COURT FILE NO.: 00-CV-197409CP
DATE: 20070118

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:	
ALINE BOULANGER	Gary R. Will, Joel P. Rochon, Paul Miller, and Sakie Tambakos, for the Plaintiff
Plaintiff	
- and -	
JOHNSON & JOHNSON CORPORATION, JOHNSON & JOHNSON MEDICAL PRODUCTS INC./PRODUITS MEDICAUX JOHNSON & JOHNSON INC., and JANSSEN-ORTHO INC. and THE ATTORNEY GENERAL OF CANADA	S. Gordon McKee and Robin D. Linley, for the Janssen-Ortho Inc. Defendants Gina M. Scarcella and Suzanne Duncan, for The Attorney General of Canada
Defendants	
	Heard: December 19, 20, & 21, 2005

Ellen Macdonald J.

REASONS FOR DECISION

[1] At the outset, I record that the claims against the defendant, The Attorney General of Canada, were withdrawn on consent

[2] Aline Boulanger, the proposed representative plaintiff, moves to have this case certified as a class action on behalf of certain individuals in Canada (other than Quebec) who ingested Prepulsid (generic name cisapride). By order of Mr. Justice Nordheimer this action was consolidated with *Young v Janssen-Ortho Inc. et al*, Toronto Court File No. 00-CV- 197409CP Justice Nordheimer also ordered that Ms. Boulanger become the proposed representative plaintiff for this action Ms. Boulanger now resides in Timmins, Ontario She was prescribed Prepulsid,

the drug that is in controversy in this action. In her affidavit, sworn October 15, 2003 (on which she was not cross-examined), she described the severe cardiac reactions that she experienced while taking Prepulsid beginning in 1995. She attributes these reactions to the use of Prepulsid. She is challenged in this motion as an appropriate representative plaintiff on the basis that she has an interest in conflict with members of the proposed class regarding the proposed common issues. I will deal with this later in the reasons.

[3] I conclude that the motion for certification should succeed. My reasons for coming to this conclusion are set out below.

The Drug Prepulsid

[4] Prepulsid is a "prokinetic" or motility agent that was often prescribed by physicians to treat gastroesophageal reflux disease or "GERD". GERD is characterized by the backward flow of acid from the stomach into the esophagus which irritates the walls of the esophagus and can cause a patient to experience heartburn, pain, pressure, hoarseness, cough and nocturnal asthma attacks. Chronic GERD can lead to scarring and pre-cancerous changes in the lining of the esophagus. In children, as well as in adults, GERD is associated with episodes of apnea, asthma, and aspiration. Prepulsid addressed the symptoms of GERD by stimulating muscle contractions in the esophagus and stomach, thereby improving clearance of the contents of the esophagus into the stomach and improving gastric emptying into the small intestine, leaving a lesser volume of gastric contents available for reflux into the esophagus.

[5] Prepulsid was also prescribed for treatment of other gastrointestinal motility disorders including gastroparesis (where there is a delayed emptying of the contents of the stomach) and intestinal pseudo-obstruction (where the intestines stop moving their contents forward). The effects of these disorders can be debilitating and, in some cases, life threatening.

[6] Prepulsid was first approved for use in Europe in 1988. Approximately one year later, Health Canada issued a Notice of Compliance for Prepulsid approving it for sale in Canada for specific "indications" (medical conditions) – the symptomatic management of gastrointestinal motility disorders including GERD, gastroparesis, and intestinal pseudo-obstruction. In January 1990, Prepulsid was formally launched in Canada by Janssen-Ortho Inc., the Canadian distribution company.

[7] Prepulsid was withdrawn from the market following a stop order sale directed to Janssen-Ortho in May 2000. Canadian pharmacies were permitted by Health Canada to sell their inventories off until August 7, 2002.

The Parties' Positions

[8] Before I summarize the parties' positions, I comment on a statement that appears in the opening paragraph of the plaintiff's factum. It is that this is a product liability case and as such "this is a quintessential case for certification, and follows directly in line with other certified drug and medical device cases in Canada". In response, the Ortho-Johnson defendants point out that simply because this case is a "product liability" case does not mean that it is automatically suited

to certification. They further submit each case must be assessed contextually on it own facts. See para [104] of their factum. They refer to *Ernewein v. General Motors of Canada Ltd.*, [2005] B.C.J. No. 2370 (C.A.) (QL), leave to appeal to the S.C.C. refused [2005] S.C.C.A. No. 545, wherein the following comments appear at para. 33:

> Since earlier cases. [references removed], experience has shown that not all product liability cases lend themselves to certification. In some, the complexities inherent in problems of proof of the applicable duty of care over a long period of time, changing manufacturing techniques, or multi-party involvement in the product delivery chain, have made the formulation of a common question problematic.. [references removed]. In each instance, the question must be determined "contextually" - i.e., not on the basis of a blanket assumption regarding product liability cases but in light of all the evidence concerning the specific case before the court.

