COURT OF APPEAL FOR BRITISH COLUMBIA

Citation: *Bartram v. GlaxoSmithKline Inc.*,
2013 BCCA 462

Date: 20131025
Docket: CA040507

Brought under the *Class Proceedings Act*, R.S.B.C., c. 50

Between:

**Meah Bartram, an Infant,
by her Mother and Litigation Guardian, Faith Gibson,
and the said Faith Gibson**

Respondents
(Plaintiffs)

And

GlaxoSmithKline Inc. and GlaxoSmithKline UK Limited

Appellants
(Defendants)

Before: The Honourable Madam Justice Saunders
The Honourable Madam Justice Levine
The Honourable Mr. Justice Willcock

On Appeal from an Order of the Supreme Court of British Columbia,
dated December 3, 2012 (*Bartram v. GlaxoSmithKline Inc.*, 2012 BCSC 1804, Vancouver Registry,
Docket Number S081441).

Counsel for the Appellants:	R.C. Sutton, I. Schrager
Counsel for the Respondents:	D.M. Rosenberg, Q.C. C.M. Lloyd, G.T. Kosakoski
Place and Date of Hearing:	Vancouver, British Columbia October 1, 2013
Place and Date of Judgment:	Vancouver, British Columbia October 25, 2013

Written Reasons by:
The Honourable Madam Justice Levine

Concurred in by:
The Honourable Madam Justice Saunders
The Honourable Mr. Justice Willcock

Summary:

Appeal from an order certifying as a class proceeding claims in negligence against the appellant, GlaxoSmithKline Inc., arising out of cardiovascular birth defects in infants born of mothers who used the anti-depressant drug, Paxil, during their pregnancy. The appellant claimed there was insufficient evidence to certify the class on the common issue of its duty to warn for the class period from the date Paxil was first sold (1993) to the date of certification (December 2012). It claimed that the class period on the common issue of the duty to warn should be limited to 2003 to 2005.

Held: *appeal dismissed. The appellant's arguments for limiting the class on the common issue of the duty to warn address the merits of the issue, which are not part of the inquiry on the certification issue. The appellant does not dispute the class period of 1993 to 2012 on the common issue of its duty of care, including its duty to investigate the risks to newborns of the use of Paxil by pregnant women. Limiting the class as argued by the appellant would be contrary to the object of judicial economy and unduly limit access to justice.*

Reasons for Judgment of the Honourable Madam Justice Levine:

Introduction

[1] This appeal is from the certification of a class action claiming an anti-depressant drug, Paxil, caused cardiovascular defects in some infants born of women who used the drug during their pregnancy. The appellant, GlaxoSmithKline Inc., claims there is an insufficient factual basis to justify certification on the common issue of its duty to warn for the period from the date the drug was first sold (1993) to the date of certification.

[2] In my opinion, GSK's arguments address the merits of the action, which are not part of the inquiry on a certification application. It follows that I would dismiss the appeal.

Background

Paxil

[3] GSK manufactures, markets and sells the anti-depressant drugs, Paxil and Paxil CR (collectively "Paxil") throughout Canada. Paxil was first approved for use in Canada in 1993.

[4] GSK published various documents regarding Paxil over the years, including product monographs. A product monograph is a scientific document that describes the properties, claims, indications and conditions of use of a drug, as well as information that may be required for optimal, safe and effective use. Product monographs are available for reference by doctors who prescribe the drug, as well as by members of the public. They are revised from time to time to reflect new information.

[5] GSK says that pregnant women are usually excluded from clinical trials unless approval of a new drug is sought specifically for use by them. Information about the potential effect of a new drug in pregnancy is generally obtained after the drug has been approved for sale, through case reports, pregnancy exposure registries, birth defect registries and epidemiological studies.

[6] The first product monograph for Paxil, produced in 1993, included the following statement concerning its use by pregnant women:

> Pregnancy and Lactation: Although animal studies have not shown any teratogenic or selective embryotoxic effects, the safety of PAXIL in human pregnancy has not been established. PAXIL should not be used during pregnancy unless the potential benefit to the patient outweighs the possible risk to the fetus.

