



## REASONS FOR DECISION

### CULLITY J.

[1] For reasons released on September 5, 2007, this action was certified pursuant to section 5 (1) of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6 ("CPA") in respect of the plaintiff's claims for negligence against the defendant (the "Crown").

[2] The Crown has now moved for orders striking the statement of claim pursuant to rule 21.01 (1) (b) on the ground that it discloses no cause of action; decertifying the proceeding; and dismissing the action. In the submission of its counsel, it is plain and obvious that no relationship of proximity existed between the parties that would support a duty of care owed by the Crown.

[3] Essentially the same submission had been made, and rejected, for the purpose of certification in the context of the requirement in section 5 (1) (a) of the CPA. It has now been made again because of the intervening decisions of the Court of Appeal in *Attis v. Canada*, [2008] O.J. No. 3766 and *Drady v. Canada*, [2008] O.J. No. 3772.

[4] In *Drady* certain aspects of my treatment of proximity in this case were criticised and, in the submission of counsel for the Crown, it is clear from the reasoning of the Court of Appeal that, as in *Attis* and *Drady*, it is plain and obvious that the facts pleaded in this case were insufficient to support a finding of proximity.

[5] Although, at the hearing of the motion, a certain amount of time was spent on issues of *res judicata* and issue estoppel, I do not find it necessary to deal with them. If, as I believe to be the case, my decision at certification is fundamentally inconsistent with the analysis in the subsequent decisions of the Court of Appeal, I am satisfied that the provisions of section 10 of the CPA are applicable.

- 10 (1) On the motion of a party or class member, where it appears to the court that the conditions mentioned in subsections 5 (1) and (2) are not satisfied with respect to a class proceeding, the court may amend the certification order, may decertify the proceeding or may make any other order it considers appropriate.
- (2) Where the court makes a decertification order under subsection (1), the court may permit the proceeding to continue as one or more proceedings between different parties.
- (3) For the purposes of subsections (1) and (2), the court has the powers set out in clauses 7 (a) to (c).

[6] Certification motions are intended to be made at an early stage of the proceeding and section 10 recognises that subsequent developments may justify a reconsideration of a decision

that the requirements for certification are satisfied. By expanding the case management powers of the court for this purpose, it reinforces the legislative intention reflected in section 5 that only cases that are appropriately dealt with under the CPA should be permitted to proceed to a trial of common issues.

[7] Although section 10 of the CPA is probably most likely to be used after new facts have been discovered, the legislative intention would, in my opinion, equally be served by applying the section to a case in which the reasoning on which certification was based cannot withstand the critical analysis in subsequent decisions of an appellate court.

[8] The plaintiff's claims relate to the catastrophic injuries she allegedly suffered from the insertion of implants ("Vitek implants") in a temporomandibular joint ("TMJ") in her jaw. These injuries she attributes to the negligence of the employees of the Ministry of Health ("Health Canada") exercising their statutory powers and responsibilities under the *Food and Drug Act* S.C. 1952 - 53, C. 38 ("FDA"). It is pleaded that the employees of Health Canada were, or ought to have been, aware that the implants were being imported and marketed in Canada without authorisation by the Department, and that they are prone to deterioration and disintegration with severe consequences to the health of the patients in whom they were implanted.

[9] The statement of claim contains a lengthy history of the conduct of Health Canada's employees with respect to the failure of the manufacturers of Vitek implants to obtain the requisite certificate of compliance in accordance with the provisions of the FDA and regulations, and the repeated failures of the employees to comply with, and enforce, departmental policies when they were aware that the devices were being marketed in Canada. Specific allegations relating to such conduct were summarised in paragraph 29 of my earlier reasons. My conclusions were that the allegations related to operational activities and defaults of Health Canada's employees, that, if proven, put the plaintiff and other recipients of Vitek implants at risk, and that it would be open to a court at trial to find that, in the circumstances, a relationship of proximity had been created between the Crown and the plaintiff.

[10] *Attis* and *Drady* were also concerned with medical implants - breast implants in *Attis*, and TMJ implants in *Drady*. In each case it had been held at first instance that the Crown owed no duty of care because of the absence of a relationship of proximity with the plaintiff.

[11] The claims made by the plaintiff in *Drady* and by Ms Taylor were originally asserted in a single action which was later severed. The provisions of the original pleading were retained to a very large extent in each of the statements of claim for the severed actions. There was, however, one difference that I considered to affect the issue of proximity. While the allegations relating to the conduct of Health Canada's employees in each case concerned Vitek implants, and while it was pleaded that the plaintiff in this case received a Vitek implant, this was not pleaded in *Drady*. Instead, it was stated that the manufacturer of the implant in that case was unknown.

