



2. THIS COURT ORDERS that the Patient Class be defined as:

All persons who were implanted in Canada with one or more of the following defibrillators:

Ventak Prizm 2 DR	1861
Contact Renewal	H135
Contak Renewal 2	H155
Contak Renewal 4	H190 and H195
Contak Renewal 4 HE	H197 and H199
Contak Renewal 4 AVT	M170 and M175
Contak Renewal 4 AVT HE	M177
Ventak Prizm AVT	1900
Vitality AVT	A135 and A155

[2] In the course of subsequent discussions about the notice to be given to class members, counsel for the defendants (collectively, "Guidant") objected that the recipients were defined too broadly as, in counsel's submission, the evidence indicated that, in the case of each of the models other than Ventak Prizm AVT 1900, only persons implanted with devices manufactured on or before a certain date (the "cut-off date") would have claims with any basis in fact.

[3] Guidant's counsel proposed that only such persons and their family members should be put on notice of certification and given the opportunity to opt out.

[4] Counsel also proposed that the notice received by each class member should specify the date of an advisory issued by Guidant in respect of the particular device implanted in that member. This would require five different forms of notice. In this context, counsel expressed concern that the court should not cause unnecessary anxiety and distress by suggesting that persons who received defibrillators manufactured after the appropriate cut-off dates may have been implanted with defective devices.

[5] As the plaintiffs were not initially disposed to accept these proposals - or the appropriateness of the suggested cut-off dates - Guidant subsequently moved for an order approving the proposed notices and, if necessary, amending the class definition in paragraph 2 of the certification order, or decertifying the proceeding in respect of persons implanted after the cut-off dates.

[6] By the time of the hearing of the defendants' motion on April 6, 2009, the parties had agreed on cut-off dates for each of the models in question other than for the first three. For these, the defendants suggested cut-off dates of April 16, 2002 for Ventak Prizm 2 DR 1861 ("Ventak Prizm") and August 26, 2004 for Contak Renewal H135 and Contak Renewal 2 H155 (each a "Renewal" model).

[7] At the hearing it emerged that the point of contention with respect to the cut-off dates for these models related to the efficacy, or otherwise, of remedial measures taken by Guidant on or before the dates counsel had proposed. The three devices had allegedly suffered from a similar insulation defect that gave rise to short circuiting with potentially fatal risks to the implantees. Guidant had reported in June, 2005 that it had solved the problem for Ventak Prizm by adding a further type of insulation by the cut-off date its counsel proposed. Counsel for the plaintiffs, however, submitted that there was an issue whether the defect had been remedied before a date in December, 2005 when a different form ("PEEK") of insulation tubing was substituted for the original polyimide tubing that, either alone or in conjunction with other factors, had given rise to the short circuiting.

[8] Plaintiffs' counsel pointed out, as they have done on numerous occasions during the certification hearing, that the conduct of Guidant with respect to the timeliness, comprehensiveness and accuracy of its advisories was very much in issue - an aspect of the case that they stated was ignored by Guidant's reliance on its advisories to establish the appropriate cut-off dates. Counsel indicated that, before they could properly accept Guidant's contention that the defects had been cured during April, 2002 and August, 2004, they would need to have productions and examinations for discovery that would enable them to determine whether, notwithstanding the continued use of polyimide insulation until December 2005, the defects had been remedied by the changes made earlier.

[9] As all counsel were quite properly concerned that notice should not be given to persons who were not at risk, consideration was given to the possibility that the parties might be able to reach agreement on a protocol for interim discovery limited to the issue in dispute and the hearing was adjourned to enable counsel to consult. Subsequently, after an exchange of correspondence and requests for extensive productions by plaintiffs' counsel, it became clear that the proposal for interim discovery was unlikely to provide a practicable method of resolving the issue relating to the polyimide insulation. The hearing of the defendants' motion then resumed on June 3, 2009.

[10] As section 17 (1) of the CPA requires notice of certification to be given to the class members, it is, I believe, clear that an amendment of the certification order is required. The possibility of amendments is contemplated in section 8 (3) of the CPA and, again, in section 10 (1). There is, however, an initial question relating to the admissibility of fresh evidence, and the effect of the important decision of the Divisional Court in *Risorto v. State Farm Mutual Automobile Insurance Co.* [2009] O.J. No. 820.

