Court of King's Bench of Alberta

Citation: Singh v Glaxosmithkline, 2022 ABKB 762

Date:
Docket: 1201 12838
Registry: Calgary

Between:

Fiona Singh and Muzaffar Hussain by His Litigation Representative Fiona Singh

Plaintiff

- and -

Glaxosmithkline Inc., Glaxosmithkline LLC., Glaxosmithkline Plc.,

Defendants

Memorandum of Decision
of the
Honourable Associate Chief Justice J.D. Rooke

I. Introduction

[1] This is the certification decision[1] on the class proceeding herein, under the Class Proceedings Act, SA 2003 c-C 16.5, as amended (the Act), wherein the Second Certification Statement of Claim (SCSoC) refers to the class as:

> Women who were prescribed Paxil in Canada and subsequently aborted, delivered, or miscarried children with congenital malformations after ingesting Paxil while pregnant, family members who may make claims under Family Compensation Legislation following the death of, or injury to such children, children born alive to such women, and provincial and territorial governments who paid Health Care Costs on their behalf.

[2] The Plaintiffs seek to certify the following common issues:

(a) Is paroxetine teratogenic?

(b) If so, did the Defendants breach a duty to warn physicians and patients that paroxetine is teratogenic?

(c) Did the Defendants' conduct in the marketing of Paxil to pregnant women merit an award of punitive damages?

[3] The Personal Representative Plaintiff, Fiona Singh (PRP), claims that:[2]

(a) Between October and June 2004, her physician prescribed, and she ingested, Paxil while pregnant;

(b) Because of Paxil, her child developed congenital malformations, including malformations in his skull (craniostenosis), neural tube (spina bifida), heart (atrial ventricular septal defect), genital (hypospadias, imperforate anus) and limbs (congenital talipes equinovarus).

[4] The written materials filed in respect of this Certification Application are numerous and voluminous. They include the Plaintiff's Brief of Law dated August 7, 2018 (PB1); Defendants' Brief of Law Opposing Certification filed September 10, 2018 (DB1); Defendants' Supplemental Brief of Law Opposing Certification filed April 5, 2019 (DB2); and the Plaintiffs' Reply Supplemental Brief of Law dated April 24, 2019 (PB2). In light of the delay that occurred as a result of the Change of Representation and Substitution Applications, the Plaintiffs and Defendants were invited to submit further briefs, and these are the Defendant's Third Brief of Law Opposing

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[1] This class proceeding has a unique procedural history. The Proposed Representative's (PRP) Application for Certification was heard on January 8 and 9, 2019, at the end of which I reserved my decision. While my decision was on reserve there developed a dispute between the Plaintiffs and their Counsel. I told all parties and Counsel that I would put a hold on this judgment until competing PRPs and Counsel resolved the issue, but they were not able to do so on their own. Ultimately the matter (Change of Representation and Substitution Cross-Applications) was put before me to resolve, and on April 21, 2021, I issued my decision (2021 ABQB 316), granting the PRP's Change of Representation Application and dismissing the Substitution Application. This is my Decision on the substance of the Certification Application and applicable submissions herein.

[2] SCSoC paras 3 & 4

Certification dated June 30, 2021 (DB3), and the Plaintiffs' Brief of Law in Support of Certification dated July 30, 2021 (PB3).

II. Procedural History and Parallel Actions

[5] This action was commenced by Merchant Law Group (MLG) by way of a Statement of Claim filed on October 12, 2012. MLG had already initiated similar proceedings in Ontario in 2007 (the Roman action); in British Columbia in 2007 (the Wakeman action); and in Saskatchewan in 2008 (the Duzan action). Similar class proceeding were also initiated by different law firms in British Columbia in 2008 (the Bennison and Bartram actions).[3] The history of those proceedings is set out in some detail in ***Duzan v Glaxosmithkline Inc***, 2011 SKQB 118, at paras 5-21, wherein Ball J. unconditionally stayed the Duzan action, holding (at para 21) that MLG had engaged in a "[M]ultijurisdictional game of class action 'whack-a-mole'" amounting to an abuse of process, and had failed to comply with the Saskatchewan Court's scheduling directions.

