COURT OF APPEAL FOR ONTARIO

CITATION: Taylor v. Canada (Attorney General), 2012 ONCA 479
DATE: 20120706
DOCKET: C53678

Doherty, Weiler, Laskin, Sharpe and Armstrong JJ.A.

BETWEEN

Kathryn Anne Taylor

Plaintiff

and

The Attorney General of Canada

Defendant

Kirk Baert and Celeste Poltak, for the plaintiff

P.J. Evraire, Q.C., Gina M. Scarcella and James M. Soldatich, for the defendant

Cameron Pallett and Reynold Robertson, for the intervener, Bill Sauer

Heard: September 19, 2011

A proceeding under Rule 22.03 to determine a special case stated by order of Armstrong J.A. dated March 4, 2011, with reasons reported at 2011 ONCA 181.

Doherty J.A.:

[1] Government regulation impacts on most facets of modern life, particularly matters of public health and safety. If a government regulator exercises its powers in a negligent way, people can be hurt and suffer substantial damages. The question in this proceeding, and it is far from a novel or easy one, is when does the regulator owe a *prima facie* private law duty of care to the individual harmed by the regulator's negligence?

I

THE NATURE OF THIS PROCEEDING

[2] This is not an appeal. This matter comes before the court as a special case stated under Rule 22.03 of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194. The stated case poses two questions:

1) What are the requirements in a statement of claim to establish sufficient proximity between the plaintiff and the defendant in a claim brought against a governmental body for regulatory negligence?
2) Does the amended statement of claim in this action satisfy those requirements?

[3] The special case procedure is an unusual one. Resort to it is justified in this instance by the apparent inconsistency in this court's jurisprudence, the tortured

and lengthy procedural history of this case, and the importance of the legal issue raised by the first of the two questions posed. The jurisprudential inconsistency is said to arise from this court's reasons in *Drady v. Canada (Minister of Health)*, 2008 ONCA 659, 300 D.L.R. (4th) 443, leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 492, and *Attis v. Canada (Minister of Health)*, 2008 ONCA 660, 93 O.R. (3d) 35, leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 491, on the one hand, and *Sauer v. Canada (AG)*, 2007 ONCA 454, 225 O.A.C. 143, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 454, on the other. Arguably, *Drady* and *Attis* require a more direct connection between a plaintiff and the regulator before the latter can be said to owe a duty of care to the former than does *Sauer*.

[4] Mr. Bill Sauer, the representative plaintiff in *Sauer*, was granted leave to intervene in this proceeding.

II

THE UNDERLYING CLASS ACTION PROCEEDING

(a) Nature of the Claim

[5] The plaintiff, Ms. Taylor, brings the claim as representative of the class of persons resident in Canada (except British Columbia and Québec) who have suffered damages as a result of the implantation of temporomandibular joint implants after 1968. The implants were manufactured by an American company, Vitek Inc., and sold in Canada. Although Vitek manufactured different models of

the implants, there is no need to distinguish among the various models for present purposes. I will refer to the implants as "Vitek TMJ implants", "TMJ implants" or simply as the "implants".

[6] On April 22, 1988, a Vitek TMJ implant was inserted into Ms. Taylor's right temporomandibular joint. She alleges that the insertion of that device "resulted in catastrophic and irreversible adverse biomedical consequences, resulting in permanent total disability and loss of enjoyment of life."

[7] In her claim brought against the Attorney General of Canada ("AG Canada"), Ms. Taylor alleges that the government of Canada, and specifically "Health Canada",[1] was negligent in the exercise of its responsibilities under the *Food and Drugs Act,* R.S.C. 1985, c. F-27 (the "Act"), and the regulations proclaimed under the Act. She alleges that Health Canada owed a duty of care to protect her and other class members from unsafe medical devices and that it negligently failed to perform that duty in relation to the Vitek TMJ implants.

[8] In broad terms, the Fresh Statement of Claim alleges a failure to prevent the importation and sale of the implants, a failure to adequately monitor and regulate the sale of the implants, a failure to warn doctors, dentists and consumers of the known dangers associated with the implants, and a failure to remediate the harm caused to persons who received the implants. In addition, the claim alleges that

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[1] Health Canada is defined in the Fresh Statement of Claim as the various federal Ministers, departments and other entities responsible for regulating medical devices, including implants.

Health Canada wrongly indicated that a notice of compliance had been issued for the implants when in fact none had been issued. Ms. Taylor alleges that this was a misrepresentation as to the safety of the implants.

[9] Many of the particulars of the alleged negligence are set out in para. 165 of the Fresh Statement of Claim. The allegations include the following:

- Health Canada failed to prevent the importation of the implants into Canada from 1983 forward;
- Health Canada failed to prevent the sale of the implants when it learned that they had been imported into Canada;
- Health Canada failed to properly monitor and regulate the sale of the implants in Canada;
- Health Canada failed to stop further sales of the implants when it determined that the manufacturer and distributor were not in compliance with the applicable regulations;
- Health Canada erroneously and publicly declared that a notice of compliance had been issued with respect to the implants when in fact none had been issued;

- Health Canada failed to take appropriate steps when it realized that it had wrongly and publicly declared that a notice of compliance had been issued;
- Health Canada failed to stop further sales of the implants when it became aware of serious health problems associated with the implants in the United States;
- Health Canada ignored warnings from its own "senior scientist" that the implants posed an "extreme hazard";
- Health Canada failed to provide doctors, dentists and consumers with effective and timely notice of the problems associated with the implants;
- after Health Canada became aware of the dangers associated with the implants, it failed to warn those who had received implants of those dangers; and
- when Health Canada learned of the dangers associated with the implants, it failed to take appropriate steps to mitigate any harm that had

> been caused to persons who had received the implants.

(b) Procedural History

[10] This action has a long history. It was commenced in December 1999 and is still at the pleadings stage. Ms. Taylor has been one of the representative plaintiffs since February 2003 and the only representative plaintiff since 2006. She successfully moved to certify the action under the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, in 2007: see *Taylor v. Canada (Minister of Health)* (2007), 285 D.L.R. (4th) 296 (Ont. S.C.).

[11] On the original certification motion, the motion judge, in holding that the statement of claim disclosed a reasonable cause of action in negligence, said, at paras. 39-40:

> ... In these circumstances, I believe it would be open to a court to find that Health Canada's course of conduct – including the dissemination of misinformation in its database – increased the risk to the health of the plaintiff and other potential recipients of the implants and gave rise to a relationship of proximity with them.
>
> ... 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 – existed in connection with operational acts of Health Canada. ... [Emphasis added.]

[12] The motion judge relied in part on *Sauer*.

[13] AG Canada applied for leave to appeal to the Divisional Court from the certification order. Leave was refused: see *Taylor v. Canada (AG)* (2007), 289 D.L.R. (4th) 567.

[14] Shortly after leave to appeal was refused, this court released judgments in *Drady* and *Attis*. *Drady* was an intended class action brought on behalf of individuals who had also received temporomandibular joint implants. In fact, Mr. Drady had been a co-representative plaintiff with Ms. Taylor at one time in this action. Unlike Ms. Taylor, however, Mr. Drady did not identify the manufacturer of his implant. *Attis* was an intended class action brought on behalf of women who had received breast implants.

[15] In *Drady* and *Attis*, this court held that the challenged pleadings did not allege a reasonable cause of action in that they did not contain facts capable of establishing that the regulator owed a private law duty of care to the recipients of the implants. In *Drady*, this court expressly rejected part of the analysis underlying the motion judge's original decision to certify this action: see *Drady*, at paras. 34 and 44-50.

[16] Relying on *Drady* and *Attis*, AG Canada returned to the motion judge asking him to reconsider his earlier decision and decertify this action. AG Canada argued that read in the light of the analysis in *Drady* and *Attis*, Ms. Taylor's claim

did not allege facts that could support a finding that the regulator owed a private law duty of care to Ms. Taylor.