[11] In *Risorto*, on a motion by the plaintiffs to admit fresh evidence after certification had been denied - but before the order had been entered - it was held that the court was bound to apply the principle in *671122 Ontario Limited v. Sagaz Industries Canada Inc.*, [2001] 2 S.C.R. 983. Under that test, as stated by Gray J.:

Evidence can be admitted after a trial, but before entry of a formal order, only if the evidence could not have been discovered previously by an exercise of due diligence, and the new evidence would probably have changed the result.

[12] In reversing my decision to admit the evidence, the Divisional Court held that:

... once the evidence has been presented to the court, the motion has been fully argued, and the court has rendered its judgment, the principles articulated by the Supreme Court of Canada in concerning the reopening of proceedings to allow the reception of further evidence, apply with equal force to certification motions. Indeed, in some ways they apply with even more force.... (para 39)

In my view, the interest in preventing litigation by instalments; requiring parties to put their best foot forward; and finality; are just as compelling in certification proceedings as they are in any other proceedings. (para 41).

[13] In rejecting the arguments that subsequently found favour in the Divisional Court, I had been influenced by the essentially procedural nature of certification motions and the role of the court to determine only whether – and, if so, on what conditions – a proceeding should advance to a determination of merits issues by another judge. I did not consider that there was a close analogy between a decision after a trial and one made on a motion to certify a proceeding under the CPA. On such motions, evidence that bears only on the merits of the proceeding is generally inadmissible so that the certification motion is almost necessarily decided on the basis of a very incomplete evidential record: see *Caputo v. Imperial Tobacco Ltd.*, [1997] O.J. No. 2576 (G.D.), and [2005] O.J. No. 842 (S.C.J. ), at para 21. Evidence directed at the merits may be admissible if - as in this case - it also bears on the requirements for certification in sections 5 (1) (b) through (e) but, in such cases, the issues are not decided on the basis of a balance of probabilities but rather on that of the applicable much less stringent test of "some basis in fact" *Hollick v. City of Toronto*, [2001] 3 S.C.R. 158, at paras 16-26; *Lambert v. Guidant Corporation*. [2009] O.J. No. 1910, at paras 56-74. As Goudge J.A. stated in *Cloud v. Canada*, [2004] O.J. No. 4924 (C.A.), at para 50:

... on a certification motion the court is ill equipped to resolve conflicts in the evidence or to engage in finely calibrated assessments of evidentiary weight. What it must find is some basis in fact for the certification requirement in issue.

[14] Whether or not the distinction I attempted to draw in *Dumoulin v. Ontario*, [2005] O.J. No. 3961 is tenable, I adhere to the view that the minimum evidential standard affirmed in *Hollick*, applies to factual issues that may be determinative of both the requirements for certification and the merits of the claims advanced on behalf of the class. The usual process of fact-finding is, therefore, not intended to be a feature of certification motions and this court has deprecated the delivery of extensive motion records by the parties and taken this into account when awarding costs.

[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 plaintiffs 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.

[16] As section 2 (3) of the CPA indicates, certification motions, that determine whether a case can be appropriately dealt with under the special procedure in the CPA, are intended to be made at an early stage of the litigation and before discoveries which, in a case like this, can be of immense significance for the ultimate disposition of the claims asserted on behalf of the class. 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.

[17] Given the role of the court, the general exclusion of evidence relevant to the merits of the claims asserted, and the flexibility permitted for the purposes of certification, it was my opinion that the other rules governing the admissibility of evidence must be similarly flexible and that a rigid rule of exclusion such as that in *Sagaz* would not be appropriate.

[18] By insisting on the finality of an order denying certification, *Risorto* has administered an important corrective to what had appeared to be the flexibility of the system under the CPA. Whether the decision will be applied in other cases – where for example a plaintiff seeks to substitute a class representative for one that has been rejected by the court in denying certification – and whether it will lead to an increase in the evidence filed for certification purposes – remains to be seen. The question whether the decision applies when a defendant moves to amend an order certifying a proceeding cannot, I believe, be ignored in this case.

[19] For the purpose of the motion the defendants delivered a further affidavit of Mr Brooks Berg, the Manager of Systems Engineering at the Cardiac Rhythm Management Division of Boston Scientific Corporation, the present owner of Guidant. Mr Berg had earlier deposed to the various manufacturing changes that Guidant had implemented to mitigate the problems detected with the models referred to in the class definition. In this fresh affidavit, he provided additional information of the modifications made to the three devices whose cut-off dates are in issue as well as Guidant's belief that these changes have been fully effective.

