears to the judge hearing the motion good reason to doubt the correctness of the order in question and the proposed appeal involves matters of such importance that, in his or her opinion, leave to appeal should be granted. R.R.O. 1990, Reg. 194, r.62.02(4)

62.02(4)(a)

[25] This motion for leave to appeal from dismissal of a motion to amend a certification order was brought after the defendants unsuccessfully sought leave to appeal from the certification order itself. The decision to grant or deny an amendment is fact-driven, discretionary and embedded in the expertise of the certification judge, who is familiar with both certification procedure, and the facts, issues and dynamics of the case.

[26] There are no conflicting decisions on point. In my view, it is not desirable for leave to appeal to be granted. It is in the interest of the parties, particularly the plaintiffs, to proceed with the litigation.

62.02(4)(b)

[27] The law is clear that for a certification order to be granted there must be some basis in fact to substantiate the order sought. The motions judge correctly considered the evidence and applied the principles enunciated in *Hollick v. Toronto (City)* (2001), 205 D.L.R. (4th) 19 (S.C.C.). It is not the role of the certification judge to proceed to the merits and weigh the evidence on each interlocutory motion, as apparently urged upon me by the defense. The motions court judge confirmed at paragraph 15 of the Amendment Decision the appropriate role of the certification judge when he or she considers the evidence:

[15] While an important part of the function of a motions judge is to decide whether there are issues to be tried, the exercise is not the same as in determining whether there are genuine issues for trial for the purposes of motions for summary judgment. Nor do the plaintiff's have to demonstrate that there is a *prima facie* case for the claims that are said to raise common issues. Either approach – as well as that recommended by the Ontario Law Reform Commission and rejected in the CPA – would be inconsistent with the rule that evidence that goes directly to the merits is generally inadmissible and the absence of a preliminary merits test: see *Hollick*, at paras. 16 and 25; *Lambert*, paras. 67-70. Hence the frequently heard complaint of defendants' counsel in this case – as well as others – that the requirements for certification in sections 5(1)(b) and 5(1)(c) are too easily satisfied and do not provide sufficient protection for the rights of their clients.

[28] The defendants sought to limit the class to those who received the Advisory Notices, rather than those who received a defibrillator before the polyamide insulation was replaced by

PEEK in December 2005. The motions judge was live to the issue and reached a conclusion in favour of the plaintiffs. He states at paragraph 28:

[28] In the submission of plaintiffs' counsel, the question whether the contents of the advisories were accurate is central to the issues to be tried and is not to be decided on this motion. The relevant question for present purposes was simply whether there was some basis in fact for claims that would raise the issue of the effectiveness of the remedial measures taken before the use of polyamide installation was discontinued in December, 2005.

[29] There is no reason to doubt the correctness of the learned motions judge's decision. Quite to the contrary. He concluded that the plaintiffs had proved some basis in fact that in the three models in question the root cause of the problem was the polyamide insulation. He concluded that, notwithstanding the cut off dates of the Advisory Notices, once the plaintiffs had met the preliminary onus of proof that the root cause was polyamide, the defendants were then required to provide cogent evidence that the mitigation efforts were effective. This is not shifting the burden of proof. This is placing the burden upon the defendants once a certification order has been granted to justify an amendment. Further, once a defect is identified, for a cutoff date to be inserted, the defendants must provide cogent evidence that the problem has been rectified. Given the refusals, and the incomplete, and selective disclosure by the defendants, the motions judge concluded that this issue was one to be determined at the trial.

[30] I find, therefore, that there is no good reason to doubt the correctness of the motions judge's decision. Nor does the proposed appeal involve matters of such importance that leave ought to be granted.

Conclusion

[31] For these reasons, the motion for leave to appeal is dismissed. Counsel agreed that the successful party is entitled to costs fixed in the amount of \$12,500.00 plus GST and disbursements. Therefore the defendants shall pay this sum to the plaintiffs forthwith.

"J. Wilson"

JANET WILSON J.

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MARIE HERON

Plaintiffs

- and -

GUIDANT CORPORATION, GUIDANT
CANADA CORPORATION, GUIDANT SALES
CORPORATION and CARDIAC PACEMAKERS
INC.

Defendants

REASONS FOR JUDGMENT

JANET WILSON J.

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