[17] In his reasons on the motion to decertify, the motion judge expressed considerable difficulty in reconciling *Drady* and *Attis* with *Sauer*. He determined, however, that the pleadings in this case could not be distinguished from the pleadings in *Drady*. Like the *Drady* pleadings, these did not allege a relationship of sufficient proximity. The motion judge further held, however, that Ms. Taylor should be given an opportunity to amend her pleadings: see *Taylor v. Canada (Ministry of Health)*, 2010 ONSC 4799, 81 C.C.L.T. (3d) 106, at paras. 21-26, 48-49 and 76.

[18] Ms. Taylor produced a Fresh Statement of Claim in which she alleged, among other things, various public representations made by Health Canada to the effect that its regulatory scheme was designed to protect individual consumers who used medical devices like the Vitek implants by the enforcement of that scheme and the exercise of the investigatory powers available under that scheme. The motion judge held, at para. 73, that these representations, considered in the context of the rest of the claim, and read generously, were sufficient to allow the claim to survive the pleadings stage:

> I believe I should accept the amended pleadings 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.

[19] AG Canada filed an application for leave to appeal from that decision to the Divisional Court. The parties ultimately agreed, however, that in the very unusual circumstances of this case, a motion should be brought to this court to state a special case under Rule 22.03, thereby bringing the dispute directly to this court.

III

THE LEGAL CONTEXT

[20] The special case arises out of a class action and a motion to decertify the class action on the basis that the statement of claim does not allege a reasonable cause of action against AG Canada. That context brings two legal principles to the forefront.

[21] First, the statement of claim must disclose that the representative plaintiff, Ms. Taylor, has a reasonable cause of action against AG Canada. In the context of a negligence claim, this requirement means that the pleadings provide a basis upon which AG Canada could be said to owe a private law duty of care to Ms. Taylor. It is not enough that on the pleadings some other member or members of

the class may have a cause of action in negligence against AG Canada: see *Hughes v. Sunbeam Corp. (Canada) Ltd.* (2002), 61 O.R. (3d) 433, at paras. 10-18 (C.A.); *Taylor v. Canada (Ministry of Health)*, 2010 ONSC 4799, at para. 61.

[22] Second, the claim can only be struck at this stage if, assuming the facts pleaded are true, it is plain and obvious that the pleading discloses no reasonable cause of action, meaning that the plaintiff has no reasonable prospect of success: see *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, at 980; *R. v. Imperial Tobacco Canada Ltd.*, 2011 S.C.C. 42, [2011] 3 S.C.R. 45, at paras. 17-19; *Wellington v. Her Majesty the Queen (Ontario)* (2011) ONCA 274 at para. 14. Placing the test to be applied on a motion to strike a claim in the context of the issue raised here, the question becomes – has AG Canada demonstrated that Ms. Taylor does not have a reasonable prospect, on the facts as alleged, of establishing that Health Canada owed her and the other members of her class a private law duty of care? If the question gives rise to genuine legal or factual uncertainties, it cannot be answered at this stage and the answer must await a trial and a complete record.

IV

THE PLEADINGS

[23] The questions posed by the special case require an examination of the substance of the Fresh Statement of Claim. That examination is not an easy one. The Fresh Statement of Claim is lengthy (61 pages, 268 paragraphs), prolix, and somewhat disorganized. I will begin with an outline of the relevant chronology and then turn to the parts of the claim that address the representations made by Health Canada and the reliance on those representations by Ms. Taylor and other class members.[2] The bracketed references are to paragraph numbers in the Fresh Statement of Claim.

(a) Chronology

[24] In January 1983, Vitek and its Canadian distributor, Instrumentarium, began advertising Vitek TMJ implants in various Canadian and American journals directed at doctors and dentists. The advertisements continued over several years (para. 59).

[25] Vitek TMJ implants were first sold in Canada in March 1983 (para. 80). Health Canada was not made aware of those sales by Vitek until 1987 (paras. 79-80).

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[2] Of course, the claim contains only allegations, not facts. They are, however, accepted as true for the purposes of this exercise.

[26] In May 1983, Vitek advised Health Canada that it intended to export TMJ implants to Canada. Vitek sought confirmation from Health Canada that the importation would be permitted by Health Canada (para. 54). A Health Canada official replied that as the devices were medical implants, they could be sold in Canada only if Vitek obtained a notice of compliance from Health Canada under the regulations (para. 55). Health Canada officials reiterated this position on several occasions in 1983 and 1984 (paras. 60-61, 63-64). No steps were taken to prevent Vitek or its distributor from selling the implants in Canada during the period from 1983 to 1985 (para. 66).

[27] In March 1986, an official with Health Canada advised the distributor that a notice of compliance was not required before the TMJ implants could be sold in Canada. This position contradicted the position taken by Health Canada in the three previous years. This official was, however, critical of the distributor's compliance with various regulations. No follow-up inspections were made (paras. 71-73).

[28] In September 1986, surgeons in the United States reported biomechanical failures of Vitek TMJ implants (para. 78).

[29] In early 1987, Vitek delivered submissions to Health Canada in support of the application for a notice of compliance in respect of the implants (para. 79). Throughout 1987, contrary to its position in March 1986, Health Canada officials

corresponded with Vitek and its distributor, indicating that further and better information was needed before a notice of compliance could be issued. In 1987, Vitek, with Health Canada's knowledge, continued to sell the implants in Canada (paras. 79, 81-84). In December 1987, a Health Canada official again advised Vitek and its distributor that the implants could not be sold in Canada unless Vitek obtained a notice of compliance (para. 86).

[30] On April 22, 1988, Ms. Taylor underwent surgery at Toronto General Hospital. A Vitek TMJ implant was placed in her right temporomandibular joint (para. 175).

[31] Throughout 1988, Vitek continued to make submissions to Health Canada in support of its efforts to obtain a notice of compliance. It also contended that as it had sold Vitek TMJ implants in Canada prior to April 1, 1983, those implants were "grandfathered" under the regulations and did not require a notice of compliance before they could be sold. Health Canada officials continued to request further documentation (paras. 94-97, 100).

[32] Sometime in 1988, Health Canada erroneously indicated in its database that notices of compliance had been issued for Vitek TMJ implants (paras. 102-107). In April 1989, a Health Canada official, relying on this error, indicated that Vitek was in compliance with the regulations and had data establishing the safety of the implants (para. 105). In August 1989, in reliance on the error in the database,

Health Canada circulated Information Letter #765 indicating that notices of compliance had been issued for Vitek TMJ implants (para. 106). The error was not discovered until 1990. No steps were taken to notify health professionals or their patients of the error when it was discovered (para. 107).

[33] In July 1988, Vitek withdrew TMJ implants from the market. U.S. authorities reported a lack of mechanical testing of the implants (para. 103).

[34] In March 1990, Vitek issued a voluntary safety alert for Vitek TMJ implants (para. 111). In May 1990, U.S. authorities ordered a recall of Vitek TMJ implants and notified Health Canada. In the notification, the American authorities indicated that Vitek TMJ implants could fragment and lead to progressive bone degenerative change and giant cell reaction. Health Canada took no immediate action (para. 112).

[35] In August 1990, Health Canada asked Instrumentarium to voluntarily refrain from distributing certain of the implants. In October 1990, Instrumentarium undertook a voluntary recall and notified surgeons who had used the implants. Health Canada supervised the recall and notification (paras. 117-119).

[36] Between December 1990 and May 1992, U.S. authorities issued a number of safety alerts, recalls, public health notices, and import alerts in respect of the TMJ implants (paras. 119-120, 122, 128-129, 131, 133). Health Canada was advised of these actions and specifically, in April 1991, was advised that a recall

had been initiated after U.S. authorities had determined that the failure of the implants could expose patients to a high risk of serious adverse health consequences. Health Canada took no direct action in response to these notices (para. 122).