[12] In paragraph 28 of my reasons for certification in this case, I referred to the fact that, under the FDA and the regulations, Health Canada does not regulate devices generically or by categories. Its powers and responsibilities are confined to dealing with particular devices sold, or to be sold, in Canada on a case-by-case basis. The Crown's alleged negligent conduct in respect of the defaults of the Vitek implants distributor could not in my opinion create proximity with

Mr *Drady* if it was not alleged that he received such a device. It appeared to me that, while the absence of a close causal connection between a defendant's conduct and harm suffered by a plaintiff may not always be fatal to a claim of proximity, it was essential on the facts of *Drady*. In my judgment, the scope of any duty of care that might exist between the Crown and recipients of a product to which Health Canada's conduct related would not extend to a person who did not receive that product.

[13] In finding that it was not plain and obvious that there was no relationship of proximity between the Crown and Miss Taylor, I held that the impugned conduct of Health Canada's employees fell within the category of operational activities rather than policy decisions so that the existence of a duty of care would be determined at the first stage of the *Anns* inquiry. In this context, I referred to the statement of Wilson J. in *City of Kamloops v. Neilson*, [1984] 2 S.C.R. 2 at page 24 that governmental inaction for no reason or for an improper reason cannot be a policy decision made in a *bona fide* exercise of discretion.

[14] It followed that the question whether there was such a duty would fall to be determined by reference to reasonable foresight of harm on the part of Health Canada and the issue of proximity. In this context, I cited the following passages from the reasons of McLachlin C.J.C. and Major J. in *Cooper v. Hobart* at para 38:

It is at this second stage of the analysis that the distinction between government policy and the execution of policy fails to be considered. It is established that government actors are not liable in negligence for policy decisions, but only operational decisions. The basis of this immunity is that policy is the prerogative of the elected legislature. It is inappropriate for courts to impose liability for the consequences of a particular policy decision. *On the other hand, a government actor may be liable in negligence for the manner in which it executes or carries out the policy.* (my emphasis)

[15] At para 44, in a passage that has been quoted with approval by the Court of Appeal of British Columbia in *Knight v. Imperial Tobacco Canada Limited*, [2009] B.C.J. No. 2445 at para 58, I stated:

Inaction by governmental bodies where statutory powers are conferred for the protection of the public will not ordinarily engage a duty of care even though harm to individuals is reasonably foreseeable. Absent a statutory provision, or implication, to the contrary, any duty to exercise the powers will be owed to the public and not to private individuals. The missing element - proximity - may, however, be supplied if, by a course of conduct in a purported exercise of the powers, the agency creates, or contributes to, a foreseeable risk of harm to a discrete group.

[16] My conclusion on section 5 (1) (a) was stated earlier at paragraph 40:

It is possible that the plaintiff will not be able to prove the allegations of fact in the statement of claim - or that a different complexion may be placed on them when all the evidence on each side is before the court at trial. These are not matters I am concerned with on this motion. On the basis of the pleading alone, I do not consider it to be plain and obvious that Ms Taylor has no chance of success in establishing that a relationship of proximity - as required to establish a private law duty of care - exists in connection with the operational acts of Health Canada.

[17] The Court of Appeal in *Drady* was critical of three aspects of my approach to the question of proximity.

[18] One criticism was that by describing the conduct of Health Canada's employees as "operational" for this purpose, I had "distracted the analysis from the first stage consideration of proximity". The point was, however, simply that, as the impugned conduct was, in my opinion, operational and did not involve policy decisions, an inquiry into proximity was required. At the conclusion of the reasons in *Drady*, the court agreed that, if there had been a finding of proximity, the impugned conduct of Health Canada's employees could be characterized as operational.

[19] A second criticism was that I had assumed that "without more" conduct that increases risk creates a relationship of proximity. That was not my intention. The factors I found could establish proximity at trial were not merely the increased risk to the plaintiff and the other class members, but the combination of that and other circumstances involving the conduct of Health Canada's employees. These included the fact that, in the performance of its responsibilities in regulating medical devices on a case-by-case basis - and unlike the facts pleaded in *Drady* - Health Canada's allegedly negligent operational conduct related to the same particular device that was implanted in the plaintiff and other members of a discrete group. It was, moreover, pleaded that this conduct occurred in the face of Health Canada's knowledge that patients, dentists and oral surgeons assumed that all medical devices available on the Canadian market had been approved by Health Canada, and that the department had represented that it took a lead role in alerting the public to safety concerns.

[20] Given that physical proximity is not the test and that the question whether there is a sufficiently direct interaction between the plaintiff and the defendant's conduct to establish proximity may involve questions of degree, I concluded that the combination of the factors I have mentioned left open the possibility that a finding of proximity might be made at trial.