I am mindful of the point made by the defendants. I agree with it. I do not approach the analysis of the legal issues raised in this motion on the basis that a so-called product liability case is automatically suited to certification.

[9] The essence of the representative plaintiff's claim is that the defendants owed various duties of care to her and other members of the class. It is alleged that these duties were breached by negligently developing, testing, manufacturing, licensing, distributing, and marketing Prepulsid in Canada. There is also an allegation that the defendants failed to adequately warn Canadian physicians and their patients of the main risks associated with the ingestion of Prepulsid.

[10] The defendants' response is that this action should not be certified as a class proceeding for the following reasons:

(a) The class definition proposed, essentially all 3.4 million persons in Canada other than in Quebec who ingested Prepulsid, plus potentially millions of family members, is not appropriate. The definition is overly broad as it encompasses persons who clearly have no claim against the corporate defendants for any of the relief pleaded, let alone a claim that raises common issues. Further, the class definition does not bear a rational relationship to the proposed common issues.

(b) The proposed common issues, when looked at closely and in context, breakdown into a myriad of issues that are not common to <u>each</u> class member's claim, as the class is currently defined.

(c) A class action is not the preferable procedure because it will not be a fair, efficient or manageable method of advancing the claims. A trial judge would immediately discover that any common issues that could be formulated in this case will not assist in addressing what is really in issue,

that there is no economy in the proceeding and that the trial will be unmanageable. Because of the problems of proving the applicable standard of care over a long period of time and multi party involvement by health care professionals and patients, individual or at least non-common issues in this case are complex and inextricably interwoven into the liability questions, and individual discovery and trials will be necessary regardless of success on any common issues trial. A class action will result in the Court rehearing evidence on standard of care and general causation in order to decide questions of apportionment and specific causation in each individual case. Resolution of any alleged common issue will not meaningfully advance the individual claims sufficiently to warrant a class proceeding. Further, access to justice is not an issue for the individual claimants on the evidence before this Court. A common issues trial will actually delay all parties' assessment of the critical causation question in each case and will likely increase the costs to all and further burden judicial resources.

(d) Under the circumstances, individual trials with common discovery are the preferable procedure for resolving the handful of individual claims. The cardiac events in question will either be serious enough to warrant an individual claim, or did not result in any injury. As demonstrated by the existence of individual claims in Canada and the trials that have already taken place in the United States, individual claims are not only viable but will be more quickly resolved than a complex, time consuming and expensive class proceeding.

(e) If this case can be certified as a class action, then any proposed class action based on a known and disclosed risk inherent in the use of a medicine, (such as an increased risk of bleeding with aspirin use) can be certified. This is not how the law has been applied in Canada, nor should it be given the negative impact such an application could have on the development and availability of medical products that improve the health and well being of Canadians.

[11] The representative plaintiff raises a number of issues in reply that suggest that the defendants misconstrue the letter and spirit of the *Class Proceedings Act 1992*, S.O. 1992, c. 6 ("CPA") by urging the court not to follow leading analogous decisions that have dealt with defective drugs and medical devices. The representative plaintiff also says that the position being advanced by the defendants ignores "recent admonitions in the Ontario Court of Appeal[1] which forcefully direct that a more liberal approach be taken to certification of class proceedings."

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[1] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (C.A.) and *Pearson v. Inco Ltd.*, [2005] O.J. No. 4918 (C.A.)

[12] The representative plaintiff reminds this court that debates over issues surrounding the efficacy of Prepulsid have no place at a certification motion. The representative plaintiff says that the questions arising from the complex determination of the efficacy of Prepulsid are issues to be dealt with following certification. In short, the reply submission on this point is that the defendants seek to impose an "evidence based" battle on this certification motion, akin to a summary judgment motion which the representative plaintiff says is entirely contrary to the decision in *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at para. 15 *Hollick* confirms the procedural nature of the certification motion

[13] Keeping these points in mind, I will now examine whether the requirements of s. 5 (1) of the CPA have been satisfied.

ANALYSIS

[14] It has been said that if ordinary citizens have any hope of access to justice, class actions are essential. This statement points to the importance of the certification motion. Described in the jurisprudence as procedural and not a test of the merits of the action, it is a screening process, which compels a scrutiny of each of the requirements of s. 5 (1) of the CPA.

[15] Subsection 5 (1) of the CPA provides that an action must be certified as a class action where certain criteria are satisfied. The provision reads as follows:

Certification

5. (1) The court shall certify a class proceeding on a motion under section 2, 3 or 4 if,

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

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

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

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

(e) there is a representative plaintiff or defendant who,

(i) would fairly and adequately represent the interests of the class,

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

(iii) does not have, on the common issues for the class, an interest in conflict with the interests of other class members.

The Cause of Action Criterion – s. 5 (1) (a)

[16] The representative plaintiff alleges that the defendants breached various duties of care owed to the class by negligently developing, testing, manufacturing, licensing, distributing, and

marketing Prepulsid in Canada, and by failing to adequately warn Canadian physicians and their patients of the risks associated with ingesting Prepulsid. The defendants did not contest these proposed causes of action. I find that the representative plaintiff's claim discloses a cause of action in satisfaction of s. 5 (1) (a).