[7] In August 2004, information was published concerning some respiratory and other complications requiring prolonged hospitalization of newborns who had been exposed to Paxil during the third trimester of pregnancy. GSK's product monograph was revised to include this information in November 2004. These complications are not in issue in this litigation.

[8] GSK first published information about the type of birth defect at issue in this litigation in a letter it sent to health professionals on September 29, 2005. The letter referred to preliminary results from "a retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy from January 1995 to June 2003." The study showed an increased incidence of cardiovascular defects in babies born to women who took Paxil during the first trimester of pregnancy, and the letter recommended that doctors "carefully evaluate this new information when considering the use of [Paxil] in women who are pregnant or planning pregnancy."

[9] Further information about the effects of Paxil on newborns was published by GSK over the following months. It disclosed that the risk of cardiovascular defects in infants born of mothers who used Paxil during the first trimester of pregnancy was twice that of the general population. On February 3, 2006, the product monograph for Paxil was updated to include the following information:

> Pregnant Women and Newborns: Epidemiological studies of pregnancy outcomes following maternal exposure to antidepressants in the first trimester have reported an increase in the risk of congenital malformations, particularly cardiovascular (e.g. ventricular and atrial septal defects), associated with the use of paroxetine. The data suggest that the risk of having an infant with a cardiovascular defect following maternal paroxetine exposure is approximately 1/50 (2%), compared with an expected rate for such defects of approximately 1/100 (1%) infants in the general population. In general, septal defects range from those that are symptomatic and may require surgery, to those that are asymptomatic and may resolve spontaneously. Information about the severity of the septal defects reported in the studies is not available.
>
> If a patient becomes pregnant while taking PAXIL®, or intends to be become pregnant, she should be informed of the current estimate of increased risk to the fetus with PAXIL® over other antidepressants. Examinations of additional databases, as well as updated analyses, may result in changes to the current risk estimates. Consideration should be given to switching to other treatment options, including another antidepressant or non-pharmaceutical treatment such as cognitive behavioral therapy. Treatment with PAXIL® should only be continued for an individual patient, if the potential benefits outweigh the potential risks …
>
> Initiation of paroxetine: For women who intend to become pregnant, or are in their first trimester of pregnancy, initiation of paroxetine should be considered only after other treatment options have been evaluated.

[10] The product monograph for Paxil continues to include this statement.

The Respondents

[11] The respondent, Faith Gibson, was prescribed Paxil in December 2002. She continued to take it for years, including throughout her pregnancy. Her child, the other respondent, was born on September 14, 2005, with a ventricular septal defect, one of the cardiovascular defects noted in GSK's published information.

The Action

[12] Ms. Gibson commenced the action as a class proceeding on behalf of herself, her child, and others similarly affected. The statement of claim alleged:

> 22. The Defendants at all material times owed a duty of care to the Plaintiffs to:
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> a. ensure that Paxil was fit for its intended or reasonably foreseeable use;
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> b. conduct appropriate testing to determine whether and to what extent ingestion of Paxil posed serious health risks to pregnant women, including the risk of serious adverse complications for newborn children of mothers who ingest Paxil during pregnancy; and
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> c. warn the Plaintiff, Faith Gibson and her physicians that the ingestion of Paxil carries the risk of serious adverse complications for newborn children of mothers who ingest Paxil during pregnancy.
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> 23. The Defendants negligently breached their duty of care, particulars of which are set out in the following paragraph.

[13] The particulars of negligence set out in the statement of claim extended to 17 allegations.

[14] Ms. Gibson also claimed GSK had breached the provisions of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2.