[21] Although the Court of Appeal in *Drady* did not state explicitly that the conclusion I had reached on the pleading in this case was incorrect, I believe this is the only reasonable conclusion that can be drawn from the court's analysis. In particular, the court found - the third criticism - that "the motion judge erred to the extent that he based his decision on the non-identification of the manufacturer". While, in the court's reasons, this may not have been

directed at the issue of proximity specifically, it is, I believe, clear from the reasons in *Drady* that, overall, the court did not accept the ground on which I distinguished *Drady* and the significance I attributed to the factors that I considered to justify the decision to leave proximity to be tried.

[22] I was informed that the Court of Appeal was not provided with the pleading in this case. The parts of the statement of claim that I relied on were, however, identical in all material respects to those in *Drady* other than the ability to identify the manufacturer of the implants. Counsel for the plaintiff were the same in each case and it appears that they argued in the Court of Appeal that the two cases were indistinguishable. The Court of Appeal agreed with counsel on this point, but not on the consequences that followed.

[23] The approach to the existence of proximity in *Drady* is far less expansive than that adopted at certification in this case.

[24] In *Drady* the focus of the analysis was indicated in the paragraph 40 of the judgment delivered by Lang J.A.:

In the absence of a duty based solely on the statutory framework, I will consider whether Health Canada assumed a proximate relationship with the appellant rooted in the interactions between the parties. According to the authorities discussed in *Attis*, if the parties' reasonable expectations, representations or reliance demonstrate a close and direct relationship, there may be a basis to conclude that it is fair and just to impose liability.

[25] Having concluded that, without more, conduct that increases risk will not create a relationship of proximity, the reasons in *Drady* continue as follows:

53. It is therefore necessary to turn to the appellant's pleadings about his expectations, representations, and reliance on Health Canada regarding the safety of the TMJ implants. The pleadings do not contain, and there was no suggestion they could contain, any allegations of direct interactions or communication with particular Health Canada employees or the receipt of, or reliance upon, some assurance regarding the safety of the implants. However, the pleadings include three allegations that distinguish the claim from that in *Attis*. The first is that "Health Canada represented that it monitored the effectiveness of recalls by manufacturers and it took a lead role in alerting the public of recalls and safety concerns". The second is that, in 1983, Health Canada issued an information letter explaining that the issuance of a notice of compliance "meant that Health Canada was satisfied that the manufacturer had carried out tests and had submitted appropriate results to Health Canada to demonstrate a

reasonable probability of safety of the devices and effectiveness of the devices in humans." The third is that Health Canada failed to "to respond to requests for information made by members of the public concerning devices".

54. The pleadings do not allege that any of these communications came to the appellant's attention or to the attention of any specific member of the public. Nowhere does the appellant plead specific representation made to him by Health Canada. Moreover, nowhere does the appellant assert reliance, other than by pleading that members of the public generally relied on Health Canada to implement its public law duties. *In the absence of a specific representation or reliance on Health Canada regarding the safety of the implants, in my view, it is plain and obvious that the appellant cannot establish a direct and close relationship or proximity that makes it just and fair to impose a private law duty of care on Health Canada.* (my emphasis)

[26] In my opinion, the reasoning in these paragraphs must necessarily apply equally to the pleading in this case and, on that ground - and subject to the possibility of amendments to the pleading that would remedy the deficiencies identified by the Court of Appeal - the Attorney General's motion to strike and to decertify the action must be granted.

[27] In reaching this conclusion, I have not overlooked the decision in *Sauer v. Canada*, [2007] 225 O.A.C. 143 (C.A.) which counsel were not able to reconcile with *Drady* and which I had, at certification, described as consistent with my conclusion on proximity.

[28] The claims in *Sauer* arose after a cow in Alberta had been diagnosed with mad cow disease ("BSE") in 2003. As a consequence, Canada's borders with a number of countries were closed to Canadian cattle and beef products with extremely severe economic consequences for the commercial cattle industry in Canada.

[29] The plaintiff was a cattle farmer who commenced a class action on behalf of approximately 100,000 commercial cattle farmers in seven provinces. As described by the Court of Appeal, the claims against the Crown were "for negligent regulation of the cattle industry in a number of respects". Specifically, the plaintiff claimed negligence in designing and promulgating regulations that permitted a BSE contaminant to be included in cattle food, and in failing to ban this practice subsequently. Mr *Sauer* had not fed the contaminated food to his cattle. His claim was for the financial losses he suffered as a consequence of the Crown's alleged negligence.

