# IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Bartram v. GlaxoSmithKline Inc.,*
2016 BCSC 2516

Date: 20161213
Docket: S081441
Registry: Vancouver



Between:

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

Plaintiffs

And:

**GlaxoSmithKline Inc. and GlaxoSmithKline UK Limited**

Defendants

Before: The Honourable Mr. Justice N. Smith

## Oral Reasons for Judgment
## at Trial Management Conference

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|---|---|
| Counsel for the Plaintiffs: | D. Rosenberg, Q.C.<br>G. Kosakoski<br>D. Moriarty |
| Counsel for the Defendants: | D. Bennett, Q.C.<br>R. Sutton<br>S. Chesworth |
| Place and Date of Hearing: | Vancouver, B.C.<br>December 13, 2016 |
| Place and Date of Judgment: | Vancouver, B.C.<br>December 13, 2016 |

[1] **THE COURT:** The trial of common issues in this class action is set to begin in approximately one month and the parties have brought a series of applications.

[2] The plaintiff alleges that the anti-depressant drug Paxil caused cardiovascular birth defects in babies born to women who had used the drug during pregnancy. The common issues include:

a) Does Paxil cause or increase the likelihood of cardiovascular birth defects?;

b) Is Paxil unfit for use during pregnancy?;

c) Did the defendant GlaxoSmithKline warn class members and/or Health Canada of the true risk of cardiovascular birth defects caused by using Paxil?;

d) Did the defendants breach a duty of care to class members, and if so when and how?;

e) Does the conduct of the defendants warrant an award of punitive damages, and if so what amount?

[3] These applications had to be ruled on with some urgency because of the imminent trial date, and are necessarily brief.

[4] Beginning with the plaintiffs' applications, in no particular order.

[5] The first application is that the defendant GlaxoSmithKline UK Limited (“GSK UK”) produce a representative for examination for discovery. Defence counsel questions the practical utility of that, noting the limited role GSK UK has played in the litigation, and the fact that there will be a continued examination of a GSK Canada representative who may be required to inform himself through inquiries to the related UK company.

[6] That may be, but GSK is a named party that has filed pleadings and, pursuant to my earlier order, delivered a list of documents. The right of the plaintiffs to have

each defendant produce a representative for discovery pursuant to R. 7-2(1) is absolute, and I order that that representative be produced for discovery.

[7] The next application relates to certain redactions in documents produced by GSK Canada. These documents are adverse reaction reports received by GSK and the redacted information is the name and address of the person providing the report. The plaintiffs wish to obtain that information for the purpose of determining whether it identifies potential class members and, if so, contact them to notify them of the class action.

[8] Defence counsel has determined that, of the 53 such documents produced, only five potentially fall into that category. The rest either did not originate in Canada or do not contain patient names. Plaintiffs' counsel says that nevertheless indicates 10 individuals, a mother and child in each case, who may not have been previously identified and who may not know of this proceeding.

[9] When first argued, it was assumed that these adverse inference reports came from physicians and the defence relied on the decision of the Court of Appeal in *Logan v. Dermatech*, 2014 BCSC 2520 where the court held it was not appropriate for plaintiff’s counsel to obtain medical records from doctors for the purpose of identifying class members. If doctors had, in fact, provided information about their patients to GSK, that disclosure would similarly have arisen out of the doctor/patient relationship, and there was no evidence of whether patients consented to that release or under what terms.

[10] I would have held that *Logan* governs. However, it now appears that these reports did not come from physicians but came as the result of litigation or from material on a website. That implies disclosure by the patient outside the context of the doctor/patient relationship and some entry of the information to the public domain.

[11] On that basis, it is appropriate that I order disclosure of the redacted portion of the documents, on the condition that should plaintiffs' counsel contact those

individuals, the nature of that contact be nothing more than the previously-approved notice of the class action. In other words, they can send a copy of that notice to whatever address is contained in that material, and nothing more than that.