The Identifiable Class Criterion – s. 5 (1) (b)

[17] The representative plaintiff has proposed that the class be all persons in Canada other than in Quebec who ingested Prepulsid as well as their estates and certain family members. There is a dispute among the parties on the matter of the size of the class. The defendants say that the class contains 3.4 million people, and the representative plaintiff says that the size of the class is estimated at 350,000. Other parts of the record suggest that given the drug's duration of use the size of the class might be lower. The inability to precisely determine the number of class members is not fatal to certification. It is sufficient for the representative plaintiff to define the class in a way to allow a determination on an objective basis whether or not any given individual fits within it: *Robertson v. Thomson Corp.* (1999), 43 O.R. (3d) 161 at 169 (Gen. Div.) [*Robertson*] I do not agree with the defendants' position that what is really in issue is whether an extraordinarily rare adverse event that "may have occurred in a handful of patients" was caused or materially contributed to by Prepulsid. This position is not in accordance with the evidence. While the defendants may not agree with the representative plaintiff's analysis of the numbers of those who may have been adversely affected by the use of Prepulsid, it is certainly more than a handful of people.

[18] In my opinion, the proposed class satisfies s. 5 (1) (b). As required by *Robertson*, *supra*, and *Hollick*, *supra* at para. 17, the class is defined by objective criteria and class membership can be determined without reference to the merits of the action. The class definition is tied to ingestion of Prepulsid, therefore class membership can be objectively determined through prescription and medical records.

[19] The defendants' primary complaint is that the proposed class is overly broad because it would include persons who do not have a claim against them. The representative plaintiff in reply asserts that it is incorrect in law to restrict the class to those who have sustained injury because this would improperly introduce a merits analysis to determining class membership. I agree.

[20] It has often been repeated in the jurisprudence that the purpose of a certification motion under s. 5 (1) of the CPA is to determine how the litigation is to proceed and *not* to address the merits of the plaintiff's claim. Before certification, there is to be no preliminary review of the merits of the claim. See the reasons of Cullity J. in *Morston v. Ontario Municipal Employees Retirement Board*, [2004] O.J. No. 4338 at para. 33 (Super. Ct.) and McLachlin C.J. in *Hollick v. Toronto (City)*, [2001] 3 S.C.R. 158 at paras. 28-9.

[21] I have not lost sight of the reality that not all class members stand to recover damages at the same level and that some class members may not be able to demonstrate that they have

sustained injuries and losses. Others may not be able to establish that the defendants caused their injuries and losses.

[22] While the proposed class may include persons who ultimately will not have a claim against the defendants, this is not fatal. This principle was affirmed by Winkler J. in *Bywater v Toronto Transit Commission*, [1998] O.J. No. 4913 at para. 10. In *Bywater*, Winkler J. accepted a proposed class that included people who suffered no damage and would therefore be unable to establish liability against the defendant. This leads me to the conclusion that, at this stage of the class proceeding, the court should not place undue emphasis on the fact that some or many members of the proposed class will be unable to establish liability against the defendants.

[23] However, this conclusion does not end the inquiry. To conclude that the class is not overly broad, *Hollick*, *supra* at para. 18, requires that the plaintiff show a "rational relationship" between the class and the common issues. The Ontario Court of Appeal in *Pearson*, *supra* recently confirmed that this is not an onerous test. Citing *Hollick*, Rosenberg J.A. said, at para. 57, that all that is required is "some showing" that the class is not unnecessarily broad. In support of his conclusion, at para. 58 of his reasons Rosenberg J.A. referred to the application of the "rational relationship" test by the Supreme Court in *Hollick*, *supra*. In *Hollick* the claim was for damages arising from noise and physical pollution. The proposed class contained 30,000 people in a defined geographic area surrounding a landfill. The Supreme Court held that evidence demonstrating that only two per cent of the proposed class had complained was sufficient to show some rational relationship between the class and the common issues.

[24] To my mind, it is a persuasive consideration that Health Canada ordered Prepulsid off the market. This is one of the factors that demonstrate a rational relationship between the proposed class and the common issues, which are discussed in greater detail below. Health Canada ordered Prepulsid off the market because of increasing safety concerns and potential harm to patients arising from the use of Prepulsid. The proposed common issues all concern the alleged negligence of the defendants. The representative plaintiff says that this negligence resulted in harm to Prepulsid consumers. Consequently, for the purposes of s. 5 (1) (b) of the CPA, the class is not overly broad since there is a "rational relationship" between the proposed common issues and the class.