[30] The action against the Crown was certified in this court notwithstanding Canada's position that it could not be liable in negligence for legislative action, or inaction. In certifying the proceeding Winkler R.S.J. held that a duty of care had been disclosed in the pleading. The learned judge had, it seems, no doubt that a relationship of proximity had been pleaded sufficiently as he addressed only the issues of policy that are relevant at the second stage of the

*Anns* inquiry. These issues, he held, could not properly be decided on the basis of the pleadings alone and should be tried.

[31] In the Court of Appeal the question of proximity was considered and was found to have been sufficiently supported in the pleading to satisfy the plain and obvious test. The question was dealt with in paragraphs 61 and 62 of the reasons delivered by Goudge J.A.:

61. As for the first stage, Canada does not seriously contest the foreseeability requirement. However, he does argue that there can be no relationship of sufficient proximity between commercial cattle farmers in Canada when Canada makes legislative decisions.

62. On the other hand, *Sauer* argues that he has pleaded the facts required to show sufficient proximity between Canada and commercial cattle farmers to raise a *prima facie* duty of care. In particular, he points to the many public representations by Canada that it regulates the content of cattle feed to protect commercial cattle farmers among others. He says this shows that Canada was acting with their interests in mind rather than the broad public interest. *Sauer* says that Canada's public assumption of a duty to Canadian cattle farmers to ensure the safety of cattle feed yields the conclusion that it is not plain and obvious that his claim of a *prima facie* duty of care will not succeed. I agree.

[32] The reference to the Crown's public assumption of a duty to cattle farmers echoes the statement in paragraph 9 of the Amended Fresh as Amended Statement of Claim in *Sauer* that the Crown assumed both policy and operational responsibilities for ensuring the safety of all animal food in Canada - a statement that is materially identical to that in paragraph 7 of the plaintiff's pleading in this case except that here the reference is to the safety of medical devices in Canada.

[33] As I have indicated, at the certification stage I referred to *Sauer* as consistent with the conclusion I had reached on the question of proximity. I did not discern a significant distinction between cattle farmers who suffered as a result of the Crown's failure to prohibit the use of the contaminated food product and the Crown's failure in this case to prohibit the importation and sale of Vitek implants. Notwithstanding the comments that follow, I am still of that opinion. In this connection I refer in particular to paragraph 44 of my reasons that I have set out above.

[34] In two subsequent cases I have heard since then, *Sauer* has been described by defendant's counsel as wrongly decided. That is obviously not a finding that is open to me. *Sauer* has, moreover, been referred to - and its correctness has not been questioned - in a number of subsequent cases in the Court of Appeal including *Williams v. Canada*, [2009] O.J. No. 1819, *Attis, Drady and Heaslip Estate v. Mansfield Ski Club Inc.*, [2009] O.J. No. 3185.

[35] The treatment of *Sauer* in these cases is typified by the following comments in *Attis* and *Drady*:

[In *Sauer*] this court found a sufficient pleading of proximity at para. 62 on the basis of the many express "public representations by Canada that it regulated cattle feed to protect *commercial cattle farmers* among others" (emphasis added). Accordingly, the result in *Sauer* depended on the allegation of specific representations by the Government that it was acting in the interests of the plaintiffs. On this basis, *Sauer* is distinguishable because the appellants in this case do not plead any specific representations by Health Canada that it was acting to protect the particular interests of the consumers of breast implants. (*Attis* at para 49)

Proximity was also adequately pleaded in *Sauer* on the basis of the many express public representations by the government that it was acting for the explicit purpose of protecting the commercial cattle farmers. These representations supported the plaintiff's allegation that the government assumed a private law duty to act on behalf of the farmers. (*Drady* at para 42)

[36] See, also, *Williams* at para 33, and *Heaslip* at para 21.

[37] The significance attributed to the representations in *Sauer* would appear to have considerable precedential importance for counsel and motions judges when considering the kind of representations by the Crown that could give rise to a sufficiently close relationship with the plaintiff. Relevant parts of the pleading in *Sauer* are in paragraphs 54 and 115 and contain quotations from the Annual Report of Agriculture Canada to Parliament for the year 1988 - 89.

[38] The first quotation was from the introductory paragraph to the report that described the Mandate of the department as follows:

In 1988 - 89 Agriculture Canada's objective was to promote the growth, stability and competitiveness of the agri-food sector, and until September 19, 1988 also those of the forest sector, by making available policies programs and services that are most appropriately provided by the federal government, so that the sectors make their maximum contribution to the economy.

[39] The other paragraphs from which the quotations were taken appear in the chapter headed "Livestock":

Agriculture Canada's activities in the livestock sector support the entire Canadian livestock industry. The department's

programs protect food users and Canadian animals from disease.

Agriculture's Canada's Food Program controls livestock feeds manufactured, imported and sold in Canada to protect users and the public from health hazards and marketing fraud.

