SUPREME COURT OF NOVA SCOTIA
Citation: Sweetland v. Glaxosmithkline Inc., 2014 NSSC 216

Date: 20140709
Docket: Hfx No. 315567
Registry: Halifax

Between:

Albert Carl Sweetland and ~~The Estate of Mary Agnes Addicott~~, Mary Patricia Addicott-Andrews, ~~Audrey Leone Addicott Nguyen, Ruthanne Tobin, Paul Allen Addicott, John Wendell Addicott, Julian Leigh Andrews, by her Litigation Guardian Mary Patricia Addicott Andrews, Jeffrey Paul Addicott, Justine Lynn Addicott, Shenoa Lee Matheson, Connor Tobin, Shawn Andrew Addicott, Jordyn Ayres, by her Litigation Guardian Mary Patricia Addicott Andrews, and Lynda Trottier, by her Litigation Guardian Mary Patricia Addicott Andrews~~

Plaintiffs

v.

Glaxosmithkline Inc., Glaxosmithkline PLC, Glaxosmithkline Services Unlimited and Smithkline Beecham Corporation

Defendants

Judge:	The Honourable Justice Michael J. Wood
Heard:	May 21, 2014, in Halifax, Nova Scotia
Written Decision:	July 9, 2014
Counsel:	Raymond F. Wagner, Q.C. and Michael Dull, for the Plaintiffs Mary M. Thomson and Scott R. Campbell, for the Defendants

By the Court:

[1] The plaintiffs began this proceeding in August, 2009, alleging that the defendants are liable for damages caused by their use of the medication Avandia. They wish to have the proceeding certified under the *Class Proceedings Act*, S.N.S. 2007, c. 28, although no certification motion has yet been scheduled.

[2] The defendants are alleged to be pharmaceutical companies involved in the development, production, advertising, distribution and sale of Avandia. Avandia is a prescription drug used in the treatment of certain forms of diabetes. The plaintiffs allege that its use creates a significant increase in the risk of heart attack in patients.

[3] I have been assigned to case manage this proceeding and, as a result, have the responsibility of dealing with motions leading up to the certification hearing.

[4] On May 21, 2014, I was scheduled to hear three motions. The first was by the plaintiff to amend the statement of claim and the others were motions by the defendants to strike portions of the affidavit evidence proposed to be filed by the plaintiffs on the certification motion, and for production of medical and pharmaceutical records for the plaintiffs.

[5] At the time of the hearing, counsel for the parties jointly requested an adjournment of the plaintiffs' amendment motion so that they could discuss a potential resolution. They also reached an agreement on most of the issues arising out of the plaintiffs' affidavits, and narrowed the scope of the medical information in dispute.

[6] This is my decision on the issues which remain outstanding in relation to the defendants' motions.

MOTION TO STRIKE EVIDENCE

[7] The defendants' notice of motion requested an order striking portions of the affidavits filed by the plaintiffs in support of their certification motion. At the time of the hearing, there had been no such affidavits filed with the Court, although copies had been given to the defendants by counsel for the plaintiffs.

Despite the absence of any filed affidavit, the parties requested that I deal with the evidentiary dispute which had arisen and I agreed to do so.

[8] One of the affidavits which the plaintiffs proposed to file on the certification motion is from Dr. Lorraine Lipscombe. She attaches as an exhibit a document entitled *"Staff Report on Glaxosmithkline and the Diabetes Drug Avandia"*. The cover page of the report indicates that it was prepared by staff of the Committee on Finance of the United States Senate. The defendants say that the report is both inadmissible and irrelevant to the certification motion.

[9] The body of the report is 15 pages long and there are four appendices. The first two set out an apparent time line of events between 2004 and 2007. The third appendix is a list definitions. The final appendix is over 300 pages of materials described as "Documents not Publicly Available". It includes many items referred to as internal documents of Glaxosmithkline.