The Common Issues Criterion – s. 5 (1) (c)

[25] Before examining the common issues proposed by the representative plaintiff, it is important to briefly review the backdrop of applicable jurisprudence. In *Hollick*, *supra* at para. 18, the Supreme Court said that an issue is a "common issue" where it is a substantial ingredient of each class member's claim and where its resolution is necessary to the resolution of each class member's claim. The Ontario Court of Appeal in *Cloud* and *Pearson*, *supra*, has recently clarified the law regarding the common issues criterion. The burden is on the representative plaintiff to provide sufficient evidence to satisfy this criterion: *Cloud*, *supra* at para. 49. This requirement is not an onerous one: *Cloud*, *supra* at para. 52; *Pearson*, *supra* at para. 65. As stated by Goudge J.A. in *Cloud*, *supra* at para. 53, "an issue can constitute a substantial ingredient of the claims and satisfy s. 5(1)(c) even if it makes up a very limited aspect of the

liability question and even though many individual issues remain to be decided after its resolution." At para. 58, Goudge J.A. also made an observation that is particularly relevant to this case given the defendants' submissions: "the fact that beyond the common issues there are numerous issues that require individual resolution does not undermine the commonality conclusion. Rather, that is to be considered in the assessment of whether a class action would be the preferable procedure."

[26] The representative plaintiff proposes the following as common issues:

a) Whether Prepulsid can cause or materially contribute to cardiac arrhythmia, including ventricular tachycardia, cardiac arrest, prolonged QT, *torsades de pointes*, ventricular fibrillation, sudden death and other heart disease;

b) Whether the Corporate Defendants breached a duty of care owed to class members by reason of the design, manufacture, marketing, sale and such other acts taken in placing and maintaining Prepulsid into the stream of Canadian commerce, and if so, who, when and how;

c) Whether Prepulsid was fit for its intended purpose;

d) Whether Johnson & Johnson Corporation is responsible in law for the acts and omissions of Janssen-Ortho Inc. in respect of the marketing, distribution, and placing and maintaining Prepulsid into the stream of Canadian commerce;

e) Whether the Corporate Defendants, or any of them, are liable for the subrogated health care costs of Class members incurred in the screening, diagnosis and treatment of conditions related to Prepulsid, and if so, whether these costs may be assessed on a global basis; and

f) Whether the conduct of any one or more of the Corporate Defendants justifies an award of punitive damages, and if so, against whom, in what amount and to whom.

Proposed common issue (a) – Whether Prepulsid causes adverse cardiac events

[27] The defendants attack proposed common issue (a) on two fronts. First, the defendants claim that the question of whether Prepulsid caused a number of cardiac events is not a common issue because the evidence shows that millions of people in the proposed class have not experienced these cardiac events and likely never will. Second, the defendants claim that the issue of causation will inevitably breakdown into a myriad of individual issues that will have to be examined separately. At para. [74] of the defendants' factum they say, "the question of whether Prepulsid caused each of the listed events will have to be looked at separately and in some cases even more discretely within each event – (i.e., monomorphic versus polymorphic ventricular tachycardia). When broken down by cardiac event, as it will need to be, the question will not be an ingredient of every proposed class member's claim."

[28] The representative plaintiff in her reply counters that issues of generic causation have been and continue to be certified in defective drug class actions. She claims that certifying this common issue will make it easier to address individual issues of proximate causation, allocation of fault and damages. It seems to me that matters of causation as framed by the defendants are more merits based rather than procedural. It is not the Court's task at this stage of the proceedings to make any ruling on the merits as to whether Prepulsid in fact causes adverse cardiac events: see *Bywater*, *supra*. Rather, the Court's role is to determine if the question of whether Prepulsid caused adverse cardiac events is a common issue of fact, the resolution of which moves the litigation forward for the class. As noted in *Cloud* and *Pearson*, *supra*, this test is a low bar, and the fact that many individual issues may remain after resolution of this common issue (like those identified by the defendants, set out above) is not a bar to certification.

[29] In my view, there is sufficient evidence to conclude that this proposed common issue satisfies the test set out in *Cloud* and *Pearson*, *supra*. During the ten years that Prepulsid was on the market in Canada, serious heart problems were reported in connection with Prepulsid use. As already mentioned, Health Canada ordered Prepulsid off the market due to cardiac safety concerns associated with the ingestion of Prepulsid. In its letter for Health Canada, therapeutics product program, dated May 30, 2000, and addressed to health care professionals the following comments appear:

> Health Canada would like to advise you that the prokinetic drug, PREPULSID (cisapride), will no longer be available from pharmacies effective August 7, 2000. PREPULSID, marketed by Janssen-Ortho Inc., is a prescription drug indicated for the treatment of gastroparesis, intestinal pseudo-obstruction, and gastroesophageal reflux disease which is refractory to lifestyle modifications, antacids, and gastric acid reducing agents. The decision to withdraw PREPULSID from the market is founded on the association of the drug with serious cardiac arrhythmias (e.g. ventricular tachycardia, *torsades de pointes*, and ventricular fibrillation) and sudden cardiac deaths. Between its introduction in 1990 and February 2000, Health Canada received at least 44 spontaneous domestic reports of potential cardiac rhythm abnormalities[1] associated with PREPULSID, including at least 10 reports of death. In the United States, the Food and Drug Administration has received 341 reports of cardiac rhythm abnormalities, including 80 fatalities. The continuing occurrence of such adverse events, despite several letters to health care professionals and changes to the Product Monograph, has led to the conclusion that the risks associated with PREPULSID are not manageable in the setting of licensed drug use.
>
> [1] Potential cardiac rhythm adverse events included QT interval prolongation; *torsades de pointes*; ventricular tachycardia/fibrillation; cardiac arrest; arrhythmia; sudden death; heart block; palpitation/tachycardia; new onset of syncope/seizures