[40] In addition to these extracts from the Annual Report, the pleading in *Sauer* contains references to Regulatory Impact Statements of the purpose of legislation and regulations dealing with livestock foods and animal health. These were described as being for the protection of consumers and livestock producers against potential health hazards from contaminants in livestock products, and to prevent the spread within Canada of animal diseases that would either affect human health or have a significant impact on the livestock industry. The statements may be compared with the more general reference in paragraph 14 of the pleading in *Drady* and in this case:

At all material times at issue, her Majesty operated a comprehensive regulatory regime to ensure that no Canadian suffered from the use of the device which when used according to directions or under such conditions as were customary or usual, would cause injury to the health of the Purchaser or user thereof.

[41] Finally, the pleading in *Sauer* contained a reference to paragraph 7 of The Code of Regulatory Fairness published annually as part of the Federal Regulatory Plan. This states that:

The government will ensure that officials responsible for developing, implementing or enforcing regulations are held accountable for their advice and actions.

[42] This statement has no counterpart in the pleading in *Drady*, or in this case, although it would, presumably, apply equally to regulations under the FDA.

[43] The statements in the pleading in *Sauer* were considered to be more than a description of the objectives and policies adopted by the Crown in the performance of its statutory responsibilities to the public. Notwithstanding the references to consumers, the public and safeguarding human health, they are to be understood as indicating an intention to assume a private law obligation to Canadian cattle farmers specifically. The question whether the representations referred to in paragraph 53 of *Drady* might be interpreted similarly so as to indicate the Crown's assumption of a private law obligation towards patients who required TMJ implants was not, it seems, considered in that case as it had not been pleaded that the representations came to the attention of the plaintiff and were relied on by her.

[44] In contrast, it was pleaded in *Sauer* that the plaintiffs and the other class members were entitled to rely "and did rely" on the representations in the Annual Report for 1988-89. The nature of such reliance is not explained in the pleading. As the plaintiff did not feed the contaminated food to his cattle, as it is not pleaded that he altered his conduct as a consequence of the representations, and as it does not appear how he might have done so, it is not clear that

the asserted reliance can mean anything more than that he and each of the other 100,000 cattle farmers knew of the contents of the Report made more than 14 years before the BSE-infected cow was discovered, and assumed that it contained an accurate statement of the department's activities and objectives. At this stage, of course, the court is concerned only with the pleading and it must be assumed that even unlikely allegations in the pleading will be proven at trial if they are not manifestly incapable of proof.

[45] No express or, it seems, implied requirement of reliance as a condition for proximity was mentioned in the reasons of the Court of Appeal in *Sauer*. Nor was it pleaded that the plaintiff was aware of the regulatory impact statements of the purposes of the various statutes and regulations dealing with livestock feed. However, if, as I must accept, the decision and the analysis in *Sauer* are consistent with that in *Drady* - and in particular, with the comments of the Court of Appeal in paras 53 and 54 of the reasons in that case - it appears necessary to conclude that the pleading in *Sauer* satisfies the insistence in *Drady* that there be "a specific representation or reliance on [the Crown] regarding the safety of [the product]". On this basis - and as far as the three representations referred to in para 53 of *Drady* are concerned - the crucial distinguishing factor may be the inclusion of the three words "and did rely" in *Sauer* and the omission of those words in *Drady* and this case. If this is so, the line between an acceptable pleading of proximity and one that will not pass the plain and obvious test is very fine indeed.

[46] It is, perhaps, possible that the court in *Drady* intended to distinguish between representations in that case, and those in *Sauer* which were understood to indicate the Crown's assumption of a private law duty for which knowledge of, and reliance by, the plaintiff would not be required. This interpretation does not seem to me to be consistent with the fact that the court did not find it necessary to consider whether the representations in *Drady* were of the latter kind. If, however, it is correct - so that significantly different inferences are to be drawn from the contents of the representations pleaded in the two cases - the line drawing exercise would be no less difficult.

[47] It is fundamental in cases under section 5 (1) (a) of the CPA, as well as in motions under rule 21.01 (1) (b), that the question is not whether proximity existed but whether it could be found to exist if the allegations of fact in the pleading are proven at trial. In *Hunt v. Carey Canada Ltd.*, [1990] 2 S.C.R. 959 - still the leading case on the plain and obvious test - it was stated that, for this purpose, pleadings are to be read generously without regard to drafting deficiencies, and that questions that are important and difficult should be left to be dealt with on the basis of a full evidentiary record at trial. Thus, it has been held repeatedly that a finding that no cause of action has been disclosed should not be made if it is dependent on a resolution of a question of law that is not fully settled in the jurisprudence: *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 (C.A.), at page 679; *Toronto-Dominion Bank v. Deloitte Haskins & Sells* (1991), 5 O.R. (3d) 417 (G.D.); *Nash v. Ontario* (1995), 27 O.R. (3d) 1 (C.A.), at para. 11; *R. D. Belanger and Associates Ltd v. Stadium Corporation of Ontario Ltd.* (1991), 5 O.R. (3d) 778 (C.A.), at page 782.