[20] This evidence was obviously available to the defendants at the hearing of the certification motion and, if *Risorto* and the *Sagaz* principle are to be applied, it could not be admitted for the purpose of amending the order. Defendants' counsel quite frankly stated that they had previously overlooked the significance of the omission of cut-off dates that had initially appeared in the class definition proposed by the plaintiffs.

[21] Implicitly, the view of the Divisional Court appears to have been that the *Sagaz* test was as applicable to motions to decertify as it was to the decision to deny certification in that case. At para 42 of the court's reasons, Gray J stated:

It should be noted that as acknowledged by Mr Baert, fairness dictates that the same test for the reception of new evidence would apply whether a motion for its reception is brought by the plaintiffs or the defendants. Thus, if the test adopted by the motions judge is the correct one, it would be open to a defendant to move to reopen a successful motion for certification where there is an arguable case that proposed new evidence might justify an order dismissing the motion. In such a case, a plaintiff's interest in finality would be just as deserving of protection as that of a defendant.

[22] A similar opinion was expressed by John Macdonald J. in his reasons for giving leave to appeal in *Risorto*.

[23] In *Pearson*, [2009] O.J. No. 780 (S.C.J.), at para 26, I considered that these views were *obiter* and, while affording, I hope, the appropriate degree of respect due to them, I believed there were additional matters relevant to motions to decertify that should be considered. In particular, I did not believe the objectives of the CPA, or the interests of an efficient administration of justice, would justify, for example, the exclusion of evidence that would demonstrate that a class proceeding would be unmanageable, or that common issues previously accepted by the court lacked commonality. The application of the *Sagaz* principle to such cases would oblige defendants to proceed, through what in cases such as these can be exorbitantly expensive discoveries, to a trial in which the excluded evidence would be admissible and the relevant time and cost of preparing the case for trial would be wasted. This would be inimical to judicial economy, and finality would not have been achieved by excluding the evidence.

[24] Similar considerations apply in this case where, unlike the position in *Risorto*, the provisions of the CPA expressly contemplate that orders made at the certification stage may subsequently be amended. It is, in my opinion, one thing to apply the *Sagaz* principle to orders that are not otherwise subject to amendment and something significantly different to impose it for the purposes of motions to exercise the express powers of amendment in sections 8 and 10 of the CPA. The function of the motions court when certification is found to be appropriate is to frame the class and the issues for the trial judge. In my judgment, the *Sagaz* principle should not be applied to send to discovery and trial a case with an unnecessarily over-inclusive class, and to leave to the trial judge the task of restricting the class to those whose claims have some basis in fact. The task is, I believe, essentially that of the motions judge who case manages the

proceeding and, it is for such purposes that the express authority to amend certification orders was included in the CPA.

[25] In addition, to the extent that the defendants' motion to insert cut-off dates might depend on the new evidence of Mr Berg, its rejection on the basis of the *Sagaz* principle alone could have the consequence that, by giving notice to persons not at risk, the court may cause precisely the kind of emotional distress and anxiety for which the plaintiffs are seeking damages on behalf of the class.

[26] In short, while accepting that *Risorto* must be followed in this court, I believe the decision is distinguishable and ought not to be applied to motions to amend certification orders such as this or, indeed, to decertification motions as in *Pearson*. It follows that, in my judgment, defendants' counsel were correct in their assumption that *Risorto* has no application to the present motion. This was not disputed by counsel for the plaintiffs who, however, submitted that there should be a heavy onus on a party who seeks an amendment on the basis of evidence previously within its knowledge or discoverable by an exercise of due diligence.

[27] The defendants' motion was opposed by the plaintiffs on the ground that there was a sufficient factual basis for cut-off dates in December 2005 for each of the three models in question. They were prepared to consent to an amendment that would restrict membership in the class of persons implanted with one or another of these models to those who received devices manufactured before these dates. Whether these dates, or the earlier date favoured by defendants' counsel, were those by which Guidant was successful in remedying the defects discovered in February 2002, and not disclosed by it until May 2005, is not an issue to be decided on this motion on a balance of probabilities, or otherwise. The task of the court, again, is to define for the court at trial issues that have some basis in fact.

[28] The submissions of the parties were, in general, similar to those made in *Lambert* in that, as well as the evidence of Mr Berg, defendants' counsel relied heavily on statements made in its own advisories and in reports to the FDA and Health Canada. 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 polyimide installation was discontinued in December, 2005.