[10] The Executive Summary of the Senate Committee Report states as follows:

> This staff report was developed over the last 2 years by U.S. Senate Committee on Finance investigators who reviewed over 250,000 pages of documents provided by GlaxoSmithKline (GSK/the Company), the Food and Drug Administration (FDA), the University of North Carolina, and others. Committee investigators also conducted numerous interviews and phone calls with GSK, the FDA, and anonymous whistleblowers.
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> Committee staff began this investigation in May 2007 after a study was published in the *New England Journal of Medicine*, showing a link between the diabetes drug Avandia (rosiglitazone) and heart attacks. However, the reviewed evidence suggests that GSK knew for several years prior to this study that there were possible cardiac risks associated with Avandia. As a result, it can be argued that GSK had a duty to warn patients and the FDA of the Company's concerns. Instead, GSK executives attempted to intimidate independent physicians, focused on strategies to minimize or misrepresent findings that Avandia may increase cardiovascular risk, and sought ways to downplay findings that a competing drug might reduce cardiovascular risk.
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> When an independent scientist sought to publish a study in 2007 pointing out the cardiovascular risk of Avandia, GSK acquired a leaked copy of that study from one of its consultants prior to the study being published. The company's own experts analyzed the study, found it to be statistically reliable, and then

> attacked the soundness of that study in press releases and public comments. GSK also sought to counter the study's findings by quickly releasing preliminary results from its own study on Avandia, even though the company's internal communications established that its study was not primarily designed to answer questions about cardiovascular risk.

[11] It is my understanding that Dr. Lipscombe had no involvement in preparing the report and no personal knowledge of it, except to say that she has seen it.

[12] *Civil Procedure Rule 22.15* deals with the rules of evidence on a motion. It states as follows:

> **22.15** (1) The rules of evidence apply to the hearing of a motion, including the affidavits, unless these Rules or legislation provides otherwise.
>
> (2) Hearsay not excepted from the rule of evidence excluding hearsay may be offered on any of the following motions:
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> (a) an *ex parte* motion, if the judge permits;
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> (b) a motion on which representations of fact, instead of affidavits, are permitted, if the hearsay is restricted to facts that cannot be contested;
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> (c) a motion to determine a procedural right;
>
> (d) a motion for an order that affects only the interests of a party who is disentitled to notice or files only a demand of notice, if the judge or the prothonotary hearing the motion permits;
>
> (e) a motion on which a Rule or legislation allows hearsay.
>
> (3) A party presenting hearsay must establish the source, and the witness' belief, of the information.
>
> (4) A judge, prothonotary, commissioner, or referee may act on representations of fact that cannot reasonably by contested.

[13] A certification motion in a class proceeding is considered to be procedural and, therefore, hearsay evidence is permissible provided the deponent establishes the source and the witness' belief of the information.

[14] The evidentiary onus on plaintiffs seeking certification of a class proceeding is not high. It is sufficient that they show "some basis in fact" for each of the certification requirements. Indeed, courts on certification motions are not expected to resolve conflicts in the evidence or engage in assessments of evidentiary weight.

[15] The low threshold of proof required on a certification motion should not be equated with a relaxation of the requirements for admissibility of evidence. A certification motion, like any motion, can only be decided on evidence that is properly before the court. The motion record must comply with the rules of evidence. For procedural motions this includes hearsay, provided the source is identified and the witness is able to establish their belief in the information. These requirements allow the court to assess the credibility and reliability of the hearsay statements being offered.

[16] The Senate staff report is clearly inadmissible when examined against the elementary rules dealing with admission of evidence. It is hearsay and the author is not identified. It appears to be the work of multiple people employed by the Committee on Finance of the United States Senate. The text of the report contains conclusions of fact based upon reviews of documents and information obtained from telephone interviews. In some cases, the sources are anonymous. The report is rife with opinion on factual, medical and legal issues.