[48] For the reasons given, I have assumed that *Sauer* is consistent in all material respects with the reasoning and the decision in *Drady*. If I did not feel compelled to make that assumption, *Sauer* would, I believe, be susceptible of an interpretation less compatible with Crown immunity in this case. Despite these considerations, I am satisfied that the Court of

Appeal in *Drady* has indicated that, in its considered opinion, the pleading in this case cannot support a relationship of proximity. As this was considered to be plain and obvious, it presumably cannot be regarded as difficult for the purpose of applying *Hunt*. I am also satisfied that, for the purpose of this motion - and subject to the possibility of amendments to the pleading - that is the end of the matter.

[49] Counsel for the plaintiff requested leave to amend the pleading but did not indicate the nature of the amendments they would wish to make. In view of the fact that the Court of Appeal has accepted that the analysis and decision in *Sauer* are consistent with that in *Drady*, I believed I should permit the question of leave to be addressed before finally disposing of the present motion. I indicated that a decision to grant or refuse leave would depend upon the adequacy of any proposed amendments to cure the deficiencies that have been revealed by the Court of Appeal as well, of course, on any considerations of prejudice to the defendant and submissions on behalf of the Crown. Subject to any such amendments, there will be an order decertifying this proceeding.

[50] Finally, the central issue in this motion is of importance not only because of the more than 30 similar pending cases in this court that involve allegedly catastrophic injuries caused by TMJ implants. It is important also because, although most fundamentally it concerns requirements of pleading, it bears also on what will be required to establish proximity at trial.

[51] In this connection, I note that, in the extracts from *Drady* that I have quoted, the references to representations and reliance are sometimes linked disjunctively. I do not understand this to leave open the possibility that acceptable reliance, in some sense, might occur in the absence of a representation that came to the attention of the plaintiff. It was expressly pleaded that Health Canada took a lead role in alerting the public to safety concerns with medical devices, and that patients, dentists and oral surgeons assumed that all such devices sold in Canada had been approved by Health Canada. Given that these allegations were considered to be insufficient, I would find it difficult to infer that the Court of Appeal contemplated the possibility of reliance in a weak sense that could be satisfied independently of representations or assurances by Health Canada. It is, I believe, more likely that the court was referring to "specific" representations - in the sense of representations made directly to a plaintiff - and representations made publicly. Either would be sufficient to establish proximity but only if reliance on them was pleaded and is proven at trial.

[52] If reliance on representations is required, the analysis in *Drady* will exclude recovery in class proceedings for other individuals who suffered the same injuries as a plaintiff to whom a representation was made, and who, like the plaintiff, would not have been harmed if employees of Health Canada had complied with departmental policies. If the representation was made in response to an enquiry by, or on behalf, of a plaintiff, there may be no class for the plaintiff to represent. Even where an otherwise material representation was made publicly, only those class members who could prove that it came to their attention - fortuitously or otherwise - will be able to establish proximity at trial and only then if they can prove reliance on the representation. They would be the only people to whom Crown employees would have a duty to exercise care when implementing regulatory policies - and to whom the Crown would be accountable for reasonably foreseeable harm suffered as a consequence of the employees' failure to exercise care when doing so.

[53] It remains to be seen whether the requirements of proximity for regulatory negligence have now been assimilated to those applicable to claims based solely on negligent misrepresentation to the extent that reliance will not only be required, it must also be shown to have been both reasonable and reasonably foreseeable. Although, read without reference to *Attis* and *Drady*, the reasoning in *Sauer* might be understood to support a less restrictive approach, that of the Court of Appeal in these more recent cases appears to leave no room for presumed reasonable reliance that would justify the imposition of a duty of care in similar circumstances.

[54] For the above reasons, released on January 11, 2010, the motion was adjourned pending advice from plaintiff's counsel of the proposed amendments to the pleading.

[55] Counsel for the plaintiff subsequently requested the consent of the Attorney General to the delivery of a fresh statement of claim containing numerous amendments to the pleading as at the time of certification.

[56] Consent having been refused, a motion for leave to make the amendments was heard on June 3, 2010.

[57] The proposed amendments are intended, in part, to meet the criticisms of the Court of Appeal in *Drady* relating to the inadequacy of the prior pleading to justify a finding of proximity on the facts as pleaded. For this purpose, the amendments take cognizance of the emphasis that the Court of Appeal gave to the importance of pleading representations relied on by the plaintiff and the distinction that the court drew between the pleading in *Sauer* - or at least the references to it in the reasons of Goudge J.A. - and in *Drady* and this case.