[29] On these questions of principle, which underline the special and probably unique nature of certification motions, I believe plaintiffs' counsel were correct and I will not repeat the comments I made in *Lambert* on the similar submissions of counsel in that case. I will note only that, in my opinion, issues of fact that are determinative of the merits are not to be decided at the certification stage. To the extent that they may have some relevance to the requirements for certification, the test, and the standard to be applied, are to be found in the reasons in *Hollick*, at paras 16 – 26, where the learned Chief Justice addressed the limited admissibility of evidence at the certification stage, and the standard of "proof" to be applied. In view of the minimum evidential standard applicable, it was, in my opinion, neither necessary nor appropriate to resolve

the question of class definition by requiring the defendants to undergo, at this threshold stage of the proceeding, what I was assured would be a very lengthy process of productions and discoveries directed at the issue.

[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 polyimide 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.

[33] In the meantime, in April 2002 Guidant had taken steps to remedy the problem without knowing that at least one of its sources was to be found in a tendency of the polyimide insulation to crack and leak. This was not discovered until towards the end of 2004 by which time further polyimide had been added to the device in November 2002.

[34] In an advisory that was issued by Guidant on June 17, 2005 and posted on Health Canada's website, the problems with the polyimide insulation were identified as one of the contributing factors to the malfunctioning of the Ventak Prizm model. It was stated that manufacturing changes had been made on April 16, 2002 and November 13, 2002 and that no reports of malfunctioning had been received in connection with the altered devices. It was also stated - and it is not disputed - that Guidant recognised that incidents of malfunctioning are under-reported and that the defibrillators of deceased patients were rarely returned to Guidant for examination.

[35] An FDA report of June 16, 2005 contains the following statements:

Early production "Prizm - 2" and "Renewal" devices are subject to failure of the Polyimide insulation located inside the header section of the devices. The header is not hermetically sealed, and the close spacing places considerable demands on the insulation. The manufacturer may not have been aware that this material deteriorates in humid environments and is subject to cracking at bends. Polyimide insulation has been studied in relation to aircraft crashes. The deterioration is progressive and then results in sudden failure. ...

The April 2002 manufacturing change to the Prizm - 2 consisted of application of a layer of RTV's silicone to a metal component (backfill tube) in the header, and allowing the RTV to cure before subsequent assembly. ... A similar change to the "Renewal" manufacturing was made in November 2004. ... There are no reports of the arcing failures in devices made using these new manufacturing procedures.

A manufacturing change order for the use of PEEK ... instead of Polyimide in the header of the "Renewal" is included in the firm's information provided June 7, 2005. The change has not been instituted. The change order mentions the possibility of this change for other Guidant devices.

[36] A footnote to the first of the paragraphs from the report quoted above states:

This failure mode appears to have been eliminated by applying and curing the silicone RTV adhesive specifically as insulation, and other manufacturing changes in "Prizm - 2" manufactured after April 2002 and "Renewal", after August 2004.

[37] There is no evidence that the comment in the footnote was based on anything other than information provided by Guidant. In cross-examination, Guidant's vice-president and deponent, Mr Nuernberg, stated that, in his experience, the FDA had never requested more than formal wording changes to Guidant's advisories to which the FDA's Recall classification was applied. In any event, Guidant's *Product Performance Report* for 2009, refers now to four instances of the short-circuiting malfunctions in devices manufactured between April 16, 2002 and November 13, 2002.

[38] In its subsequent updates to its advisories with respect to the defects in the three models, the cut-off dates of April 16, 2002 and August 26, 2004 were repeated.

[39] Guidant's annual report of manufacturing changes to the Renewal models for the period April 1, 2004 and March 31, 2005 contains a description of corrective measures implemented to deal with the problem of arcing. After referring to the initial addition of a second layer of insulation protection, the report continues:

After further investigation, review of returned products, and internal testing, arcing was determined to be caused by a combination of a cracked polyimide insulating tube around the feed thru wire and limited MA coverage between the wire and the can. As a result, the change stated above was subsequently superseded by three further changes per the following submissions that were approved by FDA. ...

- ...
- ...

- Replace the existing Polyimide tubing that currently insulates the feed thru wires in the pulse generator header assembly with [PEEK].