[30] The evidence of Ms. Wendy Arnott was that there have been 58 reports of serious adverse drug reactions involving ventricular arrhythmia associated with the ingestion of

Prepulsid. The evidence of Ms. Cindy MacDonald was that there have been 127 reports of suspected adverse drug reactions associated with the ingestion of Prepulsid, 70 of which were of a serious nature, including 12 fatalities. On cross-examination, Dr. Brian Gillespie said that Prepulsid alone can cause serious cardiac arrhythmias.

[31] In addition, a number of published studies associate adverse cardiac events with Prepulsid ingestion. In a double blind randomized study published in *the European Journal of Clinical Pharmacology* in 1986, there was a finding that Prepulsid produced tachycardia. The summary conclusion was that "Cisapride produced a significant tachycardia ... which probably reflects a peripheral vasodilator action. Cisapride may therefore alter pharmacokinetics and dynamics of concurrently administered drugs." In 1992, the *British Medical Journal* published a case series entitled *Tachycardia During Cisapride Treatment*, which indicated that Prepulsid may occasionally induce tachycardia. In 1997, the *Journal of Pediatrics* published an article noting the cardiotoxic side effects of Prepulsid at both overdose and therapeutic dosages. An article in the *Archives of Disease and Childhood* concluded that Prepulsid significantly increased QT interval. In 2001, an article in the *American Journal of Gastroenterology* concluded that Prepulsid is associated with prolonged QT interval and *torsades de pointes*.

[32] I acknowledge that neither the experts nor the medical/academic literature are unanimous in concluding that Prepulsid caused adverse cardiac events, but this is not fatal to the representative plaintiff's position. Whether there is sufficient evidence to support a finding of fact that Prepulsid ingestion actually caused adverse cardiac events is a question that will be answered later in these proceedings.

[33] At this stage of the proceedings, the representative plaintiff is not required to put forward evidence that each and every member of the proposed class suffered an adverse cardiac event. It is sufficient that the representative plaintiff has presented some evidence of cardiotoxicity associated with Prepulsid ingestion. This makes the proposed common issue rationally connected to the proposed class, since Prepulsid ingestion is a prerequisite for class membership. The resolution of this common issue will therefore move the litigation forward for all class members.

Proposed common issue (b) – Negligent design, manufacture, marketing, and sale of Prepulsid

[34] The defendants argue that this proposed common issue is framed too generally and should not be certified because an examination of negligence in this case will, like common issue (a), inevitably break down at trial into a myriad of individual issues. The defendants raise a number of examples of this break down. First, the question of whether the defendants have met the applicable standard of care will depend on the time and duration that each individual class member used Prepulsid because the scientific and medical knowledge regarding Prepulsid use evolved over time, and so did people's understanding of the risks and benefits. Second, whether the defendants have met the applicable standard of care will vary for each cardiac event a plaintiff is alleging was caused by Prepulsid and the testing that was available at the time the plaintiff suffered the event. There is evidence from Dr. Andrew Krahn that over the entire time

Prepulsid was sold in Canada there was no single test that could have been used to determine if Prepulsid was the cause of an adverse cardiac event. Dr. Krahn's practice and research focus is devoted to the diagnosis and treatment of patients with abnormal hearth rhythms (arrhythmias). Third, the role of health care professionals in treatment and prescribing decisions must be assessed in each individual case. There is evidence that the conduct of patients and health care professionals other than the defendants will have to be considered in any claim

[35] The representative plaintiff points out that negligence has been certified as a common issue in a number of cases, including *Wilson v. Servier Canada Inc.* (2000), 50 O.R. (3d) 219 (Super. Ct.) [*Wilson*], Anderson v. *St. Jude Medical Inc.*, [2003] O.J. No. 3356 (Super. Ct.) [*St. Jude*], *Nantais et al v. Telectronics Proprietary (Canada) Ltd. et al* (1995), 129 D.L.R. (4th) 110 (Ont. Gen. Div.) [*Nantais*], and *Wheadon v. Bayer Inc.*, [2004] N.J. No. 147 (S.C. (T.D.)), leave to appeal ref'd [2005] N.J. No. 122 (C.A.), [2005] S.C.C.A. No. 211 [*Bayer*]. The representative plaintiff submits that the question of whether the defendants breached the standard of care advances the case of every class member, regardless of whether they allege damages arising from an adverse cardiac event or allege damages arising from the purchase of an inefficacious drug.