[58] In addition, a large number of the amendments elaborate on the regulatory powers and responsibilities of Health Canada with respect to the importation of medical devices generally and the particular activities of the department's officials that are relied on to establish a breach of a duty to take reasonable care in connection with the importation and sale of Vitek implants. As I have indicated, these were accepted in *Drady* as being operational in nature - a classification that, however, does not bear on the question of proximity.

[59] On that question, the amendments contain numerous statements of the regulatory body - far more than those in *Sauer* - that plaintiff's counsel submitted were representations that were relied on by Ms Taylor. They include the following and others to similar effect:

1. The public, the plaintiff and the class members relied reasonably on representations made by Health Canada - in Regulatory Impact Assessment Statements ("RIAS") published in the Canada Gazette - that the medical device regulations were designed to protect individual patients and other specific users of medical devices;
2. The RIAS stated that Canadians must have confidence in the regulatory measures undertaken to provide safe and effective medical decisions and that suspected violations of the regulations would be investigated and compliance action enforced when required; and

3. Annual Projected Area Reviews conducted by Health Canada were intended to minimise the exposure of Canadians to unsafe and ineffective medical devices and thereby reduce the level of device-related mortality and morbidity.

[60] In the submission of plaintiff's counsel, the statement of claim, as amended, would remedy the pleading deficiencies identified in *Drady* and bring it squarely within the ratio of *Sauer*. Mr Baert relied also on the more recent decision of the Supreme Court of Canada in *Fallowka v. Pinkerton's of Canada Ltd.*, [2010] 1 S.C.R. 132 which, he submitted, was inconsistent with the view that specific representations made to, and relied on by, the plaintiff were essential to a finding of proximity.

[61] On the first point, the response of Mr Evraire was that, in a class proceeding, it is the plaintiff's cause of action - and not that of the other class members - that must be disclosed in the pleading. I believe that proposition is correct. It followed in Mr Evraire's submission, that Ms Taylor could not have relied on the contents of the RIAS because the practice of issuing such statements commenced after 1988 - the year in which she received the Vitek implant.

[62] Although there was no evidence to support Mr Evraire's factual assertion about the practice of issuing RIAS, it was not contradicted by Mr Baert and, more to the point, all of the examples of the representations on which Ms Taylor is alleged to have relied were in RIAS issued after 1988.

[63] As it was not pleaded that the Annual Projected Area Reviews were ever made public or relied on by Ms Taylor, it was Mr Evraire's submission that the critical deficiency that was identified in *Drady* - the absence of "a specific representation or reliance on Health Canada regarding the safety of the implants" - would not be remedied by the proposed amendments.

[64] Similarly, in his submission, a failure to plead any public representations made by Health Canada before Ms Taylor received the implants that it was acting to protect the users of such devices would prevent the pleading from being accepted - as in *Sauer* - on the alternative ground of a public assumption of a private law duty of care.

[65] To the extent that a finding of proximity would depend upon Ms Taylor's reliance on representations made by the Crown, I am in agreement with counsel for the Attorney General that those made after she received the Vitek implant - and those made earlier that are not pleaded to have come to her attention - could not satisfy the requirement.

[66] The question of timing is not so obviously relevant to the possibility that the RIAS pleaded should be considered to constitute a public assumption of a private law duty in the administration of the FDA and its regulations. I see no reason why the RIAS should be interpreted as reflecting an entirely prospective intention. The timing of the release of such statements would, however, still be important if proximity based on a public assumption of a duty of care is limited to cases in which it was relied on by the plaintiff.

[67] In paras 45 and 46 of the above reasons - which were released at the time of the adjournment - I touched on this question. I found it difficult to reconcile the possibility that the

Court of Appeal in *Drady* did not regard such knowledge and reliance as essential with the reasoning of the court in paragraphs 53 and 54 of the decision that I have quoted above.

[68] On the other hand, as I indicated, knowledge and reliance were not referred to as relevant in *Sauer* or in any of the explanations of that decision in subsequent decisions of the Court of Appeal including *Attis* and *Drady*. As I am unable to distinguish the contents of the RIAS that would be pleaded in this case from those from which a public assumption of a private law duty was inferred in *Sauer*, the question whether the plaintiff's knowledge of, and reliance on, such representations is required must be confronted.

[69] In approaching the question, I am mindful of the comments of an eminent English judge in *Turner v. Ford* (1877), 37 L.T. (N.S.) 351 (M.R.):

It is always very dangerous for a judge to deal in distinctions. I will not, therefore, attempt to distinguish this case from the cases in the Court of Appeal which have been cited. I am bound to follow these cases, if I can find a principle on which they are founded, but I have not the remotest idea on what principle they were founded. I will not extend those cases. (per Jessel M.R.)