[17] Leaving aside the fact that the report and its contents are not admissible, the plaintiffs have not satisfied me that it contains information relevant to the issue of certification. In their written submissions, counsel for the plaintiffs suggest that it is relevant to the determination of common issues, class definition and preferable procedure, all of which are requirements for certification. The difficulty is that they do not explain how the information is relevant and it is not apparent to me that there is anything in the report which could be of assistance in determining whether the certification criteria have been met. In a situation where material is challenged on the basis of relevance, it is incumbent on counsel to explain how the

information can be used in deciding whether the certification criteria have been met. It is insufficient to say that it provides background or context.

[18] Counsel for the plaintiffs argued that similar reports had been accepted and considered in other certification motions in class proceedings. Two specific examples were the report of the Honourable Thomas Berger, Q.C., which was considered in *Rumley v. British Columbia*, [2001] 3 S.C.R. 184 and the report of the Commission chaired by the Honourable Paul S. Creaghan which was considered in *Gay v. Regional Health Authority 7,* 2010 NBQB 128. In my view, these reports are completely different than the Senate report relied on in this case. In the *Rumley* case, the claim related to sexual abuse at a residential school for deaf children. The Attorney General appointed Mr. Berger as special counsel to carry out an investigation of the abuse in response to lawsuits initiated against the Province. I have read the trial, appeal and Supreme Court of Canada decisions in *Rumley* and at no time did any party dispute the admissibility of the Berger report. In fact, many of its conclusions were not in dispute. I also note that the information in the Berger report was used in determining whether the certification criteria were met, including whether the class action was the preferable proceeding.

[19] The Creaghan report was as a result of a Commission of Inquiry appointed by Order-in-Council. The defendant disputed its admissibility; however, the New Brunswick Court of Queen's Bench determined that it was admissible under s. 43 of the *Evidence Act*. The issue of the admissibility of the report was also considered by the New Brunswick Court of Appeal (2014 NBSC 10) where the Court stated as follows:

> [18] In due course, the Commission, chaired by the Honorable Paul S. Creaghan, produced a comprehensive report, which was received in evidence at the hearing in the court below. The motion judge's decision on admissibility is reported at 2010 NBCB 128, 361 N.B.R. (2d) 1. While that ruling was challenged in the Regional Hospital's written submission on appeal, the issue was not forcefully pressed at the hearing. The fact is that the disposition of the present appeal does not turn on any controversial feature of the Commission's report and, in any event, we have not been persuaded that the motion judge's admissibility ruling is unsustainable, having regard to the limited purpose for which the report was received.

> [19] That said, all acknowledge the Commission found serious and alarming deficiencies in Dr. Menon's work over the years, a pattern of errors that, arguably, should have been detected and corrected sooner. Amongst other findings, the Commission identified deficiencies in the recruitment and hiring policies of the Regional Hospital in Dr. Menon's case and a distressing lack of quality assurance and quality control programs in the pathology laboratory which, in turn, meant there was no meaningful peer review of Dr. Menon's work throughout the years he functioned as Chief of Pathology, Director of Clinical Laboratory Services and as an anatomical pathologist.

[20] The class action involved claims by patients who were allegedly adversely affected by the pathology practices examined by Justice Creaghan.

[21] Both of these reports were the product of formal quasi-judicial proceedings where the rules of evidence and procedure were known. The reports also dealt with the specific factual circumstances which underlay the class actions. There was never any serious dispute about the usefulness of the information in the reports, nor its application to the issues on certification.

[22] I do not think that the Senate report is an analogous document. I have no information with respect to the identity or qualification of the authors and no evidence with respect to the mandate or authority under which the report was prepared. There is no indication of the rules of procedural fairness or evidence which were applied.

[23] I have concluded that the staff report prepared for the Committee on Finance of the United States Senate is both inadmissible and irrelevant to the certification motion in this proceeding.