[40] In response to a request for information from Health Canada of January 31, 2006, Guidant stated that the substitution of PEEK insulation began in December 2005 and had not previously been reported because it was not part of the corrective action as

polyimide by itself was not the cause of device failure but rather it was in combination with other specific factors (unstated). PEEK is stated to have similar insulative properties but better hydrolytic and stress performance.

[41] By way of contrast, in a Trend Report prepared by Guidant as of June 14, 2006, it was stated that “the root cause of the issue is shorting due to breaches in the polyimide insulation on the feedthru wires in the area of the backfill tube.” It was stated that the addition of further polyimide tubing on November 13, 2002 was believed to fully correct the situation but that a replacement for polyimide had been identified.

[42] Requests of plaintiffs’ counsel for information with respect to the exact dates on which the polyimide 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 polyimide 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


[43] Given the identification of the use of polyimide tubing as either the root cause of the arcing problem, or a contributing factor, and that manufacturing changes to eliminate its use were being made in December 2005, and had been contemplated previously in connection with the problems that had been identified, I am of the opinion that the plaintiffs are entitled to treat the defendants’ contention that the defects were cured before that time – so that the changes might be considered to be improvements and not remedial – as a matter that is legitimately in issue. I do not accept the submission of defendants’ counsel that the plaintiffs have not satisfied the minimum evidential burden - some basis in fact - required to raise an issue with regard to the identification of the devices that suffered from the alleged defects. On motions to certify proceedings, that is all that is required of them. Decisions on the merits of the claims advanced on behalf of class members are not to be decided on such motions. Nor, in my opinion, should persons be lightly excluded from the class on the basis of merits-based considerations, and an incomplete evidential record.

[44] In my opinion, the submissions of defendants' counsel were misconceived in that, as in *Lambert*, they attempted to require the plaintiffs to accept as proven self-serving statements of the defendants with respect to their own conduct on merits-based issues, to the extent that the plaintiffs had not delivered evidence in rebuttal, or moved on the multitude of refusals and unanswered questions in the cross-examinations of the defendants' deponents. The court has, in effect, been asked to treat the cross-examinations as completed discoveries and to cross into forbidden territory where merits-based issues are decided and the minimal evidential standard required of the plaintiffs does not apply.

[45] Even more fundamentally, the attempts to tie the class definition to the contents of the advisories is quite inconsistent with the case the plaintiffs have pleaded. Guidant's conduct with respect to its advisories is very much in issue. From the viewpoint of the plaintiffs, it is part of the problem. Questions relating to when Guidant discovered defects with its defibrillators – or when it should have done so – what actions it took to remediate them, whether such actions were effective and what and when disclosure was made to physicians, patients, the FDA and Health Canada are at the centre of the claims advanced by the plaintiffs. There are also important questions relating to the extent that the regulatory officials attempt, and are able, to verify statements such as those made by Guidant in its response to Health Canada's enquiry of January 31, 2006. These are all matters to be tried. It would be to beg questions that go to the merits if the advisories were relied on at this stage to provide a solution to the issues of class definition.

[46] In consequence, the defendants' motion to add the cut-off days of days of April 16, 2002 and August 26, 2004 is dismissed. The date or dates in December 2005 on which PEEK was substituted for polyimide insulation are to be provided to plaintiffs' counsel by Guidant within 21 days of the release of these reasons. These dates are to be inserted in the notices and the class definition in the certification order will be amended accordingly. Other consequential changes to the draft notice to class members can be dealt with at a case conference.

[47] Costs maybe spoken to or, if the parties would prefer to make their submissions in writing, those of the plaintiffs should be made within 14 days and the defendants will have a further seven days in which to respond.

  
CULLITY J.

COURT FILE NO.: 05-CV-292387 CP

DATE: 20090611

ONTARIO

SUPERIOR COURT OF JUSTICE

**B E T W E E N:**

Adrien LeFrancois, Sally Anne Georgiu, George  
Georgiu, Cynthia Ann Quenneville, Robert  
Quenneville, Shanti Devi Pandey, Madhuri Singh,  
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Herbert Bruce Heron and Madeleine Marie Hcron

Respondents/Plaintiffs

**- and -**

Guidant Corporation, Guidant Canada  
Corporation, Guidant Sales Corporation and  
Cardiac Pacemakers Inc. -

Moving Parties/Defendants

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REASONS FOR DECISION

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CULLITY J.

Released: June 11, 2009