[70] Here, however, the Court of Appeal has held that its decisions in *Sauer* and *Drady* are distinguishable and I cannot avoid the task of deciding whether the amended pleading would place this case on the acceptable, or the unacceptable, side of the line. In doing this I must keep in mind that the plaintiff is not to be deprived of a trial unless it is plain and obvious that proximity could not be established on the facts as pleaded.

[71] Although the plaintiff's reliance on statements in a report by Agriculture Canada to Parliament was pleaded in *Sauer* - though not referred to by the Court of Appeal - I suggested earlier in these reasons that such reliance appears to have amounted to little more than knowledge that the statements were made and, perhaps, a belief that the Government would honour them. There is a question whether "reliance" even in this weak sense is required to establish proximity where there has been a public assumption of duty and, if it is not, whether statements evidencing such an assumption can confer rights on persons like Ms Taylor who received implants before the statements were made.

[72] I have found nothing to suggest that the Court of Appeal in *Sauer* considered the plaintiff's knowledge or reliance to have been essential to its decision, and - although I have indicated some doubt on this question - I am not satisfied that this was the interpretation placed on *Sauer* in *Drady*. Nor is it obvious to me why the plaintiff's knowledge or reliance should have any relevance to the question whether the Crown has made an effective public assumption of a private law duty of care owed to the users of medical devices that included the Vittek implants.

[73] In these circumstances, I believe I should accept the amended pleading on the ground that - when it is read generously - it is not plain and obvious that a finding of proximity could not be made at trial if the factual allegations pleaded are proven. At the very least, in view of the need for clarification of the requirements for an effective public assumption of a private law duty of

care, I consider that this is a case in which it should be held that the particular issue on which proximity turns is not fully settled in the jurisprudence within the meaning of the decisions cited in paragraph 47 above. In such cases it has been held that the issue in dispute is best left to be dealt with at trial on the basis of a full evidentiary record.

[74] By way of a general comment, I doubt whether any rational individual not bound by *stare decisis* would understand why it should be considered fair and reasonable to impose a duty of care on a government regulatory body in *Sauer* but not in this case when the amendments are made. The question of proximity was not even considered by an experienced judge to merit discussion at first instance in *Sauer* and the Court of Appeal had no doubt that proximity had been sufficiently pleaded. Any distinctions to be drawn on the words of the pleadings appear to me to be sufficiently close to hair-splitting as to be incompatible with the principles propounded in *Hunt* - at least as far as they have been traditionally applied in cases in which the Crown was not the moving party.

[75] Finally, in deference to counsel's submissions, I will note that the analysis in *Fallowka* is not, in my opinion, inconsistent in any respect with that in *Drady*. While that of the Supreme Court would not have caused me to resile from the finding of proximity made on the motion to certify the proceeding in this case - and while that analysis is inconsistent with an interpretation of *Drady* that would limit findings of proximity with regulatory bodies to cases of specific representations and reliance - the three factors that, in combination, were found to be determinative of a finding of proximity on the facts of *Fallowka*, as found at trial, are not present in this case: see paras 43-45 of the reasons delivered by Cromwell J. In my opinion, the finding of a relationship of proximity by the Supreme Court is in no way inconsistent with its absence as found by the Court of Appeal on the very different facts pleaded in *Drady* and in this case as originally pleaded. The potential relevance of expectations, representations and reliance on very different facts was recognized in *Fallowka* at para 40, but I do not find the decision to be helpful in resolving, either way, the issue raised by the decisions of the Court of Appeal.

[76] It follows from the above that leave to amend the pleading is granted and the motion to decertify the proceeding is denied. The parties have agreed on the costs of the adjourned hearing. Any costs of the motion for leave to amend are to be in the cause if not agreed.

  
CULLITY J.

**CITATION:** Taylor v. The Queen, 2010 ONSC 4799  
**COURT FILE NO.:** 99-CV-181819 CP  
**DATE:** 2010-09-07

**ONTARIO**

**SUPERIOR COURT OF JUSTICE**

**BETWEEN:**

KATHYRN ANN TAYLOR

Respondent/Plaintiff

**and -**

HER MAJESTY THE QUEEN IN RIGHT OF  
CANADA, as REPRESENTED by the MINISTRY  
OF HEALTH and the ATTORNEY GENERAL OF  
CANADA

Moving Party/Defendant

**and -**

UNIVERSITY HEALTH NETWORK (formerly  
Toronto General Hospital) and DR. W.  
DOBROVOLSKY

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**REASONS FOR JUDGMENT**

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Cullity J.

**Released:** September 7, 2010