Certification

[15] The certification judge certified the action as a class proceeding in December 2012. He ordered:

> 2. The Class is defined as:
>
> > "any person in Canada, born with cardiovascular defects, to women who ingested Paxil while pregnant, and the mothers of those persons."
>
> The "Class Period" runs from 1993 to December 3, 2012.
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> 3. The Class will be divided into members resident in British Columbia, and those members not resident in British Columbia;
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> 4. Faith Gibson is appointed as the representative Plaintiff for the Class proceeding.
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> . . .
>
> 6. The nature of the claims asserted by the Class members are in negligence and for Class members who were supplied Paxil in British Columbia, a claim under the *Business Practices and Consumer Protection Act* [S.B.C. 2004 c. 57] ("BCPCA").
>
> . . .
>
> 8. The certified common issues pertaining to the Class are as follows:
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> a. Does Paxil cause or increase the likelihood of cardiovascular birth defects?
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> b. Is Paxil unfit for use during pregnancy?
>
> c. Did the Defendant GlaxoSmithKline Inc. fail to warn Class members and/or Health Canada of the true risk of cardiovascular birth defects caused by using Paxil?
>
> d. Did the Defendant GlaxoSmithKline Inc. breach a duty of care to Class members, and if so, when and how?
>
> e. Does the conduct of the Defendant GlaxoSmithKline Inc. warrant an award of punitive damages, and if so, what amount of punitive damages should be awarded?
>
> . . .

Certification Judge's Reasons for Judgment

[16] The certification judge found there was "no doubt" that the allegations in the statement of claim stated a cause of action in negligence (at para. 20). He commented that the alleged particulars "cover a broad range of conduct", and that discovery may assist in narrowing the claim (at para. 21).

[17] In certifying the class covering the period from 1993 to the date of certification, the judge acknowledged that the class may not succeed, or even proceed, to trial. He said (at para. 26):

> For example, even if the plaintiffs prove that GSK failed to disclose what it knew or should have known, the evidence may show a date before which GSK could not reasonably have had the critical information and/or a date after which it made adequate disclosure. Such a result would narrow the class period and disqualify many potential class members, perhaps to the point where, as the defendant suggests, the class would become vanishingly small. But in my view it is premature to speculate on such matters and I find that on the evidence now before me, there is an identifiable class.

[18] On the common issue of whether Paxil causes or increases the likelihood of cardiovascular birth defects, the judge found that GSK's own published material acknowledged that its epidemiological studies suggest that the use of Paxil during pregnancy is associated with an increased risk of cardiovascular birth defects in infants (at para. 29). He declined to weigh the expert evidence or consider the limitations of the experts' expertise, finding it was "neither necessary nor appropriate on a certification application" to do so (at para. 29).

[19] On the issue of the duty to warn, the judge said (at para. 38):

> The essence of this issue is – to use a popular formulation – "what did GSK know and when did it know it?" The plaintiffs have produced evidence on this application that, at some point, GSK became aware of and disclosed information that associated Paxil, at least on a statistical basis, with an increased incidence of cardiovascular defects. The question is whether the information published by GSK at any given time reflected all that it knew or ought to have known, and whether the warnings it issued could and should have been issued at an earlier date. Evidence on those points is likely to be largely, if not entirely, within the control of GSK and would only become available to the plaintiffs through the discovery process.

[20] He commented on the evidence on this issue (at para. 39):

> The plaintiffs rely in part on a transcript of testimony given by a witness in an American proceeding relating to the times when, in the opinion of that witness, the danger was, or should have been, known. The defendant objects to that evidence as hearsay and I agree the transcript alone would not be admissible at trial. That does not necessarily make the evidence inadmissible on a certification application, but I do not need to decide the point because the evidence is unnecessary for present purposes. The information that GSK itself made public, combined with the fact that it alone controls the evidence of what else it may or may not have known and when, constitutes a sufficient evidentiary basis at this stage of the proceedings. [Emphasis added.]

[21] On the issue of whether GSK breached a duty of care to class members, the judge said (at para. 42):

> This issue is linked to the previous ones and, depending on what findings are made on the other issues, the answer may be self-evident. But for present purposes, I find it to be clearly a common issue.

The Appeal

[22] GSK's appeal focuses on the certification of the issue of its duty to warn as a common issue. It

argues, first, that there was no evidence of a duty to warn or breach of that duty between 1993 and 2003; that is, there is no evidence that during that time it had any more information than it provided to doctors and consumers. It says, secondly, that the information it published in 2005 provided doctors with sufficient information to advise pregnant patients, and there was no duty to warn or breach of a duty to warn after that. GSK claims the certification judge erred in finding that the published information and information within its control which will be revealed in the discovery process were a sufficient evidentiary basis for certification of the breach of a duty to warn as a common issue for the class for the entire period.