[37] Health Canada first reacted to the reported failures of the implants and the serious health consequences flowing from those failures around June 1991 when it asked the Canadian Dental Association to publish in its journal a safety alert that had been issued by American regulators six months earlier (para. 124). A similar request was made of another professional organization in Canada in October 1991 (paras. 130, 132).

[38] In October 1992, Health Canada sent a notice of the December 28, 1990 safety alert issued by the American authorities to surgeons whose names appeared on a list provided by the American authorities. Health Canada chose not to send this information to all doctors and dentists in Canada (paras. 136-138).

[39] In August 1994, Health Canada, in response to calls it had received, drafted an alert regarding the Vitek TMJ implants to be sent only to the 200 professionals who had been supplied with the device prior to 1991 (para. 147). In September 1994, more than two years after the U.S. authorities had acted, Health Canada

issued a national import alert forbidding the importation of Vitek TMJ implants into Canada (para. 148).

[40] In October 1994, Health Canada sent certain material to health professionals alerting them to the risks associated with the implants and advising of the steps that should be taken to monitor patients who had received the implants (para. 151). Also in October 1994, Health Canada sent a "Dear TMJ Patient" letter to individuals who had received the implants, advising of the risks associated with the implants and the need for ongoing medical monitoring. The letter also indicated that recipients of the letter would receive updates as they became available. The letter provided a hotline number to these individuals who were told that they could use the hotline to keep abreast of any new developments (para. 156).

[41] In November 1995, Health Canada sent an information package to each member of the Quebec Association of Oral and Maxillofacial Surgeons. No other provincial association received that information (para. 159).

[42] Beginning in February 1996, employees within Health Canada expressed concerns about the adequacy of the notification that had been given to patients who had received the implants. These concerns were expressed over a number of months. Ultimately, Health Canada decided that no further notification to those who had received the implants was necessary (paras. 160-164).

(b) The Alleged Representations and Reliance

[43] On the motion to decertify, the motion judge, at para. 51, focussed on the absence of any alleged representations made by Health Canada that came to the attention of Ms. Taylor and were relied on by her. The motion judge expressed the concern that in the light of *Drady*, the failure to allege any direct representations and reliance could be fatal to the allegation of a private law duty of care owed by Health Canada to Ms. Taylor.

[44] Ms. Taylor attempted to meet the motion judge's concerns in her proposed amendments. She alleged representations made by Health Canada through documents described in the Fresh Statement of Claim as Regulatory Impact Assessment Statements ("RIAS") and representations made in documents described as annual Project Area Reviews. The allegations in respect of the RIAS are found in paras. 25-30 of the Fresh Statement of Claim. Because of their significance on the motion, I will set out paras. 25, 26 and 29 in full:

> 25. The Regulatory Impact Assessment Statements ("RIAS") were published by Health Canada in the Canada Gazette to provide a contextual public explanation for individual amendments to the Medical Device[s] Regulations. As official government publications, the RIAS are *prima facie* representations of Health Canada's habitual practice to monitor and assure the safety of medical devices used by Class Members. These representations were intended to be, and were, reasonably relied upon by the public, including the representative plaintiff and Class Members. It was reasonably foreseeable for the

> representative plaintiff and Class Members to rely upon those representations with respect to the safety of medical devices, in general, and the Vitek TMJ implants, specifically, given Health Canada's stated authority to regulate medical devices and the repeated, public nature of the assurances.
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> ...
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> 26. The RIAS contain a number of statements that demonstrate that Health Canada clearly understood and was representing to the Class that the Medical Device[s] Regulations were designed to protect individual patients and other specific users of medical devices.
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> 29. The RIAS also clearly stated to the public that the Medical Device[s] Regulations were and are actively enforced by Her Majesty. [Emphasis added.]

[45] Paragraphs 27-28 and 30 of the Fresh Statement of Claim summarize the content of several RIAS issued by Health Canada. All postdate Ms. Taylor's receipt of the implants by several years and none refer to the implants specifically.

[46] The allegations in respect of the annual Project Area Reviews are found in paras. 36-39 of the Fresh Statement of Claim. Paragraph 36 alleges that the Project Area Reviews were conducted:

> ...to improve the various divisions in the Bureau [a division of Health Canada] and to evaluate past and future goals to be executed by Health Canada.

[47] The Fresh Statement of Claim does not expressly allege representations made in the Project Area Reviews that were relied on by Ms. Taylor or other class members. Nor is there any allegation that the contents of the Project Area

Reviews were known to, or available to the public. Several references to different Project Area Reviews stress the need to protect users from the hazards associated with the clinical use of medical devices. Other extracts describe the goal of improving the safety of medical devices through adequate standards and testing, thereby minimizing the exposure of Canadians to "unsafe and ineffective medical devices". None of the extracts from the Project Area Reviews refers to the implants, although para. 37 alleges that previous Project Area Reviews addressed generically the problems and risks associated with dental and reconstructive implants.

[48] In addition to the representations and reliance outlined above, the Fresh Statement of Claim alleged that Health Canada knew that dentists, oral surgeons, and their patients assumed and understood that medical devices such as the implants had been approved by Health Canada for sale and use in Canada (para. 21). The Fresh Statement of Claim further claimed that Health Canada represented to Ms. Taylor and class members that it exercised responsible, professional oversight of medical devices in Canada, and that class members reasonably relied on Health Canada's representations to their detriment (paras. 106, 189-94). Finally, Ms. Taylor alleges that due to Health Canada's inadequate attempts at remediation, she and other class members retained the implants when doing so posed a danger to their health (para. 209).

(c) The Legislative Scheme

[49] The events described in the Fresh Statement of Claim occurred principally between 1983 and 1995. During that time period, the Vitek TMJ implant was a "device" within the meaning of the *Food and Drugs Act*, R.S.C. 1970, c. F-27, and its successor, the *Food and Drugs Act*, R.S.C. 1985, c. F-27. The TMJ implant was also subject to regulations made under the *Food and Drugs Act*, primarily the *Medical Devices Regulations*, R.R.C 1978, c. 871, as amended by SOR/82-914 (the "Regulations").[3]

[50] Section 14 of the Regulations prohibited the sale of a device (including implants) unless the manufacturer had conducted tests which demonstrated the efficacy of the product. Section 15 required that evidence of those tests be supplied to Health Canada on request. Section 16 of the Regulations prohibited the importation for sale into Canada of devices the sale of which would violate any part of the Act or Regulations. Health Canada was given broad powers of inspection by ss. 17 through 19 of the Regulations.

[51] Section 28 of the Regulations authorized the Director to request evidence from the manufacturer to establish the safety of a particular device. If the evidence was not provided by the specified date or if the Director was not

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[3] These regulations were replaced by a very different regulatory regime in 1998: see *Medical Devices Regulations*, SOR/98-282 (May 7, 1998).

satisfied with the evidence, then, subject to the submission of further evidence, the sale of the device after the specified date was prohibited.

[52] Part V of the Regulations spoke directly to "new devices" and merits further examination.[4] Under s. 32 of the Regulations, a "new device" was defined in part as:

> ...a device listed in the table to this Part that
>
> (a) has not been sold previously in Canada by that manufacturer...

[53] The "table" referred to in the definition of "new device" included only intra-uterine devices and cardiac pacemakers in 1978. The table was amended by SOR/82-914 (October 8, 1982), to include:

> Any device designed to be implanted into the tissues or body cavities of a person for 30 days or more.

[54] After the amendment to the table, TMJ implants were a "new device" under Part V of the Regulations unless they had been sold in Canada by Vitek prior to the amendment to the Table in October 1982.[5]

[55] Assuming, as alleged by Ms. Taylor, that the implants were a "new device", s. 33 of the Regulations prohibited any manufacturer from selling or advertising

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[4] The Fresh Statement of Claim (para. 15) refers to "Part V of the *Food and Drugs Act* which was enacted on April 1, 1983. There is no Part V of the *Food and Drugs Act*. The reference would appear to be to Part V of the *Medical Devices Regulations*. The reference to April 1, 1983 is also in error. Part V existed long before 1983.