[6] The Bennison action in British Columbia was discontinued in January, 2011. The Bartram action was certified by Smith J. in ***Bartram v GlaxoSmithKline Inc.***, 2012 BCSC 1804 (***Bartram SC***); aff'd: 2013 BCCA 462. At para 14, Smith J. set out the common issues the Plaintiffs sought to certify:

(a) Did Paxil cause or increase the likelihood of birth defects?

(b) Is Paxil unfit for its intended purpose?

(c) Did the Defendant, GLAXOSMITHKLINE INC. fail to warn class members and/or Health Canada of the true risk of 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 Defendant, GLAXOSMITHKLINE INC. warrant an award of punitive damages, and if so, what amount of punitive damages should be awarded?

(f) Did the Defendant, GLAXOSMITHKLINE INC.'s solicitations, offers, advertisements, promotions, sales and supply of Paxil for personal use by class members fall within the meaning of "consumer transactions" in the *Business Practices and Consumer Protection Act* [SBC 2004 c. 57] (the "BPCPA")?

(g) With respect to the sales in British Columbia of Paxil to class members for their personal use, was the Defendant, GLAXOSMITHKLINE INC. a "supplier" as defined in the BPCPA?

(h) Are the class members "consumers" as defined by the BPCPA?

(i) Did the Defendant, GLAXOSMITHKLINE INC. engage in conduct, as alleged in the Statement of Claim, that amounted to deceptive acts or practices contrary to the BPCPA?

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[3] The history of parallel proceedings is set out in the October 10, 2013 Marc Kestenberg Affidavit as well as ***Duzan v Glaxosmithkline Inc***, 2011 SKQB 118.

[7] In granting certification, Smith J. directed two modifications to the common issues set out above. At para 36, he noted that there was no evidence that Paxil is generally unfit for its intended use in treating depression and other psychiatric conditions, and therefore directed that the common issue (b) should be phrased as whether Paxil is unfit for use during pregnancy. At para 35, importantly for the case at bar, Smith J. held:

> I would, however, narrow the question to whether Paxil causes or increases the likelihood of cardiovascular birth defects. That is the type of defect alleged in the case of the proposed representative plaintiff and is the only type referred to in the proposed class definition. [Emphasis added]

[8] A settlement was arrived at in ***Bartram*** prior to the hearing of this Certification Application.[4]

[9] After the certification hearing, a dispute arose between competing Personal Representative Counsel and Plaintiffs' initial Counsel (described in footnote 1 herein), resulting in a change in the representation for the Plaintiffs.

III. General and Evidentiary Background

[10] Paxil is the brand name for a pharmaceutical belonging to a family of medications called selective serotonin reuptake inhibitors. The active ingredient in Paxil, and its generic name, is paroxetine. The Defendant GSK Inc (GSK Canada) has marketed Paxil in Canada for the treatment of depressive illness, beginning in 1993. GSK Canada also marketed Paxil for the treatment of obsessive-compulsive and panic disorder (starting in November 1995); social phobia (starting April 1999); generalized anxiety disorder (starting August 2001) and post-traumatic stress disorder (starting April 2002).[5]

[11] A congenital malformation is a structural anomaly present at the birth of a child that originates prior to birth and may be discovered well after. The common term for a congenital malformation is a birth defect.

[12] A teratogen is an exposure that, based on dose, timing, and composition, is capable of causing a congenital malformation or birth defect. A pharmaceutical that causes a birth defect at some time during pregnancy may be described as a teratogen, or teratogenic.

[13] A significant amount of evidence, much but not all of it expert, has been filed in respect of this application by both the Plaintiffs and Defendants.[6] Summarizing all of it would require volumes. Considerable time and effort has been expended in the various briefs to undermine the qualifications or limit the scope various experts' evidence. On the whole, this effort to undermine the experts has not been helpful, as much of it is better suited to a merits argument than it is on this Certification Application, where the questions are, *inter alia*, whether there is some evidence to support the causes of action pleaded, the existence of an identifiable class, and the existence of

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[4] The Settlement Agreement is attached as Exhibit B to the January 3, 2019 Affidavit of Mario D'Angelo

[5] October 11, 2013 Karen Feltmate Affidavit, Schedule B

[6] According to the PB1 para 131, which I accept, the Plaintiffs and Defendants had filed 25,642 pages of evidence as of the date of the hearing. They have filed more since then.

common issues.[7] I will attempt to very briefly summarize the evidence of the experts relevant to the most significant issue in this application, which is the proposed common issue of general causation (ie., is paroxetine teratogenic?). It is impossible to do justice to the complexity of the expert evidence in a brief summary; I include it here only in the context of the "some basis in fact" standard applicable to this certification application.