[36] I agree with the representative plaintiff that this issue is sufficiently common and would advance the case of each class member. Regarding the allegations of breach of duty of care in the design and manufacture of the drug, the evidence of Dr. Gillespie was that the protocols used to assess the safety of Prepulsid in clinical studies were highly inadequate. Regarding the allegations of breach of duty of care in marketing and sale of Prepulsid, Ms. MacDonald's evidence is that reports of cardiotoxicity and associated risks of Prepulsid use were known since at least 1986, four years before Prepulsid was sold in Canada, and that these risks were not disclosed under the warnings section of the product monograph. Ms. Arnott's evidence is that the patient information sheet failed to provide any warning at all in respect to cardiac arrhythmia or other events. It is also important to note that Dr. Gillespie's evidence on cross-examination was that the FDA reprimanded the defendant Janssen-Ortho in June 1998 for disseminating false and misleading information about the use of Prepulsid, including the failure to refer to the risks associated with the drug. I find that the requirements of s. 5 (1) (b) are satisfied.

Proposed common issue (c) – Whether Prepulsid was fit for its intended purpose

[37] The defendants assert that there is no evidence to support the proposition that Prepulsid was "defectively designed", and that even if there were, the relevant evidence required to address this issue would vary significantly over time. They say that where a design defect is alleged, the court must determine if the risk of the product outweighs its benefits, and that this risk/benefit profile varies over time due to the factors that must be considered. These factors include the utility of the product to the individual user, the availability of safer alternatives, the ability to avoid injury by careful use, and the degree of awareness of potential danger of the product that can reasonably be attributed to the user. The defendants allege that in the case of Prepulsid, the evidence shows that the drug's risk/benefit profile changed over time because of the evolution of the scientific and medical communities' knowledge of alternative remedies and the risks associated with Prepulsid use. In addition, the defendants assert that there is no evidence to

suggest that it made a common representation or warranty of fitness to all class members. On this point they argue that the evidence demonstrates that many doctors prescribed Prepulsid "off label" for conditions the defendants said it should *not* be used.

[38] The representative plaintiff, in reply, simply states that the question of whether a drug is defective or unfit for its intended purpose is ideally suited for class treatment because if the drug is found to be ineffective, this finding advances the claim of all members of the proposed class because all class members took the drug with the expectation that it would alleviate the malady it was prescribed for.

[39] I conclude that this is a common issue that will further the case of each class member. In Ms. MacDonald's evidence, she referred to a 1999 article in the *British Medical Journal* entitled "Heartburn treatment in primary care randomized, double blind study for 8 weeks", which concluded that Prepulsid was not significantly more effective than a placebo. In addition, Dr. Gillespie's evidence was that Prepulsid was essentially ineffective, showing results for its indicated uses that were comparable to a placebo.

Proposed common issue (d) – Vicarious liability

[40] The defendants submit that vicarious liability was not pleaded by the plaintiff in the Amended Fresh as Amended Statement of Claim, and even if it were it would not sufficiently move the litigation forward to justify being certified as a common issue.

[41] The representative plaintiff counters that the claim for vicarious liability can be implied from the pleadings and that a similar common issue was certified in *Wilson*, *supra*.

[42] I find that the claim for vicarious liability can be implied from the pleadings. Ms. Arnott's evidence is that the defendant Janssen-Ortho INC. is a wholly owned subsidiary of the defendant Johnson & Johnson Corporation that distributes prescription pharmaceuticals which are manufactured by affiliated companies within the Johnson & Johnson group of companies. These corporate relationships do not exclude vicarious liability, which is another issue that will be tested as this action proceeds.

Proposed common issue (e) – Subrogated health care costs

[43] Third party health insurers are entitled by statute to recover the costs of treatment where injuries are caused by the negligence of someone other than the insured. If the plaintiff's action succeeds, the Ministry of Health of Ontario and those in provinces other than Ontario where proposed class members reside would be entitled to advance subrogated claims to recover the costs from the defendants of treatment of the representative plaintiff and other unidentified members of the class.

[44] The defendants submit that liability for subrogated health care costs is quintessentially an individual issue because each individual in the proposed class will have to demonstrate a compensable injury that was caused by Prepulsid use and that the injury resulted in physician provided treatment that was paid for by the health insurer. This theme is expressed repeatedly in

the defendants' submissions and in their factum. As an example, I refer to para. [107] of the defendants' factum. They say that whatever common issues there may be, they are not certifiable because "they are inextricably intertwined with and subsumed by a plethora of individual and/or non-common issues which would necessitate lengthy, substantial and complex individual trials for every proposed class member. Each patient's experience and condition is unique and liability would be subject to numerous variables for each class member." It is apparent from these reasons that I do not agree with the defendants on this point.

[45] The representative plaintiff concedes that subrogated health care costs cannot be assessed globally at the first common issues trial, but can be commonly assessed in a second common issues trial after resolution of the individual issues.