[5] The Fresh Statement of Claim treats April 1, 1983 as the operative date for determining whether the implants were "grandfathered" under the definition of "new device" in the applicable regulations. The discrepancy in the dates is irrelevant for present purposes.

the implants except in accordance with the Regulations. Sections 34 and 35 directed that a manufacturer must obtain a notice of compliance from the "Director", a senior official in Health Canada, before selling a "new device".

[56] In the application for a notice of compliance, the manufacturer was required to provide evidence of the safety and effectiveness of the device. Section 35 of the Regulations outlined some of the specific topics that had to be addressed in the material provided by the manufacturer. For example, the manufacturer was required to submit evidence of the "quality control program and procedures used during manufacturing...": see s. 35(1)(a)(vii). The manufacturer was also required to submit evidence of "the results of all clinical trials to show the effectiveness of the device": see s. 35(b)(i). Section 39 required information referable to labelling and packaging.

[57] The Director had 60 days from the receipt of the manufacturer's material to decide whether to issue a notice of compliance. The Director could require further and better information from the manufacturer: see ss. 35(2) and 36.

[58] Section 36 set out the test the Director was to apply in deciding whether to issue a notice of compliance:

> 36. Within 60 days after the latest date of the receipt by the Director of evidence, materials or information submitted by a manufacturer under section 35,
>
> (a) where the Director is satisfied that the manufacturer has provided substantial evidence that

> (i) the conditions of production and quality control are suitable for controlling the quality, stability, safety and performance of the new device,
>
> (ii) the new device can be used for the purpose and under the conditions of use recommended by the manufacturer without undue risk to humans,
>
> (iii) the new device is clinically effective for the purpose and under the conditions of use recommended by the manufacturer or that sufficient animal studies have been carried out to establish a probability of effectiveness in humans, and
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> (iv) the drafts of all labels, package inserts, product brochures and file cards to be used in connection with the device are adequate,
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> the Director shall issue to the manufacturer a notice of compliance... [Emphasis added.]

[59] The Regulations were clear that the Director "shall" issue the notice of compliance if he or she is satisfied that the manufacturer has provided "substantial evidence" to support the criteria set out in s. 36(a). The Director did not make a determination as to the ultimate efficacy of the device, the risks associated with the use of the device, or the adequacy of any warnings or instructions provided with the device.

[60] Section 40 of the Regulations allowed the Director to suspend or cancel a notice of compliance where "it is necessary to do so in order to safeguard public health or promote public safety". The power to suspend or cancel was discretionary. If a notice of compliance were suspended, the medical device could not be sold in Canada while the suspension was in effect. Under s. 41, the

Director could also require a manufacturer who has received a notice of compliance in respect of a medical device to file additional material referable to the criteria set out in s. 33. The Director could require the further information to satisfy him or herself that the requirements for issuing the notice of compliance continue to exist.

[61] This court examined the relevant provisions of the *Food and Drugs Act* and the regulations made under that Act referable to medical devices in *Attis*, at paras. 54-58, and *Drady*, at paras. 15-19. As explained in *Attis*, at para. 56, the *Food and Drugs Act* placed obligations as to the safety of medical devices on the manufacturer and distributor of those devices. Further, as observed in *Drady*, at para. 19, nothing in the Act or Regulations placed any obligation on Health Canada to issue warnings relating to medical devices.

[62] The legislative landscape was described by Lang J.A. in *Attis*, at para. 57:

> A reading of the legislative history of the regulations discloses that there was no obligation on Health Canada to undertake safety and efficacy testing, or to engage in any other compliance or enforcement mechanism. The regulations simply authorized Health Canada to enforce the various aspects of the compliance requirements if it chose to do so. Thus, Health Canada was akin to an overseer or watchdog, able to employ discretionary, but not mandatory, enforcement of the legislative scheme. [Emphasis added.]

V

THE FIRST QUESTION

[63] For convenience, I repeat the first question posed by the special case:

> What are the requirements in a statement of claim to establish sufficient proximity between the plaintiff and the defendant in a claim brought against a governmental body[6] for regulatory negligence?

[64] This question engages the broader consideration of when it will be said that a government regulator owes a private law duty of care to those affected by the actions of the regulator. None of the parties to this appeal suggests that this question admits of a definitive, exhaustive answer. The jurisprudence in the last decade, particularly several cases from the Supreme Court of Canada, does, however, delineate the approach to be taken when faced with a claim in negligence brought against a government regulator.

(a) The Duty of Care Inquiry

[65] Liability in negligence is predicated on the existence of a duty owed by the defendant to the plaintiff to take reasonable care in the circumstances. Proximity is essential to, but alone does not establish a duty of care. Proximity is one aspect of the broader duty of care inquiry: see *Odhavji Estate v. Woodhouse*, 2003 SCC 69, [2003] 2 S.C.R. 263, at paras. 45-46.

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[6] I will use the word "regulator" interchangeably with the phrase "governmental body".

[66] The proximity requirement cannot be reduced to a list of factors or circumstances which, if they exist, will always create a relationship of proximity between a plaintiff and a defendant. Proximity is a concept, not a test: see *Canadian National Railway Co. v. Norsk Pacific Steamship Co.*, [1992] 1 S.C.R. 1021, at 1151. The concept of proximity describes a relationship between a plaintiff and a defendant that is sufficiently close and direct to render it fair and reasonable to require that the defendant, in the conduct of its affairs, be mindful of the plaintiff's legitimate interests: see *Cooper v. Hobart*, 2001 SCC 79, [2001] 3 S.C.R. 537, at paras. 32-36.

[67] Reasonable foreseeability of harm, arguably the basis upon which at least a *prima facie* duty of care was imposed pre-*Cooper*,[7] does not necessarily establish a relationship of proximity: see *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41, [2007] 3 S.C.R. 129, at para. 23; *Childs v. Desormeaux*, 2006 SCC 18, [2006] 1 S.C.R. 643, at para. 31. As explained in *R. v. Imperial Tobacco Canada Limited*, 2011 SCC 42, [2011] 3 S.C.R. 45, at para. 41:

> Proximity and foreseeability are two aspects of one inquiry – the inquiry into whether the facts disclose a relationship that gives rise to a *prima facie* duty of care at common law. Foreseeability is the touchstone of negligence law. However, not every foreseeable

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[7] See L. Klar, "The Tort Liability of Public Authorities: The Canadian Experience" in S. Degeling, J. Edelman, & J. Goudkamp, eds., *Torts in Commercial Law* (Australia: Thompson Reuters, 2011) Chap. 12.

> outcome will attract a commensurate duty of care. Foreseeability must be grounded in a relationship of sufficient closeness or proximity, to make it just and reasonable to impose an obligation on one party to take reasonable care not to injure the other.

[68] If reasonable foreseeability is established, the court will look to the other factors that inform the nature of the relationship between the plaintiff and the defendant to determine whether that relationship is one of sufficient proximity. *Cooper* describes the factors as "diverse" and case-specific: see para. 35. In *Hill*, at para. 29, the court provides this insight:

> The most basic factor upon which the proximity analysis fixes is whether there is a relationship between the alleged wrongdoer and the victim, usually described by the words "close and direct". This factor is not concerned with how intimate the plaintiff and defendant were or with their physical proximity, so much as with whether the *actions* of the alleged wrongdoer have a close or direct effect on the victim, such that the wrongdoer ought to have had the victim in mind as a person potentially harmed. A sufficiently close and direct connection between the actions of the wrongdoer and the victim may exist where there is a personal relationship between the alleged wrongdoer and victim. However, it may also exist where there is no personal relationship between the victim and wrongdoer. [Italic emphasis in original. Underline emphasis added.]