PRODUCTION MOTION

[24] The scope of information sought by the defendants from the plaintiffs has been narrowed through discussions between counsel. What the defendants seek is production of existing medical and pharmaceutical records in relation to:

- diagnosis of diabetes for Mr. Sweetland and Ms. Addicott;
- prior treatment of their diabetes;

- date of first prescription of Avandia;
- decision and reason for the treating physician(s) to prescribe Avandia;
- advice given by physicians/pharmacies to Mr. Sweetland and Ms. Addicott regarding product usage, warnings and adverse effects related to Avandia;
- indication of dose and duration for each prescription period;
- records of cardiovascular events allegedly related to Avandia use including ischemic events (myocardial infarction or stroke) and/or CHF;
- records of prior (pre-Avandia) cardiovascular events including ischemic events (myocardial infarction or stroke) and/or CHF; and
- advice received in relation to cessation of Avandia use.

[25] Counsel for the defendants does not know if these records exist or, if they do, whether they contain information that might be relevant to the issues on the certification motion. Counsel argues that there may be information in these records which will assist the Court in determining whether there are two or more members of the proposed class, whether the plaintiffs are appropriate representatives for the class and the nature of any issues which are common to class members.

[26] The plaintiffs oppose the production request on principle and say that it is not appropriate at this stage in the proceeding for them to be required to provide this degree of personal, medical and pharmaceutical information. It is not necessary nor relevant to the certification motion in their view. There was no suggestion that it would be difficult or expensive to obtain and provide the requested information.

[27] Although I was not provided with copies, I understood from counsel that the plaintiffs had signed affidavits providing some information concerning their medical history and, in particular, the prescription of Avandia and allegedly

related cardiac issues. In addition to the requested information being relevant to the issues on certification, the defendants say that these records are necessary in order to effectively cross-examine the plaintiffs on their affidavits.

[28] There appear to be differing judicial opinions on whether proposed representative plaintiffs should be required to disclose their medical records prior to certification taking place. An example of the view that disclosure should not be ordered is *Jones v. Zimmer GmbH,* 2010 BCSC 1504, which involved an allegedly defective hip implant. The defendant sought disclosure of the plaintiff's medical records and said that it was necessary for the certification application because it might disclose differences in surgical techniques that could support an argument against the existence of common issues. The Court dismissed the motion for the following reasons:

> 28 From my review of authorities, I accept that generally the courts in Canada have refused to order that medical records be produced prior to certification, except in exceptional circumstances, including where the record on the certification issue may be inadequate. The party requesting production has the onus of demonstrating that the documents are necessary for the certification application.

[29] Other examples where production was not ordered include: *Pardy v. Bayer Inc.*, 2003 NLSCTD 130 and *Pearson v. Inco Ltd.*, 2002 CarswellOnt 1572.

[30] Cases in which production of medical records was ordered include *Caputo v. Imperial Tobacco Ltd.*, 1997 CarswellOnt 2401, *Roveredo v. Bard Canada Inc.,* 2010 ONSC 5240 and *Schroeder v. DJO Canada Inc.*, 2009 SKQB 169.

[31] In the *Roveredo* case, the proposed class action was in connection with a medical device used for repair of hernias. The plaintiffs allege that the device was used in their surgery and ultimately malfunctioned. In the affidavits filed in support of certification, the plaintiffs described their medical problems leading to the surgery and the medical difficulties encountered thereafter. The plaintiffs voluntarily disclosed certain information, but the defendants sought broader (but still limited) disclosure including information concerning prior surgeries. The Court granted further disclosure for the following reasons:

[10] Ultimately, the decision is driven by the circumstances of the particular case and requires a degree of balancing, so as to be fair to both parties. In this case, I have concluded that the records in question should be produced for the following reasons:

(a) the records relate directly to medical conditions to which the plaintiffs have referred in their affidavits, the treatment they received for those conditions, and the consequences of that treatment;