[12] The next application is to extend the opt-in/opt-out period of the class for the last business day before the common issues trial. I approved a new notice plan in July after the initial one had not been successful. The deadline was September 23. The new plan was more successful. Plaintiffs' counsel was contacted by 36 potential class members plus four more after the deadline. I agree with the defendants that a notice plan, as approved by the court, was carried out.

[13] The only evidence of potential class members who may have been excluded relates to the four who contacted counsel after the deadline, plus perhaps some of those referred to in the redacted documents who may or may not turn out to have been already identified as class members. Those individuals can be subject to specific applications to be added to the class without the need to reopen the entire class period and the notice period.

[14] It is important to ensure that as many class members as possible know about the action, but we are now so close to trial that the balance has to tip in favour of the defendants' legitimate interest in knowing the true size of the class as it prepares for trial. So there will not be an order extending the opt-in/opt-out period.

[15] The plaintiffs seek an order that the defendants produce relevant documents produced by an affiliated company in an action in the state of Pennsylvania. Plaintiffs' counsel say they have obtained some such documents from other sources but they have not been listed by the defendants.

[16] Those documents do not appear to be documents of the present defendants, GSK Canada or GSK UK. However, as stated in my Reasons for Judgment on July 7, 2016, the evidence is that in seeking regulatory approval for Paxil in Canada, GSK Canada relied on information provided by other GSK entities, particularly in the U.S. and the UK. I said that any information in existence at the relevant times about

the safety of Paxil for use in pregnancy, and any consideration of that issue that took place in the context of applications for regulatory approval in other jurisdictions, is relevant, and the GSK representative was required when asked to inform himself as to whether such information was in the possession of other GSK entities at the relevant times.

[17] Some of the documents that plaintiffs' counsel has come into possession of appear to fall into that category, being documents about internal discussions within at least one GSK company about regulatory proceedings and about medical literature involving the safety of Paxil in pregnancy. I recognize that these are not necessarily documents within the possession or control of GSK Canada or GSK UK.

[18] The plaintiffs refer in their submissions to GSK Global as if it were a single company, and to some extent it is true that GSK represents itself as such. But the court cannot ignore the separate legal personality inherent in corporate status.

[19] The intention of my previous order was that the GSK representative being examined for discovery can be asked to inform himself about information in the possession of other GSK entities. There has not yet been a follow-up discovery, although I understand one is planned.

[20] The order I will make is that GSK Canada request the documents produced in the Pennsylvania action from the appropriate GSK entity and it make them available to counsel for the plaintiffs prior to the resumed discovery. If there is any reason they cannot be obtained, including them falling into the protective order that has been given by the Pennsylvania court, their representative will obviously have to explain that as part of his evidence at the discovery.

[21] The documents produced in the Pennsylvania action are potentially real evidence that could be used to prove or disprove material facts at trial. For the reasons set out by Madam Justice Gropper in *Stanway v. Wyeth Canada Inc.*, 2013 BCSC 2250, deposition transcripts produced in that action fall into a different

category. They would not be admissible at trial and therefore are not producible under the basic discovery provisions in R. 7-1(1).

[22] The question then is whether they are discoverable under the broader document discovery that the court has discretion to allow under R. 7-1(11), as relating to matters in question. That is the traditional *Peruvian Guano* test of relevance, the question being whether it may provide a train of inquiry that may lead to relevant and admissible evidence.

[23] Now a month before trial is very late to be worrying about new trains of inquiry, particularly when that month includes the holiday season. But to the extent that representatives of a company related to the present defendants gave evidence about matters in issue in this litigation, that is the safety of Paxil in pregnancy and the state of knowledge of that issue at various times, I find they are potentially relevant. Although they will not be admissible at trial, they may for example, identify witnesses that the plaintiffs may wish to subpoena for trial.

[24] Again I do not know if, strictly speaking, those documents are in the possession or control of the named parties, and the order will be in the same terms as the one I have just made for documents. That is, GSK will make the necessary inquiries and, if they cannot be produced, be prepared to give evidence at the continued discovery as to why they cannot be.