[69] While the authorities are careful to deny that any one factor or combination of factors is necessary to establish proximity, certain factors will routinely take a central role in the proximity analysis. These include any representations made by the defendant, especially if made directly to the plaintiff, reliance by the plaintiff on the defendant's representations, the nature of the plaintiff's property or other

interest engaged, the specific nature of any direct contact between the plaintiff and the defendant, and the nature of the overall relationship existing between the plaintiff and the defendant: see *Cooper*, at paras. 34-35; *Hill*, at paras. 29-30.

(b) The Format of the Duty of Care Inquiry

[70] The Supreme Court of Canada jurisprudence has developed and refined a template to be applied in deciding whether any given relationship between a plaintiff and a defendant gives rise to a private law duty of care. Much of that jurisprudence involves negligence allegations brought by individuals against governmental authorities.

[71] Under the approach developed in the Supreme Court jurisprudence, there are two stages to the duty of care inquiry. The first stage is directed at the specifics of the individual case and decides whether the relationship between the plaintiff and the defendant justifies the imposition of a *prima facie* duty of care. The second stage of the inquiry, reached only if a *prima facie* duty of care is found, looks beyond the specifics of the case to broader residual policy concerns and asks whether those concerns justify the negation of the *prima facie* duty of care.

[72] The two-stage approach is clearly summarized in *Edwards v. Law Society of Upper Canada*, 2001 SCC 80, [2001] 3 S.C.R. 562, at paras. 9-10:

> At the first stage of the *Anns*[8] test, the question is whether the circumstances disclose reasonably foreseeable harm and proximity sufficient to establish a *prima facie* duty of care. The focus at this stage is on factors arising from the relationship between the plaintiff and the defendant, including broad considerations of policy. The starting point for this analysis is to determine whether there are analogous categories of cases in which proximity has previously been recognized. If no such cases exist, the question then becomes whether a new duty of care should be recognized in the circumstances. Mere foreseeability is not enough to establish a *prima facie* duty of care. The plaintiff must also show proximity – that the defendant was in a close and direct relationship to him or her such that it is just to impose a duty of care in the circumstances. ...
>
> If the plaintiff is successful at the first stage of *Anns* such that a *prima facie* duty of care has been established (despite the fact that the proposed duty does not fall within an already recognized category of recovery), the second stage of the *Anns* test must be addressed. That question is whether there exist residual policy considerations which justify denying liability. Residual policy considerations include, among other things, the effect of recognizing that duty of care on other legal obligations, its impact on the legal system and, in a less precise but important consideration, the effect of imposing liability on society in general.

[73] The questions posed in this special case focus exclusively on the first stage of the duty of care inquiry described in *Edwards*. At the first stage of the inquiry, the court begins by asking whether the claim advanced describes a relationship that is the same as or analogous to a relationship that courts have previously recognized as giving rise to a *prima facie* duty of care. If the relationship fits

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[8] Referring to *Anns v. Merton London Borough Council*, [1978] A.C. 728 (U.K.H.L.).

within that description, the court, in the interest of consistency and efficiency, will assume a *prima facie* duty of care and move directly to the second stage of the duty of care inquiry. Similarly, if courts have previously determined that the same or an analogous relationship does not create a *prima facie* duty of care, the court will, generally speaking, not repeat the analysis, but will find no duty of care based on the prior authority: see *Childs*, at para. 15; *Imperial Tobacco*, at para. 37; *Heaslip Estate v. Ontario*, 2009 ONCA 594, 96 O.R. (3d) 401, at para. 21; *Wellington v. Ontario*, 2011 ONCA 274, 105 O.R. (3d) 81, at para. 16.

[74] In deciding whether an allegation fits within an established category or is analogous to an established category, the court must guard against treating the allegations at an abstract or generic level. For example, courts have long recognized a tort of negligent misrepresentation. It does not follow, however, that every allegation of negligent misrepresentation fits within that established category. As explained in *Imperial Tobacco*, at para. 37:

> The first question is whether the facts as pleaded bring Canada's relationships with consumers and the tobacco companies within a settled category that gives rise to a duty of care. If they do, a *prima facie* duty of care will be established [citation omitted]. However, it is important to note that liability for negligent misrepresentation depends on the nature of the relationship between the plaintiff and the defendant... <u>The question is not whether negligent misrepresentation is a recognized tort, but whether there is a reasonable prospect that the relationship alleged in the pleadings will give rise to liability for negligent misrepresentation.</u> [Emphasis added.]

(c) The Duty of Care Inquiry and Regulatory Negligence

[75] If the claim does not fall within an established or an analogous category, but the harm alleged was reasonably foreseeable, proximity becomes the focus of the first stage of the two-stage duty of care inquiry. Where the claim is advanced against a regulator, the proximity inquiry will focus initially on the applicable legislative scheme and secondly, on the interactions, if any, between the regulator or governmental authority and the putative plaintiff: see *Imperial Tobacco*, at paras. 43-45.

[76] The legislative scheme looms large in the proximity inquiry for two reasons. First, the question of whether a regulator should owe a private law duty of care to those individuals affected by its actions is largely a policy decision that falls squarely within the legislative bailiwick. The legislature announces that policy decision through the terms of its legislation. Second, even where the legislation is not determinative and the court must look to the interaction between the regulator and the plaintiff, the terms of the legislation describing the powers and duties of the regulator may to some extent shape the relationship between the regulator and the regulated. That relationship will be relevant in deciding whether the specific interactions between the regulator and the plaintiff are sufficient to create the degree of proximity required to establish a *prima facie* duty of care.

[77] The legislative scheme must be examined at the outset of the duty of care inquiry. If that scheme expressly or by implication forecloses or imposes a private law duty of care, the duty of care inquiry need go no further. It is not for the court to contradict the terms of the legislative scheme.

[78] Legislative schemes under which regulators operate almost inevitably impose public duties on those regulators. Plaintiffs have, generally speaking, had little success in demonstrating that those schemes impose a private law duty of care. To the contrary, courts have been more inclined to find that legislative schemes by implication preclude a private law duty of care to individuals affected by those schemes. Statutory schemes that provide immunity to the regulator, create remedies to injured parties other than tort remedies, or impose duties on the regulator that conflict with a private law duty of care to an individual have all been held to compel the conclusion that the legislative scheme implicitly forecloses a finding that the regulator owes a private law duty of care to an individual: see *Cooper*, at paras. 43-44; *Edwards*, at paras. 16-17; *Alberta v. Elder Advocates of Alberta Society*, 2011 SCC 24, [2011] 2 S.C.R. 261, at para. 69; *Syl Apps Secure Treatment Centre v. B.D.*, 2007 SCC 38, [2007] 3 S.C.R. 83, at paras. 49-50, 59-63; *Eliopoulos v. Ontario (Minister of Health and Long-Term Care)* (2006), 82 O.R. (3d) 321 (C.A), at paras. 14-20.

[79] Where the legislation is not determinative one way or the other, the courts explore the specific circumstances of the interactions between the regulator and

the plaintiff in the context of the legislative scheme to decide whether a sufficiently "close and direct" relationship exists to justify the imposition of a *prima facie* duty of care: see *Imperial Tobacco*, at para. 50; *Hill*, at paras. 26-45; *Fullowka v. Pinkerton's of Canada Ltd.*, 2010 SCC 5, [2010] 1 S.C.R. 132, at paras. 37-55; *Heaslip*, at paras. 15-31.