[46] In my view, I am entitled to take judicial notice of the fact that the only available treatment for class members suffering Prepulsid cardiotoxicity is found in our publicly funded health care system. I have already concluded that there is sufficient evidence of Prepulsid cardiotoxicity and negligence on the part of the defendants to justify certifying these matters as common issues for trial. It logically follows, then, that there is sufficient evidence of *prima facie* liability on the part of the defendants for subrogated health care costs resulting from Prepulsid cardiotoxicity and the defendants' negligence. This proposed common issue is certifiable.

[47] If the defendants are found liable for subrogated health care costs at trial, the calculations of these costs, although individual, will be one of the less complicated calculations because records of treatment and prescriptions are most likely to be available from the health care providers.

Proposed common issue (f) – Punitive Damages

[48] The defendants assert that it would be unfair to determine the entitlement to and quantum of punitive damages at a common issues trial before compensatory damages have been assessed, since punitive damages require a finding of compensatory damages. It is the defendants' position that if punitive damages are to be certified as a common issue, it should be certified for a second common issues trial that would follow the individual issues trial. The representative plaintiff concedes that it may be appropriate to assess the quantum of punitive damages following an assessment of compensatory damages, but that a *prima facie* entitlement to punitive damages can be certified as a common issue for the first common issues trial. I accept the submission of the representative plaintiff in this regard, though I emphasize that I make no finding on the merits of the claim for punitive damages.

The Preferable Procedure Criterion – s. 5 (1) (d)

[49] In *Hollick*, *supra* at paras. 27-31, McLachlin C.J. discussed the preferability inquiry. To be "preferable", a class action should be a fair, efficient and manageable method of advancing the claim, and should be preferable to other available means of resolving the claims, having regard to considerations of judicial economy, access to justice and behavioral modification. While the common issues need not predominate over individual issues, the Court must examine

the common issues in their context, taking into account their importance in relation to the claim as a whole.

[50] The defendants submit that a class action is not the preferable procedure for the reasons conveniently summarized at para. 103 of their factum, which I reproduce below:

> (a) A class proceeding in this case, as framed, will not have the advantage of judicial economy. A trial judge dealing with any of the proposed common issues would quickly discover that a class action is more likely to result in duplication of evidence and fact finding, and reduce judicial economy. Given the need for procedures to resolve the claims of the millions of people in the proposed class, a class action would be completely unmanageable. He or she will also discover that the importance of any common issues there may be, is negligible in relation to the significant individual issues that must be answered as part of the liability inquiry. Further, this is not a case where the plaintiff has demonstrated any way to prove that the alleged wrongful acts caused a class wide personal injury or a need for medical monitoring.
>
> (b) A class proceeding in this case, as framed, will not increase access to justice. There are a handful of serious claims that are individually viable. Millions of other in the proposed class will have no claim. To the extent some might have small claims, resolution of the proposed common issues will not make these claims viable given the need for an expense of the process to resolve numerous important individual issues. A class proceeding is likely to delay and increase the cost of resolving what is really in issue in each individual case (causation and appropriate use);
>
> (c) It has not been demonstrated that a class proceeding in this case will advance the goal of positive behaviour modification, and there is some risk it will do the opposite; [the defendants elaborate on this point in paras. 130-35 of their factum, saying that the pharmaceutical industry is already highly regulated and that class certification may have the negative social effect of deterring others in the industry from developing and making available in Canada innovative medical products];
>
> (d) A class proceeding risks unfairness to both potential class members and the defendants [the defendants elaborate on this point in paras. 136-42 of their factum, saying that "opting out" is "cold comfort" to those class members who encourage cisapride availability and do not wish to deter innovation in the medical products field, and that there is a risk of trial unfairness because the trier of fact will have difficulty managing evidence admissibility, the defendants will be required to disprove specific causation in individual cases after findings are made on common causation, and it is improper to decide common punitive damages before the individual issues of liability and damages are proven];

(e) There are alternative procedures better suited to resolution of the claims [the defendants elaborate on this point in paras. 143-46 of their factum, saying that individual actions are preferable for those "rare" individuals who experience *torsades des pointes*]

[51] In her reply, the representative plaintiff criticizes what she describes as the defendants "classic refrain" that the proceeding, if certified, would devolve into a myriad of complex individual and unmanageable issues – arguments that have been rejected in *Wilson*, *Bayer* and *St. Jude*, *supra*. The representative plaintiff cites *Robertson*, *supra* at 173-4, for the proposition that the mere fact that the litigation will be complex is not a bar to certification. She also says the defendants have grossly exaggerated the size of the class in order to create the impression in the eyes of the court that the proceeding would be unmanageable.

[52] The representative plaintiff says that certification of a class action promotes the three policy objectives of the CPA. First, certification enhances access to justice because the complexity and expense of pharmaceutical products liability litigation far exceeds the value of any individual class member's claim. She submits at para. [24] of her reply factum that, "absent a class action, class members would be unable to obtain the benefit of the collection of medical and scientific data and research that addresses issues relating to the diseases alleged to be caused by ingestion of the subject drugs." Second, certifying the class action serves judicial economy because in the absence of a class action, the common issues would be analyzed numerous times in individual actions, substantially draining judicial resources and increasing the risk of inconsistent findings. Third, certification of the class action would also promote behaviour modification in that pharmaceutical drug makers, including the defendants, would take greater care in developing, testing and monitoring drugs to ensure their safety.