[25] The plaintiffs seek all relevant documents produced by any GSK Global entity in the context of any other relevant U.S. litigation during the year 2015. Unlike the documents I have just referred to in the Pennsylvania action, there is no evidence of how many such actions there are, in what jurisdictions, who the parties are or what the issues raised are.

[26] Evidence in support of that application is found in the affidavit of a paralegal which says [as read in]:

> I am advised by Mr. Rosenberg and do verily believe that he has been advised by legal counsel from the US who are involved in the Kilker action, that in 2015 alone, thousands of internal documents from one or more of the

> worldwide group of GlaxoSmithKline companies have been produced in the course of US litigation. Furthermore, he has been advised that the 2015 documents were not produced during the Kilker action and that some of those contradict sworn testimony given by representatives of GSK Global during the Kilker action.



[27] That type of hearsay upon hearsay, without more, is simply not evidence upon which such a generally worded order can be made, particularly as there is no evidence that the named parties in this action were involved in or necessarily have knowledge of what other litigation is taking place in other jurisdictions, much less what documents have been produced. These again may be matters on which a representative at examination for discovery may be asked to inform himself, and the resulting evidence may form the basis for a more specific application, but there is no basis in the evidence for the order being sought at this time.

[28] I appreciate that plaintiffs' counsel would like to have as many documents as possible before resuming discovery, but issues of relevance and the extent of the defendants' control over the documents must be established before the court will order production.

[29] Similarly, the plaintiffs ask for all sales and marketing materials related to Paxil. This is a request that goes well beyond what arises directly from the order I made in July. That order related to documents about the safety of Paxil for use in pregnancy. It was made on the basis that the physical effects of the drug would not be determined according to national boundaries, and on evidence that GSK Canada relied on information received from GSK companies operating in other countries.

[30] However the common issues in this case relate to the use of Paxil in Canada, and an alleged failure of a duty to warn consumers in Canada. To the extent marketing is relevant, it is marketing in Canada, and it is only marketing in Canada for which the named defendant, GSK Canada, is responsible.

[31] The basis for this application is simply speculation that Canadian doctors who prescribed Paxil may have been exposed to or relied upon marketing material produced in other countries, or that patients may have seen advertising originating in

other countries. That, in my view, is simply not a sufficient basis for the kind of sweeping worldwide order the plaintiffs seek.

[32] Again, if the plaintiffs can establish that GSK Canada, in its Canadian marketing efforts, relied upon or adopted material produced elsewhere, or contributed to the production of material used globally, that may make some such material producible. But that is not the evidence on this application.

[33] The plaintiffs also seek an affidavit verifying a list of documents. That application is denied in part for the same reasons I denied a similar application in July. There remain *bona fide* issues between the parties about relevance.

[34] In addition, there is no evidence that the named parties have failed to produce documents within their direct possession or control. The issues concern documents of other companies and the mere fact those companies are affiliated as part of a global enterprise does not automatically put their documents within the control of the Canadian company. They may, and perhaps should, be obtainable on request, but they do not fall within the category of documents that a party must list according to the Rule.

[35] Turning to the application of the defendants, the first is for an order that the plaintiffs not call the representative plaintiffs or two other witnesses who are listed in their trial brief, or in the alternative, for an order for production of medical records related to those witnesses.

[36] The plaintiffs' trial brief identifies Faith Gibson, the representative plaintiff, as a witness who will speak about the issue of her use of Paxil while pregnant, including her pregnancy with the infant plaintiff Meah Bartram, and the effect of Meah's cardiovascular birth defect. Meah Bartram will speak about the issue of the effects of having a cardiovascular birth defect. Lay Witness #1 is identified as a mother who took Paxil while pregnant and gave birth to a child who subsequently died and will testify on the effects of losing a young child, and Witness #2 is

identified as a mother who took Paxil while pregnant and gave birth to a child who subsequently died, and will give similar evidence about the effects of losing a child.