(b) the records may be relevant to the commonality analysis under s. 5(1)(c) of the *C.P.A.* and may be particularly relevant to the preferability analysis under s. 5(1)(d) - they may assist the court in determining whether, viewed in the entire context of the case, the resolution of the common issues will sufficiently advance the claims of the class to warrant a finding that a class action is preferable to individual actions;

(c) the records may assist the court in determining whether the plaintiffs are appropriate representatives of the class, keeping in mind that the proposed action covers a variety of products;

(d) the request for records is focused - it is not a fishing expedition. It is made *bona fide* and not with the purpose of placing unwarranted and intrusive burdens on the plaintiffs;

(e) the defendants will bear the costs of obtaining the information - the plaintiffs need only provide written authorization; and

(f) the plaintiffs' privacy rights will be adequately protected by the normal rules of litigation.

[32] In the *Schroeder* litigation, the proposed class action related to an allegedly defective medical product used for pain relief following surgery. The Court described the defendants' argument in support of the production motion at para. 54:

[54] The defendants submit that the same reasons which support the exercise of the Court's discretion to order cross-examination of the plaintiffs, also support an order for pre-certification disclosure of the representative plaintiffs' medical and hospital records. Specifically, the defendants assert that the medical

> and hospital charts will likely provide relevant evidence on the decision to use a pain pump and how the pain pump was used in each representative plaintiffs' surgery which would constitute evidence that is clearly relevant to the certification criteria of common issues and preferable procedure.

[33] The Court granted the production motion for the following reasons:

> [58] I have already concluded that it is appropriate, to ensure a full and appropriate record, to permit the defendants the right to cross-examine the deponents touching matters relating to the certification motion. It follows that it would be similarly appropriate to afford the defendants the same right, on the same basis, respecting medical and hospital records. In other words, to ensure a comprehensive record, the defendants ought to be entitled to obtain, in advance of the cross-examination of the affidavits, any material, x-rays or documents that have a bearing on the certification application.
>
> [59] The practical problem that arises from such a finding is determining which material is relevant, if any, to the certification application. The most efficient way to deal with this issue is to require the two representative plaintiffs and the proposed representative plaintiff to sign authorizations permitting the defendants the right to obtain the material from the relevant medical or hospital personnel. The inconvenience to the plaintiffs would be minimal. The cost of obtaining the material would be borne by the defendants. The plaintiffs' privacy rights are not being significantly affected in that the material received by the defendants must be kept confidential and used only for purposes associated with the action and is likely information that the defendants would receive in any event, should the plaintiffs' application for certification be granted. What remains to be seen is what, if anything, will be found by the defendants that could be relevant to the issues to be determined at the certification hearing. However, it is wrong, in my view, to deny the defendants, in these circumstances, the opportunity to examine information with a view to determining if and how it ought to be presented in the certification hearing.

[34] In the present case, I am satisfied that the requested disclosure ought to be produced. Whether it results in relevant information which forms part of the evidence on the certification motion remains to be determined. The plaintiffs have made issues with respect to their medical and pharmaceutical records relevant by referring to their medical history in their affidavits to be filed on the certification motion. I am satisfied that the information requested is focused on those issues and does not amount to an unsubstantiated fishing expedition.

[35] It would have been preferable to have expert evidence explaining the potential relevance of the medical and pharmaceutical records to the questions which need to be answered on the certification motion. Counsel for the defendants has extensive experience in litigation relating to Avandia and in her submissions provided a very helpful overview of the medication, its use and the nature of the cardiac risk issues. Counsel for the plaintiffs did not object to her doing so and, as a result, I was satisfied that I had sufficient contextual information to decide the production motion.

CONCLUSION

[36] I have decided the outstanding issues in relation to the plaintiffs' affidavits and the request for production of their medical and pharmaceutical records in favour of the defendants. I will not deal with the issue of costs with respect to these motions at this time. That will be part of the costs decision following the conclusion of the certification motion.

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Wood, J.