[80] Findings of proximity based on the interactions between the regulator and the plaintiff are necessarily fact-specific. The jurisprudence does, however, suggest there are two important factual features in those cases where the court has found a *prima facie* duty of care. First, the facts demonstrate a relationship and connection between the regulator and the individual that is distinct from and more direct than the relationship between the regulator and that part of the public affected by the regulator's work. For example, in *Hill*, at para. 33, the court found that the police owed the plaintiff a duty of care in conducting their investigation because they had targeted the plaintiff in that criminal investigation. By targeting the plaintiff, the police created a relationship with the plaintiff that was much more direct than the relationship between the police and other members of the public who might also be affected by the exercise of police powers.

[81] *Fullowka* is another example of a finding of a duty of care premised on the interaction between the plaintiff and the regulator. In *Fullowka*, at paras. 44 and 55, the court stressed that the mine in which the explosion at issue had occurred had been inspected many times by the regulator. The regulator was aware of the

dangers posed to the miners by the strike-related violence and the ineffectiveness of the measures that had been taken to prevent that violence. Cromwell J., writing for the court, observed, at para. 54:

> ... [The regulators] had a clear and well substantiated belief that the mine was unsafe. ... The legislative scheme is about safety in mines, it exists to protect miners from acts of others and there were clearly identified and well documented findings that the miners were subject to unsafe working conditions.

[82] The specific facts relating to the particular mine and the well known safety problems presented at that mine were sufficient to create a direct relationship between the regulator responsible for the safety of the mine and the miners who worked there. Those actions effectively distinguished the relationship between the regulators and the workers in the specific mine from the relationship between the regulator and miners in general.

[83] *Heaslip* provides one of the best examples of the kind of interaction between a regulator and an individual that will create a *prima facie* duty of care where the operative legislative scheme imposes only public duties, but does not foreclose the existence of a private law duty that is not inconsistent with the public duties.

[84] In *Heaslip*, the plaintiffs alleged that the government agency responsible for providing air ambulance services had negligently failed to follow its own policies when it did not give their son's medical needs priority over the needs of a less

severely injured person. The plaintiffs alleged that their son died as a result of the regulator's decision to give priority to the less seriously injured individual.

[85] Sharpe J.A. acknowledged that the duties found in the relevant legislation were public duties that did not give rise to a duty of care as between the plaintiff and the regulator. Nor, however, did they foreclose the existence of that duty. Sharpe J.A. went on to examine the interaction between the regulator and the plaintiff. On the allegations, the regulator had undertaken to provide a specific medical service to the plaintiff's son. The regulator was aware that the plaintiff's son was in need of that service and dependent upon the regulator to provide that service. According to the regulator's policies, the plaintiff's son should have received that service in priority to the person to whom the service was provided.

[86] In holding that the allegations in the claim gave rise to a *prima facie* duty of care, Sharpe J.A. said, at paras. 19-20:

> This case is distinguishable from cases like *Cooper* and *Attis*. In those cases, the plaintiffs suffered harm at the hands of a party involved in an activity subject to regulatory authority and then alleged negligence on the part of the governmental authority charged with the duty of regulating the activity that gave rise to the plaintiff's loss. *Cooper* and *Attis* hold that such plaintiffs have no direct relationship with the governmental authority and can assert no higher claim to a duty of care than any other member of the public.
>
> The claim asserted here does not rest solely on the statute conferring regulatory powers, as in *Cooper* and *Attis*, but is focused instead on the specific interaction that took place between Patrick Heaslip and Ontario

> when the request for an air ambulance was made. In this case, the relationship between Patrick Heaslip and the governmental authority is direct, rather than being mediated by a party subject to the regulatory control of the governmental authority. [Emphasis added.]

[87] In holding that there was sufficient proximity, *Heaslip* draws a distinction between (i) a situation in which the actions of the regulator directly impact on the individual plaintiff and cause harm to that plaintiff, and (ii) situations in which the harm to the plaintiff is caused by the actions of a third party and the plaintiff's claim is that the regulator should have acted to prevent the actions of the third party. Not surprisingly, a finding of proximity will be more readily made in cases where the actions of the regulator directly impact on the plaintiff and cause the physical harm giving rise to the claim: see *Childs*, at para. 31; see also *Gorringe v. Calderdale Metropolitan Borough Council*, [2004] UKHL 15, [2004] 1 W.L.R. 1057, per Lord Hoffman, at para. 38.

[88] The second feature of those cases in which the courts have found that the interactions between the plaintiff and the regulator created a *prima facie* duty of care arises out of the nature of the duty actually imposed by the legislative scheme. While the statutory duties are found to be public duties and not, therefore, themselves the basis for any private law duty of care, those public duties have been found to be consistent with the existence of a private law duty of care owed to an individual plaintiff. Thus, in *Hill*, the Chief Justice found that the recognition of a private law duty of care to an individual suspect based on the

interaction between that suspect and the police promoted the broader public interest in the effective and fair police investigation of criminal activity: see paras. 36-41.

[89] *Imperial Tobacco* is instructive in that it presents both an example of an interaction between a regulator and the regulated that was sufficient to establish a *prima facie* private law duty of care and an example of an interaction that was insufficient. There were two different claims made against the regulator, Health Canada, in *Imperial Tobacco*. Cigarette manufacturers argued that Health Canada owed a private law duty of care to consumers of cigarettes and a discrete private law duty of care to the manufacturers. They alleged that Health Canada had breached both duties by making negligent representations concerning the relative safety of low-tar cigarettes.

[90] In examining the relationship between the regulator and consumers, the court looked first at the legislative scheme and found that it imposed only general duties to the public: see paras. 49-50. The court also held, however, that the legislation did not preclude the existence of a private law duty of care if the interactions between the regulators and a consumer of the product justified the imposition of such a duty. The court, however, found no specific interactions between the regulators and consumers of cigarettes. The court rejected, at para. 49, the contention that the regulator's assertions to the general smoking public

that low-tar cigarettes were less hazardous could create a relationship of proximity between the regulator and consumers of low-tar cigarettes.

[91] The court next addressed, at para. 51 and following, the relationship between the regulator and the tobacco companies. Once again, the court found no private law duty of care arising from the relevant legislative scheme. However, the court held that the allegations in the claim were capable of establishing a direct relationship between the regulator and the tobacco manufacturers. According to the allegations, the regulator had gone beyond its regulatory role and had become involved with the manufacturers in a wide variety of matters, including advising on the growing and advertising of various tobacco products. The court concluded that these interactions sufficed to create a relationship of proximity between the regulator and the manufacturers justifying a finding of a *prima facie* duty of care owed to the manufacturers by the regulator.[9]

(d) *Attis*, *Drady* and *Sauer*

[92] The approach taken to the claims in *Drady* and *Attis* is consistent with that described above. In both cases, this court looked first at the relevant legislative scheme and found that it imposed no private law duty of care: see *Attis*, at paras. 53-62; *Drady*, at paras. 37-39. The court then turned to the pleadings in each case to determine whether the interactions between the regulator and the plaintiff

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[9] The court went on to determine that the residual policy considerations at the second stage of the duty of care inquiry negated the existence of any duty of care owed by the regulator to the manufacturers.

set forth in the pleadings created a relationship of proximity such as to justify a finding of a *prima facie* duty of care. In *Attis*, Lang J.A.'s examination included the following observation, at para. 66:

> ...once the government has direct communication or interaction with the individual in the operation or implementation of a policy, a duty of care may arise, particularly where the safety of the individual is at risk. If, for example, a government decides to issue a warning about a specific danger, in this case medical devices, or to make representations about the safety of a product, the government may be liable for the manner in which it issues that warning, or the content of those representations, especially where the government disseminates the warning or representation knowing that the individual consumer will rely on its contents and the individual does so.