The Plaintiffs' Experts[8]

[14] Dr. Anick Berard is an epidemiologist and Professor of perinatal pharmacoepidemiology at the Faculty of Pharmacy of the Universite de Montreal. She has a doctorate in epidemiology and biostatistics from McGill University. She is a member of the Teratology Society and of the Organization of Teratology Information Services. It is her opinion that there is some basis that paroxetine causes an increased risk of congenital malformations; that exposure to paroxetine during the first trimester has the potential to produce defects in many organ systems; and that the increased risk of congenital malformations from paroxetine during the first trimester applies to all users, and there is an objective, population-wide basis of making that determination in a way that can be applied to any and every patient who used paroxetine during pregnancy. She further states that Canadian Paxil monographs did not provide a complete picture of the teratogenic potential of paroxetine.[9]

[15] Dr. Pierre S. Chue is a psychiatrist practicing as Medical Director of Addictions and Mental Health, Community Mental Health Services, for Alberta Health Services. He is also a Consulting Psychiatrist with Telemental Health Services and Primary Care Networks in Alberta, as well as a Clinical Professor in the Department of Psychiatry at the University of Alberta. Dr. Chue states that issues related to congenital heart, lung and other defects became focused on Paxil beginning in 2005, when GSK first notified doctors of the potential hazard.[10] Dr. Chue also cites a body of literature indicating an association between the use of Paxil during pregnancy and an increased risk of congenital malformations including spontaneous abortion, persistent pulmonary hypertension and neurological toxicity.[11]

The Defendants' Experts

[16] Dr. Anthony Scialli is an obstetrician-gynaecologist and reproductive toxicologist, specializing in reproductive and developmental toxicology and teratology (the study of the causes of congenital malformations). He is an adjunct professor of Obstetrics and Gynaecology and of Pharmacology and Physiology at Georgetown University in Washington, DC, as well as a clinical professor of Obstetrics and Gynaecology at George Washington University in Washington, DC. He is a past president of the Teratology Society and Director of the Reproductive Toxicology Center which operates a database which serves as a reference source for information on the

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[7] See, similarly, ***Bartram SC*** at para 29

[8] I am not including in this discussion the September 7, 2016 Affidavit of David Healy. Strekaf J (as she then was), the prior Case Management Justice in this action, refused to allow an earlier affidavit sworn by Dr. Healy, holding that it involved findings beyond his expertise. Because this is a certification application and not a hearing on the merits, and because the Plaintiffs have met the "some basis in fact" standard, it is not necessary to engage the controversy over Dr. Healy's evidence here.

[9] September 10, 2015 Anick Berard Affidavit

[10] January 11, 2013 Pierre S. Chue Affidavit

[11] December 19, 2012 Pierre S. Chue Affidavit

reproductive and developmental effects of chemical and other agents on reproduction. He states that labeling a medication as teratogenic provides no significant information about what specific teratogenic effect it may have, the dose required to produce the effect, or what other individual factors may lead to specific outcomes. He also states that the approved product monographs for Paxil have consistently noted that the safety of the medication for use in human pregnancy had not been established.[12]

[17] Dr. Edward Lammer, who passed away following the delivery of his affidavit, specialized in pediatrics and medical genetics at the Children's Hospital in Oakland, California. He was an associate scientist at the Children's Hospital Oakland Research Institute and a clinical geneticist with the Prenatal Diagnosis Center, East Bay Perinatal Program. Dr. Lammer had been actively involved in birth defects surveillance and research since 1982. At para 17 of his October 13, 2013 Affidavit, Dr. Lammer stated that the various pregnancy outcomes described in the Statement of Claim represent "an incredible variety of very diverse outcomes having different risk factors, causes, and pathogeneses. In his view, therefore, determining whether Paxil caused these pregnancy outcomes would require numerous and involved "general causation" analyses which will not answer the question of whether Paxil was the cause of a particular defect in a particular child.[13]