[23] Thus, GSK's case on appeal comes down to whether the information it published, and the fact that evidence of the breach of a duty to warn is within its control, were sufficient to justify certifying the class on that issue for the period before 2003 and after 2005. GSK takes no issue with the certification of the class on that evidence on the common issue of whether it breached a duty of care to class members, for the period from 1993 to the date of certification. It also agrees that its duty of care included a duty to investigate whether Paxil caused or increased the incidence of birth defects. However, GSK says that the respondents produced insufficient evidence to show that it had information that gave rise to a duty to warn before 2003, or that after 2005 doctors could not effectively discharge their duty to warn patients who were or were planning to become pregnant. In effect, they say that the class for the common issue of the duty to warn is "any person in Canada, born with cardiovascular defects, to women who ingested Paxil while pregnant between 2003 and 2005, and the mothers of those persons".

The Law

[24] The certification judge and both parties referred to the judgment of this Court in *Stanway v. Wyeth Canada Inc*., 2012 BCCA 260, for the statement of the legal principles applicable to a certification application. In *Stanway*, Madam Justice Kirkpatrick for the Court noted (at para. 3):

> It can now be said that certain issues have been settled and guiding principles (including those expressed in the *Act* [*Class Proceedings Act*, R.S.B.C 1996, c. 50]) have emerged to answer a key, and often determinative, question in the action – the certification application.

[25] The principles she then outlined were summarized in *Pro-Sys Consultants Ltd. v. Infineon Technologies AG*, 2009 BCCA 503 at paras. 64-65, leave to appeal ref'd [2010] S.C.C.A. 32, quoted in the judgment of this Court in *Jones v. Zimmer GMBH*, 2013 BCCA 21 at para. 5:

> [64] The provisions of the [*Class Proceedings Act*] should be construed generously in order to achieve its objects: judicial economy (by combining similar actions and avoiding unnecessary duplication in fact-finding and legal analysis); access to justice (by spreading litigation costs over a large number of plaintiffs, thereby making economical the prosecution of otherwise unaffordable claims); and behaviour modification (by deterring wrongdoers and

> potential wrongdoers through disabusing them of the assumption that minor but widespread harm will not result in litigation): *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534 at paras. 26-29 [*Western Canadian Shopping Centres*]; *Hollick v. Toronto (City)*, 2001 SCC 68, [2001] 3 S.C.R. 158 at para. 15 [*Hollick*].
>
> [65] The certification hearing does not involve an assessment of the merits of the claim; rather, it focuses on the form of the action in order to determine whether the action can appropriately go forward as a class proceeding: *Hollick* at para. 16. The burden is on the plaintiff to show "some basis in fact" for each of the certification requirements, other than the requirement that the pleading disclose a cause of action: *Hollick*, at para. 25. However, in conformity with the liberal and purposive approach to certification, the evidentiary burden is not an onerous one – it requires only a "minimum evidentiary basis": *Hollick*, at paras. 21, 24-25; *Stewart v. General Motors of Canada Ltd.*, [2007] O.J. No. 2319 (S.C.J.) at para. 19. As stated in *Cloud v. Canada (Attorney General)* (2004), 247 D.L.R. (4th) 667 at para. 50, 73 O.R. (3d) 401 (C.A.), leave to appeal ref'd [2005] S.C.C.A. No. 50 [*Cloud*],
>
> > [O]n a certification motion the court is ill equipped to resolve conflicts in the evidence or to engage in finely calibrated assessments of evidentiary weight. What it must find is some basis in fact for the certification requirement in issue.
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> [Emphasis added.]

[26] Applying these principles to this appeal, the question is whether the respondents demonstrated a "basis in fact" for the certification judge to find that the duty to warn was a common issue for all members of the class from 1993 to the date of certification.

Analysis

[27] The law is clear that the evidentiary burden on the plaintiff on a certification application is a low one, and that the judge is not to consider the merits of the claim.