[93] In *Attis*, at paras. 69-70, Lang J.A. went on to conclude that the facts as pleaded did not establish an interaction between the regulator and the plaintiff such as to create a *prima facie* duty of care. She noted the absence of any direct contact between the plaintiffs and Health Canada and the absence of any allegations of representations made by Health Canada and relied on by the plaintiffs. She concluded, at para. 70:

> ...there was no interaction with Health Canada that could have led the appellants to believe Health Canada had assumed a private law duty of care for product safety. Nothing in the relationship between the parties would lead an individual to assume a government product guarantee. Rather, the appellants' expectations and reliance would have been on their medical advisers, the hospital, the manufacturer and the distributer of the device. I would conclude that the pleaded facts in this

> case do not support a finding of proximity through interaction.

[94] Unlike *Attis* and *Drady*, which addressed the proximity requirement in detail, *Sauer* considers proximity in a single conclusory paragraph (para. 62). In that paragraph, the court referred to the regulator's "many public representations" declaring its intention to protect "commercial cattle farmers among others".

[95] In my view, a finding of proximity based entirely on a regulator's public acknowledgement of its public duties to those affected by its actions, coupled with reliance by those affected on the regulator's public statements, is inconsistent with the Supreme Court's rejection in *Imperial Tobacco* of the claim that Health Canada owed a private law duty of care to consumers of low-tar cigarettes because it had made public representations as to the relative safety of those cigarettes.[10]

[96] Although public representations by a regulator as to its public duties and obligations do not establish a relationship of proximity between the regulator and an individual plaintiff, they are properly included in the factual matrix to be considered in determining whether the interactions between a regulator and a plaintiff are sufficiently direct and close to warrant a finding of proximity.

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[10] Arguments of proximity based on the regulator's acknowledgement of its duties to the public and reliance on that acknowledgement seem close to the concept of "general reliance" discussed in the Australian cases, including cases like *Pyrenees Shire Council v. Day* (1998), 192 C.L.R. 330 (H.C.A.). To my knowledge, the concept of "general reliance" has not been adopted in any Canadian jurisdiction. See also *Gorringe v. Calderdale Metropolitan Borough Council*.

[97] This is not the time or place to pass upon the ultimate sufficiency of the pleadings in *Sauer*. I am satisfied, however, that the detailed analyses of proximity in *Attis* and *Drady*, particularly in the light of the subsequent judgment in *Imperial Tobacco*, are more in line with the prevailing jurisprudence. The single conclusory observation in *Sauer*, standing alone, is not consistent with that jurisprudence.

[98] The jurisprudence permits no definitive answer for the first question. As counsel for AG Canada put it in his factum, "[t]he requirements for proximity are diverse and depend on the facts of each particular case."

VI

THE SECOND QUESTION

[99] The second question states:

> Does the amended statement of claim in this action satisfy those requirements?

[100] The question is answered by applying the template fashioned in the jurisprudence to the pleadings in this case. As already indicated, this exercise is complicated by the diffuse and disorganized nature of the pleadings.

[101] I begin with the statutory regime. As outlined above, *Attis* and *Drady* dealt with the same legislative scheme that is before the court in this proceeding. Both cases held that the scheme did not expressly or by implication create a private

law duty of care. Nor did the scheme foreclose the existence of that duty in a particular situation.

[102] Neither party in this proceeding suggests that the court should reconsider the analysis of the legislative scheme conducted in *Attis* and *Drady*. I see no reason to rework that ground. The fate of these pleadings turns on whether they allege a sufficient interaction between Health Canada and the plaintiff to warrant a finding of proximity and the imposition of a *prima facie* duty of care.

[103] In considering whether allegations of interactions between the plaintiff and the regulator are sufficient to survive challenge at the pleadings stage, I bear in mind the admonition of the Chief Justice in *Imperial Tobacco*, at para. 47:

> ... where the asserted basis for proximity is grounded in specific conduct and interactions, ruling a claim out at the proximity stage may be difficult. So long as there is a reasonable prospect that the asserted interactions could, if true, result in a finding of sufficient proximity, and the statute does not exclude that possibility, the matter must be allowed to proceed to trial, subject to any policy considerations that may negate the *prima facie* duty of care at the second stage of the analysis. [Emphasis added.]

[104] Where the relationship of proximity is said to arise out of the interaction between a plaintiff and the regulator, the question must be – what is there in the factual allegations that distinguishes the relationship between this plaintiff and the regulator from the relationship that exists between the regulator and all those affected by the regulator's actions? In the amendments to her claim found in the

Fresh Statement of Claim, Ms. Taylor tries to establish a direct and close relationship with the regulator by reference to the regulator's public statements concerning its general powers and practices under the legislative scheme and her reliance on them. For example, in para. 25, she refers to the RIAS as representations of Health Canada's "habitual practice to monitor and assure the safety of medical devices used by Class Members". Ms. Taylor further alleged that these broad public representations "were intended to be and were, reasonably relied on by the public, including the representative plaintiff and Class Members."

[105] For the reasons set out above, a regulator's public statements acknowledging its public duties and obligations and its commitment to the performance of those duties, combined with the reliance on those public statements by members of the public affected by the performance of those duties, cannot, standing alone, create a relationship of proximity between individual plaintiffs and the regulator. In my view, to assert that the kind of representations made by Health Canada and relied on in the Fresh Statement of Claim can, coupled with reliance on those representations, create a relationship of proximity, is in reality to assert that the public duties set out in the legislative scheme can become a private law duty of care if relied on by an individual member of the public. The legislative scheme does not create any private law

duty of care. An individual's reliance on public representations that the regulator will do its public and statutory duty cannot by itself create one.

[106] The additional allegations concerning representations and reliance inserted into the Fresh Statement of Claim do not establish a relationship of proximity between Ms. Taylor and Health Canada. However, those allegations must be placed in the context of the more specific allegations concerning the implants made in the remainder of the Fresh Statement of Claim.

[107] I begin my review of those specific allegations with three observations. First, there is no allegation of any direct contact between the plaintiff and Health Canada. Second, it is not alleged that Health Canada's actions directly caused the harm to Ms. Taylor. Rather, it is alleged that Health Canada failed to properly regulate those who caused the harm to Ms. Taylor. These two factors make this case different from cases like *Heaslip* and *Hill*.

[108] My third observation, however, points in the opposite direction. There is nothing inconsistent with a finding of a private law duty of care owed to individuals in a particular situation and the existence of the public duties owed by Health Canada under the legislation. The private law duty of care claimed by Ms. Taylor can coexist with the duties and obligations owed by Health Canada to the public.

[109] The sustainability of Ms. Taylor's claim at this stage of the proceedings depends primarily on the allegations of Health Canada's misrepresentations as to the status of the Vitek implants between 1988 and 1990 and its failure to correct those misrepresentations in the following years during which the implants were sold into Canada without proper authorization and the evidence of the danger posed by those implants continued to mount. Those allegations can be summarized as follows:

- no later than 1987, Vitek, with Health Canada's knowledge, was selling implants in Canada without the necessary notice of compliance;
- Ms. Taylor received one of those Vitek implants in Canada in April 1988;
- sometime in 1988, Health Canada wrongly represented in its database that it had issued a notice of compliance referable to the Vitek implants;
- at various times in 1989, Health Canada, through its officials, repeated the misrepresentation concerning the status of the Vitek implants and indicated that Vitek had filed data establishing the

safety of the implants to Health Canada's satisfaction;

- in 1990 Health Canada discovered that it had wrongly represented that the Vitek implants had received a notice of compliance, but it took no steps to advise users or potential users of the implants or their health care professionals of Health Canada's misrepresentation;
- to Health Canada's knowledge, Vitek continued to sell implants in Canada between 1988 and 1990, without the requisite notice of compliance;
- beginning in 1990, Health Canada received information from various reliable sources reporting significant defects causing the implants to fail and resulting in serious health consequences for those who had received the implants;
- between 1990 and 1992, Health Canada was advised of various safety alerts, recalls, public health notices, and import alerts issued by American authorities in relation to the implants;

- between 1990 and 1996, Health Canada failed to take any or took inadequate steps in response to the information received;
- throughout the period, Health Canada represented to consumers that it monitored and assured the safety of medical devices; and
- Ms. Taylor and other class members relied on this representation.