[18] Dr. Gary Shaw is a birth defects epidemiologist who at the time of swearing his Affidavit was Associate Chair of Clinical Research in the Stanford University Department of Pediatrics at Stanford, California, as well as holding the position of Professor of Pediatrics in the Division of Neonatal and Developmental Medicine at Stanford University School of Medicine. A member of the Teratology Society, he has led nine large epidemiologic studies focused on investigating risk factors for various types of birth defects. His evidence was sought specifically in response to the Plaintiffs' expert, Dr. Berard. It is Dr. Shaw's evidence that the epidemiologic data as a whole does not demonstrate a connection between gestational paroxetine exposure and either birth defects as a collective group, in any organ or system, or of any particular type. He states that the few "sporadic associations that have been reported can be explained by other factors, such as bias, confounding, and chance, and are not indicative of an increased risk or association, much less causation."[14]

IV. The Class Proceedings Act, SA 2003 c-16.5

[19] The criteria for certification are set out in s.5(1) of the Act. Matters that a Certification Justice must consider in applying the certification criteria are set out in s.5(1), are described in s.5(2).

V. Analysis

[20] As I have indicated in prior decisions,[15] a body of law has now developed around the criteria for certification such that counsel bringing or responding to a certification application should be aware of their interpretation. As such, I do not intend to repeat now-accepted law or submissions,

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[12] October 11, 2013 Anthony Scialli Affidavit
[13] October 10, 2013 and August 29, 2014 Edward Lammer Affidavit
[14] March 6, 2017 Gary Shaw Affidavit
[15] See eg. ***Engen v Hyundai***, 2012 ABQB 740; ***Robinson v Alberta***, 2022 ABQB 497

nor engage in debate in respect of criteria not seriously at issue, nor respond to issues not specifically raised by the parties. As I said in ***Robinson v Alberta***, 2022 ABQB 497 at para 11, "...certification is a relatively broad-brush task of assessing procedural common sense and exercising reasonable discretion, not determining how many angels can dance on the head of a pin".

(a) Cause of Action

[21] The Defendants argue[16] that the action is advanced against three named Defendants (GlaxoSmithKline Inc (GSK Canada, GlaxoSmithKline PLC (GSK UK) and GlaxoSmithKline LLC (GSK USA), collectively herein referred to as GSK), but fails to state each Defendant's role in the action and fails to plead or identify specific acts undertaken by each that would ground a cause of action. In response, the Plaintiffs filed the SCSoC on January 9, 2019, adding paras 21-24, particularizing the allegations pleaded against the various Defendants.

[22] Notwithstanding these additions to the SCSoC, in oral argument counsel for GSK reiterated the position that the allegations in the SCSoC, "[D]o not support the finding that the foreign defendants were involved in the promoting, labelling, or marketing of Paxil in Canada."[17] In support of this argument, GSK refers to the decisions in ***Wall Estate v GlaxoSmithKline Inc***, 2010 SKQB 351 and ***Parker v Pfizer Canada***, 2012 ONSC 3681. In ***Wall Estate***, Popescul J. ordered that a class proceeding be dismissed against foreign defendants because (at para.43):

> Specifically, there is no claim that any of the foreign defendants played any role whatsoever in anything to do with the manufacturing, promoting, marketing, labelling or selling of Avandia in Saskatchewan. The plaintiffs have made vague, obscure and unparticularized assertions against the foreign defendants through the indiscriminate use of the term "the GSK defendants". However, the inclusion of all defendants within the collective definition of "the GSK defendants" followed by the inarticulated assertions that all defendants are connected to all the alleged wrongdoings does not provide a sufficient basis to establish the requisite real and substantial connection between Saskatchewan and the foreign defendants in the pleadings.