[37] In response to the application the plaintiffs say:

> The plaintiffs do not intend to tender, at the common issues trial, any medical records relating to the plaintiffs' Lay Witness #1 or Lay Witness #2. The evidence of these witnesses is not required in order to establish material facts needed to succeed at the common issues trial.
>
> …
>
> The evidence of lay class members is, however, relevant to the experiences of persons who fall in the class description and they ought to be permitted to testify. This is especially true in light of the fact that a jury would reasonably expect to see at least some testimony from the representative plaintiffs and other class members.

[38] I stated when I certified this case as a class action, and again when I declined to strike the jury notice, that the common issues at trial are limited to the general question of whether Paxil causes or is capable of causing birth defects and whether the defendants knew or ought to have known that. The question of whether Paxil is likely to have caused or contributed to birth defects in respect of any individual is a matter for the subsequent individual trials, if the plaintiffs succeed on the common issues.

[39] In accordance with those rulings, plaintiffs' counsel has quite properly taken the position that the representative plaintiffs' medical records are not yet relevant. Having taken that position, the plaintiffs cannot now turn around and assert that the individual position of their representative plaintiffs is relevant to the common issues at trial. Calling those witnesses at trial can have no other purpose that I see other than implicitly asking the court to conclude that Paxil did cause the birth defects that those witnesses will testify about. For the purpose of the common issues trial, their evidence will be irrelevant and, even if minimally relevant, that relevance will likely be outweighed by prejudice to the defendants, particularly if this remains a jury trial. As plaintiffs' counsel says, the jury may well wonder why they are not hearing from anyone who actually used Paxil in pregnancy, but that absence can be explained through instructions to the jury.

[40] Normally, the court does not make orders in advance of trial what witnesses can or cannot testify. In the special circumstances of a class action, the governing legislation gives the court broad discretion to control its proceedings. I can rule, and I do, that the evidence of those witnesses about their use of and experience with Paxil will not be relevant to the common issues at trial, nor are their medical records.

[41] Having said that, I cannot imagine what relevant evidence they can give, but if plaintiffs' counsel has anything that they wish to call those witnesses about that does not relate to their individual experience and their individual health, I do direct that that evidence be presented first in the absence of a jury in something similar to a criminal *voir dire* procedure, and I can rule on its evidence at that stage.

[42] That leaves an application following on an earlier direction I gave that the plaintiff, Faith Gibson, answer certain outstanding questions from the discovery, The defendants say the answers are still too vague.

[43] For example, Ms. Gibson was asked which sales brochures produced by or on behalf of GSK the plaintiffs are referring to, and to produce copies of those brochures. The answer provided simply was, product labelling monographs and all other product information provided to those persons who were pescribed Paxil during the class period. That answer was given to a number of other questions.

[44] Similarly, the plaintiff, Faith Gibson, was asked to advise which specific statements in the sales brochures are the plaintiffs impugning. The answer was, failed to warn consumers about the true causal relationship between Paxil and cardiovascular birth defects. Another category was to advise if the plaintiffs are saying that any other document created by GSK or oral communications amounts to deceptive acts or practices contrary to the *B.C. Consumer Practices Act* [sic, British Columbia *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2], and the answer provided was that the plaintiff was unable to answer without full disclosure from both defendants.

[45] I agree with the defence that those answers are far too general and unhelpful. I appreciate that document discovery is still ongoing, but the plaintiffs by now should be in a position to identify some of the documents on which they are relying as containing the alleged misrepresentations or nondisclosure, and I do order more specific answers.

[46] I understand some documents have been produced only recently and I have just ordered production of more. Answers may have to be supplemented, but I do order that these answers be provided to the extent the plaintiffs have identified documents. I direct that more specific answers be provided no later than one week before the trial, if this matter is actually going to proceed to trial as scheduled.

"Smith J."