[110] Reading Ms. Taylor's pleadings generously, they allege that between 1988 and 1990 Health Canada repeatedly misrepresented the safety of the implants Ms. Taylor and others received by wrongly representing that those implants had received a notice of compliance. The pleadings further allege that when Health Canada became aware of its misrepresentation in 1990, it failed to correct that misrepresentation despite the knowledge that the implants were being improperly imported and sold in Canada and that there was strong and growing evidence that the implants were unsafe and caused serious harm to users. These allegations, taken in combination, in my view, describe a relationship between Health Canada and the users of those implants that is different from the relationship that exists between Health Canada and consumers of medical devices at large. The more difficult question is whether the allegations create a sufficiently close relationship to give rise to a private law duty of care.

[111] In referring to the combined effect of Health Canada's misrepresentations as to the compliance of the implants and its subsequent conduct, I do not mean to suggest that because Health Canada's conduct potentially increased the risk to Ms. Taylor that it necessarily created a relationship of proximity. I agree with the observation in *Drady*, at paras. 44-62, that the fact that misrepresentations enhance the risk to users of the implants is not in and of itself germane to the proximity requirement. That requirement must focus on the nature of the relationship between Health Canada and the users created by the misrepresentations taken in combination with Health Canada's other conduct. In my view, it is arguable that the misrepresentations, combined with the failure to correct that misrepresentation in the face of knowledge of the serious and ongoing risk posed to a clearly definable and relatively small group of consumers, could be viewed as akin to the regulator's failure in *Fullowka* to act in the face of the known and ongoing dangers posed to the small and well-defined group of miners who worked in the specific mine which the regulator knew to be unsafe. In *Fullowka*, the Supreme Court found sufficient proximity between the regulator and those miners to warrant the imposition of a private law duty of care: see also *Doe v. Metropolitan Toronto (Municipality) Commissioners of Police* (1990), 74 O.R. (2d) 225 (H.C.J. Div. Ct.).

[112] No prior case is a perfect fit for this one, otherwise there would be no need to redo the proximity analysis. In *Fullowka*, the regulator was physically present

in the mine on several occasions and was required by statute to directly regulate the conduct of the miners. Those features, which do not exist in this case, render the relationship between the regulator and the miners in *Fullowka* closer than the relationship between Health Canada and the recipients of the implants.

[113] Similarly, in *Doe*, the police were aware that the plaintiff was one of a handful of persons who had potentially been targeted by a serial rapist. The police were also under a specific statutory duty to prevent crime. That degree of specificity is not present on the facts as alleged in this case.

[114] Acknowledging, however, the factual differences among the cases, one should not ignore the similarities. In *Fullowka*, *Doe* and this case, the regulator failed to act to protect the life and safety of individuals when the regulator was fixed with knowledge of a clear, present and significant danger posed to a discrete and identifiable segment of the community. On these pleadings, there are the added features of a material misstatement by the regulator, a failure to correct that misstatement, a decision to refrain from notifying at least some of those individuals whom the regulator knew to be at risk as a result of the use of the implants, and a failure to adequately warn those whom Health Canada did notify of potential problems with the implants. It is arguable that those features of the case enhance Ms. Taylor's proximity argument.

[115] I come next to the significance of allegations of representations made by the regulator and reliance placed on those representations by the plaintiff. No doubt, specific representations by a regulator to an individual, and reliance by that individual on those representations, will go a long way toward establishing a *prima facie* duty of care. The real issue here is whether that kind of direct representation and reliance is essential to a finding of a *prima facie* private law duty of care. If it is essential, Ms. Taylor has no claim as she does not allege that she was aware of, much less relied on, any of Health Canada's representations concerning the safety of the implants.

[116] In *Drady*, after referring to several allegations in the pleadings in that case, including an allegation of the very misrepresentation in issue here, this court in holding that the pleadings did not reveal a cause of action, said, at para. 54:

> In the absence of a specific representation or reliance on Health Canada regarding the safety of the implant, in my view, it is plain and obvious that the appellant cannot establish a direct and close relationship of proximity that makes it just and fair to impose a private law duty of care on Health Canada.

[117] The jurisprudence does not go so far as counsel for AG Canada suggests this passage does. The Supreme Court of Canada has imposed a *prima facie* private law duty of care on regulators in circumstances where there were no specific representations made to the plaintiff and no reliance on any specific representation by the plaintiff. *Hill* and *Fullowka* are two examples. As repeatedly

indicated in the Supreme Court of Canada jurisprudence, where a private law duty of care is said to arise from the specific relationship of the regulator and the plaintiff, the entirety of the circumstances said to constitute that relationship must be considered in determining whether that duty exists.

[118] The nature of any representations made by the regulator, and the nature of any reliance placed on those representations by the plaintiff, are part of the entirety of the circumstances to be considered in determining the directness of the relationship between the regulator and the plaintiff. Representations made specifically to a plaintiff and relied on by that plaintiff can clearly forge a direct connection between the regulator and the plaintiff. General representations made by the regulator to the public and relied on by the plaintiff as a member of the public do not, standing alone, create a direct relationship. However, general representations and reliance on those representations can, in combination with other factors, create a relationship between the regulator and the plaintiff that is sufficiently close and direct to render it fair and just to impose on the regulator, in the conduct of its duties, an obligation to be mindful of the plaintiff's legitimate interests.

[119] I would add that proximity is not necessarily an all-or-nothing proposition. Ms. Taylor advances different claims, as summarized above in para. 9. A trial judge could find a sufficiently close and direct relationship between Ms. Taylor and Health Canada to give rise to a *prima facie* duty of care in respect of some,

but not all of the claims. For example, a trial judge might conclude that the relationship between Health Canada and Ms. Taylor at the time she received the implants did not give rise to a duty of care, but that the relationship had evolved into one of sufficient proximity to give rise to a duty of care by the time Health Canada discovered its misstatements with respect to the implants, became aware of the significant risks posed to individuals who had received the implants, and failed either to notify implant recipients of the risks or to adequately advise those notified of the nature of the risks. If a trial judge found that the relationship had in fact evolved into one justifying the imposition of a private law duty of care, then Health Canada may have breached that duty by failing to warn Ms. Taylor and other recipients of the ongoing danger presented by the implants so that Ms. Taylor and the others could take steps to mitigate the harm caused by the implants.

[120] Ultimately, I come to this point. It is not clear to me that Ms. Taylor will at the end of the day succeed in making out a private law duty of care owed to her by Health Canada. However, bearing in mind that at this stage the allegations must be assumed to be true and must be read generously, and also having regard to the dynamic nature of the jurisprudence, it is not plain and obvious that the claim as pleaded is bound to fail for want of a private law duty of care. The courtroom door cannot be closed to Ms. Taylor and the other members of the class at this stage.

VII

CONCLUSION

[121] Question 1 should be answered as proposed by counsel for AG Canada:

- The requirements for proximity are diverse and depend on the facts of each particular case.

[122] Question 2 should be answered as follows:

- At this stage of the proceedings, it is not plain and obvious that the allegations in the Fresh Statement of Claim cannot support a finding that Health Canada owed the plaintiff a *prima facie* private law duty of care.

VIII

REMEDY

[123] Ms. Taylor is entitled to the remedy sought by her in the motion to determine a special case. The order of Cullity J., dated September 7, 2010, is affirmed. Ms. Taylor should be given a reasonable opportunity to reframe and streamline her pleadings in light of these reasons.

[124] The parties may address the costs of this special case in written submissions of no more than four pages. Those submissions should be exchanged and filed within 45 days.

RELEASED: JUL 06 2012

I agree L.M. Calderhead J.A.

I agree D.L. Bell J.A.

I agree Peter D. Lauwers J.A.

I agree Robert J. Sharpe J.A.