[23] In ***Parker***, Perell J. held, at para 54:

> I, however, do not see some basis in fact for a duty to warn claim against Pfizer Inc., which does not manufacture varenicline in Canada. Standing alone, the position of a shareholder, even a controlling shareholder, in a manufacturer is insufficient to impose a manufacturer's duty... Pfizer Inc. has no direct relationship to Mr. Parker or the other putative Class members who used varenicline manufactured and marketed by Pfizer Canada. There is no dispute that CHAMPIX® was sold in Canada by Pfizer Canada pursuant to Health Canada's approval, and that all of the information available to Class members or their

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[16] DB1 paras 51-62

[17] January 9, 2019 transcript at page 59, lines 2 to 5 and subsequent, the short expression for which this and other references follow the formula: "Jan 9 /19 TR 59/2-5 *et seq*"

> physicians relating to CHAMPIX® was from Pfizer Canada. Any duty to warn or breach thereof would be the responsibility of Pfizer Canada.

[24] Furthermore, GSK contends that the failure to plead a specific cause of action extends to GSK Canada specifically.[18] In this regard, they rely upon ***Martin v Astrazenica***, 2012 ONSC 2744 (aff'd: 2013 ONSC 1169 (Div Ct)), wherein the allegations pleaded are described as follows, at para 119:

> The plaintiffs fail to identify the specific acts undertaken by each defendant which support these causes of action. The only pleaded conduct that is personal to any defendant is that AZ Canada "was involved in and/or responsible for the sales, distribution and marketing of Seroquel in Canada." The defendants, AZ U.K. and AZ U.S., are identified simply as "affiliate[s]" of AZ Canada. There is no indication of which defendant was the designer or manufacturer of Seroquel. Instead, the plaintiffs attribute liability to the defendants en masse, asserting that "[t]he business of each… is inextricably interwoven with that of the other and each is the agent of the other for the purposes of research, development, manufacture, marketing, sale and/or distribution of Seroquel in Canada." This bald assertion of enterprise liability is deficient for three reasons.

[25] Had the Plaintiffs not amended the Statement of Claim to add the allegations contained in paras 21-24 of the SCSoC, I would be inclined to apply the reasoning in ***Parker*** and ***Martin***. Indeed, the pleading described by Popescul J. in ***Parker*** appears to bear a striking resemblance to the Statement of Claim in this action prior to the January 9, 2019 amendments. However, paragraphs 21-24 of the SCSoC plead, *inter alia*:

(a) As a global partnership, GSK Canada, GSK UK and GSK USA executed a common plan to manufacture and distribute Paxil throughout the world, including Canada;

(b) GSK UK prepared the New Drug Submissions ("NDSs") that GSK Canada filed with Health Canada to get market authorization for Paxil in Canada;

(c) GSK gathered information for the Canadian Paxil NOS from each GSK entity that did research and conducted clinical trials around the world. GSK centralized the information in one global database;

(d) GSK UK directed post marketing safety surveillance throughout the world, including in Canada, through a Global Clinical Safety and Pharmacovigilance department that received and recorded adverse drug event reports received worldwide, including from GSK Canada;

(e) GSK pooled Canadian reports in databases with reports from GSK entities in other countries, and the pooled reports led to changes in the Canadian Paxil product monographs;

(f) GSK UK published information about congenital malformations in Periodic Safety Update Reports ("PSURs"), which were distributed by GSK UK to GSK

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[18] Jan 9/19 TR 69/1-3

Canada to use in preparing regulatory materials that were submitted to Health Canada;

(g) GSK's Global Labeling Group, which was located in both the UK and USA reviewed the labeling of GSK's products throughout the world, including in Canada, and directed labeling changes in each country it marketed Paxil including changes to Canadian Paxil product monographs.

(h) GSK's Global Labeling Group created the data sheets indicating what information should go into product labels and given to prescribing physicians in each country in which Paxil was marketed, including Canada;

(i) GSK UK had a Worldwide Labeling Committee that audited GSK Canada to ensure compliance with CSI and other labeling standards set by GSK UK;

(j) GSK UK set standard operating procedures that set out the process by which GSK Canada was required to make changes to Canadian product monographs.