[53] I agree with the representative plaintiff's submissions. It is preferable that the common issues be resolved by a class action. Doing so promotes the three policy objectives of the CPA as set out by the representative plaintiff. In my opinion, the common issues identified above address fundamentally important issues in this action, and their resolution will significantly move the litigation forward. While individual issues of proximate causation, allocation of fault and damages would remain, their resolution will be considerably influenced by the outcome of the common issues trial. For example, proximate causation, allocation of fault and damages would become irrelevant if a trial judge concludes that Prepulsid is not cardiotoxic or otherwise ineffective, or if the trial judge concludes that the defendants were not negligent in the design, manufacture, marketing, and sale of Prepulsid.

[54] The defendants' concerns that certification will create unfairness to certain class members that encourage cisapride availability and do not wish to deter innovation in the medical products field is self-serving and I reject it. Likewise, their assertion that a class proceeding will be unfair to them is without merit. I cannot accept that the judge presiding over the common issues trial will be unable to take sufficient steps to preserve trial fairness. Experienced counsel and trial judges are alert to the danger of assessing evidence in hindsight. The combination of the experience of counsel and the trial judge will not compromise the defendants' right to a fair trial, and the management of evidence admissibility issues.

The Representative Plaintiff Criterion – s. 5 (1) (e)

[55] Earlier in these reasons I mentioned that the Janssen-Ortho defendants were challenging Ms Boulanger's adequacy as a representative plaintiff. I have concluded that this challenge is unfounded. There is nothing in all of the evidence that suggests that there is any impediment to her ability to fairly and adequately represent the interests of the class. She has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class members and of notifying the class members of the proceeding. Although suggested by the defendants, she does not have an interest in conflict with other members of the class. She has retained three law firms to assist her in the management and advancement of this litigation. These firms are well-established personal injury firms, all very experienced in class action litigation. These firms have significant resources and expertise. Ms Boulanger has entered into a contingency fee agreement with class counsel, who agreed to fund the litigation. I find that the requirements of s. 5 (1) (e) are satisfied by Ms. Boulanger.

Disposition

[56] As a result of these reasons, an order shall go as follows:

1. Certifying the within action as a class proceeding;

2. Appointing Aline Boulanger as the representative plaintiff for the class proceeding;

3. Defining the class as follows:

   (a) all persons in Canada (including their estates), excluding residents of Quebec, who ingested Prepulsid (generic name: cisapride) (the "Class" or "Class Members");

   (b) family members of the Class who are entitled to assert a claim pursuant to section 61 of the Family Law Act, R.S.O. 1990, c. F.3, as amended, and other similar provincial legislation (the "Family Class");

4. Certifying the proceeding on the basis of the following common issues:

   (a) Whether Prepulsid can cause or materially contribute to cardiac arrhythmia, including ventricular tachycardia, cardiac arrest, prolonged QT, *torsades de pointes*, ventricular fibrillation, sudden death and other heart disease;

   (b) Whether the Corporate Defendants breached a duty of care owed to class members by reason of the design, manufacture, marketing, sale and such other acts taken in placing and maintaining Prepulsid into the stream of Canadian commerce, and if so, who, when and how;

(c) Whether Prepulsid was fit for its intended purpose;

(d) Whether Johnson & Johnson Corporation is responsible in law for the acts and omissions of Janssen-Ortho Inc. in respect of the marketing, distribution, and placing and maintaining Prepulsid into the stream of Canadian commerce;

(e) Whether the Corporate Defendants, or any of them, are liable for the subrogated health care costs of Class members incurred in the screening, diagnosis and treatment of conditions related to Prepulsid, and if so, whether these costs may be assessed on a global basis; and

(f) Whether the conduct of any one or more of the Corporate Defendants justifies an award of punitive damages, and if so, against whom, in what amount and to whom.

5. Requiring that notice of the certification be given pursuant to the Litigation Plan contained in Schedule "F" of the representative plaintiff's factum;

6 Requiring that the defendants pay the costs associated with the notice of certification.

Costs

[57] I invite the parties to make brief written submission to me regarding costs within 45 days of the release of these reasons for decision.

Ellen Macdonald J.

Ellen Macdonald J.

Released: January 18, 2007

COURT FILE NO.: 00-CV-197409CP
DATE: 20070118

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:

ALINE BOULANGER

Plaintiff

- and -

JOHNSON & JOHNSON CORPORATION, JOHNSON & JOHNSON MEDICAL PRODUCTS INC./PRODUITS MEDICAUX JOHNSON & JOHNSON INC., and JANSSEN-ORTHO INC. and THE ATTORNEY GENERAL OF CANADA

Defendants

REASONS FOR DECISION

Ellen Macdonald J.