[28] GSK's argument that the judge had insufficient evidence to certify the class for the period from 1993 to the date of certification on the issue of the duty to warn turns on its rejection and interpretation of certain evidence presented by the respondents at the certification hearing.

[29] The respondents filed the affidavit of Dr. Pierre S. Chue. Dr. Chue's expertise with respect to psychiatric medications and in particular, Paxil, is not in dispute. In his affidavit, he referred to the transcript of the evidence given in a U.S. proceeding concerning birth defect problems related to Paxil. He said: "The testimony indicates that GSK was aware of indications for birth defect problems related to Paxil well before 2005". Dr. Chue went on to say: "Because GSK withheld data, no Canadian physician was able to effectively discharge their duties to their patients, prior to 2005".

[30] GSK argued at the certification hearing, and argues on appeal, that the transcript evidence is inadmissible hearsay. The judge found that he did not need to decide the question of admissibility of that evidence because it was "unnecessary for present purposes" (at para. 39). GSK says that without

that evidence, there is no evidence that GSK breached its duty to warn before 2003.

[31] With respect to its duty to warn after 2005, GSK interprets Dr. Chue's statement that Canadian physicians could not effectively discharge their duties to patients prior to 2005 as inferring that after 2005 Canadian physicians could effectively discharge their duties. Thus, GSK says that it had discharged its duty to warn in 2005.

[32] Both of these arguments require an assessment of the merits of the claim. The respondents were not required to provide direct evidence that GSK breached its duty to warn before 2003 or had discharged its duty in 2005. They were only required to show there was a "basis in fact" to claim that GSK had failed to warn users of Paxil of known or suspected risks during these periods.

[33] GSK's published information acknowledged the risk of the particular birth defect suffered by the infant respondent after her mother had used Paxil while pregnant was twice that in the population of infants whose mothers had not used Paxil. This provided some "basis in fact" that at some point before 2005 GSK had knowledge of that information. It could have been 2003, as apparently conceded by GSK, or it could have been before that. That information is solely within GSK's control. The purpose of certification is not to limit the potential claims of those who might have been affected. It is to provide notice to those individuals "who share the same interest in the resolution of the common issues" (see *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 21) and "the criteria should not depend on the outcome of the litigation" (see *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 38). As the judge found, it was not necessary to rely on the information contained in the transcript of testimony in the U.S. action to decide the certification application.

[34] Similarly, assuming it could be inferred from Dr. Chue's affidavit that in 2005 GSK had discharged its duty to warn, drawing that inference at the certification stage of the proceeding would be an unwarranted intrusion into the merits of the claims. Only GSK can know whether it disclosed all of the information it had about the risk of using Paxil from time to time, including after 2005. Neither Dr. Chue nor the respondents had any way of knowing that. They only knew that GSK had disclosed its knowledge of certain risks at a certain point in time, and that the infant respondent had suffered the very birth defect identified by GSK. That was a "basis in fact" for certification of the common issue of the duty to warn.

[35] Further, it is legally logical and efficient to define the class for the issue of the duty to warn in the same way as the issue of whether GSK breached its duty of care. Both are aspects of the claim of negligence. GSK does not dispute the definition of the class with respect to the question of whether GSK breached its duty to investigate the risks of Paxil to newborns of mothers who used Paxil during their pregnancy. It would be contrary to the object of judicial economy and unduly limit access to

justice to limit the class on the issue of duty to warn to infants born of mothers who used Paxil between 2003 and 2005, while imposing an obligation on mothers who used Paxil outside of those years to litigate their claims individually.

Summary and Conclusion

[36] The certification judge properly considered the evidence necessary to certify the issue of GSK's duty to warn as a common issue for the class for the period from 1993 to the date of certification. GSK's arguments for limiting the class on that issue address the merits of the issue, which are not part of the inquiry on a certification application. Limiting the class as argued by GSK would be contrary to the principles of judicial economy and access to justice.

[37] I would dismiss the appeal.

"The Honourable Madam Justice Levine"

I Agree:

"The Honourable Madam Justice Saunders"

I Agree:

"The Honourable Mr. Justice Willcock"