(k) GSK UK directed post marketing safety surveillance throughout the world, including in Canada, on behalf of all GSK entities, through a Global Clinical Safety and Pharmacovigilance department.

[26] The burden of establishing a properly pleaded cause of action for the purpose of class certification is, as is very often noted, not a high one. No evidence is admissible, and the facts pleaded must be accepted at this stage as true, unless they are patently ridiculous or incapable of proof. The pleading is to be read generously and will be unsatisfactory only if it is plain and obvious that the plaintiff cannot succeed. Therefore, whether the allegations contained in paras 21-24 of the SCSoC are ultimately sustainable will be a matter for the common issues Justice. I am sensitive to the Defendants' argument that elements of paras 21-24 of the SCSoC as currently pleaded may stray from facts into evidence and, as the Plaintiffs conceded in oral argument, further amendments may be required to correct for deficiencies in this regard. However, the application before me is not to strike those paragraphs for pleading evidence rather than facts; it is to consider those facts that are properly pleaded and determine whether it is plain and obvious that the Plaintiffs cannot succeed. In pleading facts supporting the proposition that the foreign defendants GSK UK and GSK USA directed and/or coordinated and collaborated in the marketing of Paxil and the development of Paxil product monographs in Canada, I conclude that the Plaintiffs have met this standard, and therefore the Plaintiffs have established the first element for certification under s.5(1)(a) of the Act.

(b) Identifiable class

[27] In their DB1 at para 65, the Defendants argue that there is no evidence on the record to show that the PRP is aware of other individuals "desirous of having their common complaint... determined as part of this proposed class action". By the time of their DB3, while the Defendants acknowledged the existence[19] of three affiants who fall within the scope of the proposed class, they argued that there is no evidence before the Court of potential class members, "[W]ho have retained the Consortium to advance their action through the vehicle of a class proceeding other than Mr. Singh and her son", and "the Consortium with carriage of the class action has recommended to

[19] DB3 para 7

potential class members that they opt out of a class proceeding to pursue their actions on an individual basis following certification."

[28] The Plaintiffs point out that the reference to three potential class members in para 7 of the Defendants' DB3 is sufficient to satisfy the statutory threshold that there be an identifiable class of over two persons under s.5(1)(b) of the Act. Moreover, there is evidence of other potential members of the class by way of an individual action filed in Saskatchewan on November 5, 2019 (the Thompson Claim), which pleads claims against GSK Canada, GSK USA and GSK UK that are, aside from the particulars of the alleged congenital defects, essentially identical to the claims in the case at bar.

[29] Furthermore, relying upon the January 3, 2019 Affidavit of Mario D'Angelo and the questioning thereon, the Plaintiffs argue that there is some basis in fact for the existence of an identifiable class on the basis of the Canadian "qualified leads" (ie., cases in which a mother has alleged to have taken Paxil during pregnancy and the child was born with a birth defect that is known to be related to the use of Paxil). Mr. D'Angelo identified in the course of his involvement with Paxil birth defect litigation in the United States. These qualified leads include cases involving cardiac and non-cardiac congenital malformations and span 10 provinces and territories.

[30] The Plaintiffs further argue, and I agree, that in framing the test in terms of identifying individuals who are "desirous" or who "wish to pursue" a class proceeding, the Defendants are missing some significant judicial refinement of that aspect of the test. GSK relies upon ***Bellaire v Independent Order of Foresters***, [2004] OJ No 2242 at para 27:

> Section 5(1)(b) requires an identifiable class of two or more persons. In my view, that entails placing evidence before the court that there are other individuals who both share the same complaint as that of the plaintiff and wish to have the complaint litigated through the mechanism of a class proceeding, save and except for those factual situations where the existence of such other individuals is obvious.

[31] As the Plaintiffs observe, the "factual situations where the existence of such other individuals is obvious" is a significant exception to the general principle set out in para 27 of ***Bellaire***. Moreover, a number of decisions subsequent to ***Bellaire*** have established the proposition that, in appropriate circumstances, it is not necessary for the plaintiff to prove, at the time of certification, that there is more than one plaintiff currently motivated to bring the class the proceeding. A helpful and thorough discussion on this point can be found in ***Keatley Surveying Ltd v Teranet Inc.***, 2014 ONSC 1677 (Div Ct); aff'd: 2015 ONCA 248, at paras 61-91. At paras 84-5 of the Divisional Court decision, Sachs J. held:

> Section 5(1)(b) of the CPA does not explicitly require evidence of a desire among class members to pursue an action. It simply requires that "there is an identifiable class of two or more persons that would be represented by the representative plaintiff or the defendant".
>
> In short, the "desirous" component of the identifiable class criterion is not mentioned in the legislation, not required to achieve the purposes of the criterion and not mentioned in the Supreme Court of Canada jurisprudence that discusses the issue.

[32] I agree with the Plaintiffs that, at a minimum, the existence of the three affiants, the Thompson proceeding and the evidence of Mr. D'Angelo in respect of "leads" constitutes some basis in fact or sufficient to show that an identifiable group of two or more persons exists.

(c) Common issues

i. Is paroxetine teratogenic?

[33] In order to properly understand the Plaintiffs' and Defendants' positions in respect of this proposed common issue, it is necessary to understand the distinction between general and specific causation, as those terms are understood in the context of epidemiology and etiology. In ***Price DC*** at para 21, the Court expressly approved the descriptions of general and specific causation set out by Perell J. in ***Price SC*** at paras 53-34:

> Etiology is the study of cause or causes, and epidemiology is the branch of medical science that studies the etiology of diseases and that identifies risk factors for disease or medical conditions. Epidemiology focuses on "general causation;" i.e., whether or not an agent has the capacity to cause a disease or medical condition rather than on "specific causation;" i.e., whether or not an agent did cause a disease or medical condition to be suffered by a specific person.
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> There are a different kind of epidemiological studies that are employed to determine the positive or adverse effects of drugs. Epidemiological studies are designed to determine whether there is an "association," which may or may not be causal, between an agent and a disease and medical condition. Association is a necessary but not sufficient precondition for a causal connect 2018 ONSC 4333 (CanLII) 14 between an agent and a consequence or effect.

[34] Broadly speaking, the core of the Defendants argument[20] is that the Plaintiffs seek to adjudicate claims involving causation and duty to warn that involve a diverse set of birth defects in a broadly framed class, where the record shows that causation and duty to warn must be examined on a defect-specific basis. In this regard, the Defendants initially placed considerable emphasis on the decision in ***Price v Lundbeck A/S***, 2018 ONSC 4333 (***Price SC***). In the period between the hearing of this certification application and this decision, however, ***Price SC*** was overturned by the Ontario Divisional Court: ***Price v Lundbeck A/S***, 2020 ONSC 913 (***Price DC***) and returned to the Superior Court of Justice for a new certification hearing.

[35] In ***Price SC***, the common issue proposed for certification was amended shortly before the hearing. The Plaintiffs had initially proposed as a common issue, "Is citalopram or may citalopram be teratogenic?", but the common issue ultimately put before Perell J. was framed as (at para 113): "From 1999, did the Defendants breach a duty to warn Canadian physicians and patients that citalopram is or may be teratogenic?"

[36] At para 125, Perell J. concluded that the amendment to the proposed common issue effectively removed the general causation question, ie. "is citalopram teratogenic", leaving only a proposed duty to warn common issue that in his view could not be certified as common (at paras 132-4):

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[20] See, eg TR Jan 9 3/6-13

> First, the duty to warn itself is not common across the class because commonality does not exist and cannot be semantically manufactured over such a broad range of dangers. Commonality does not exist in the case at bar because congenital malformations present a broad range of potential hazards ranging from the risk of minor human body imperfections of a cosmetic nature to major imperfections that destroy the quality of a person's life or that destroy life itself.
>
> As noted above, the adequacy of a warning depends upon the nature and gravity of the potential hazard and the nature and extent of any given warning will depend on what is reasonable having regard to all the facts and the circumstances relevant to the product in question. In the case there may be commonality for one or even some combinations of the more hazardous congenital malformations, but there is no conceivable commonality in warning about birth defects generally as if they were all of the same gravity.
>
> Second, the duty to warn issue is not common because the resolution of it will not avoid duplication of fact-finding or legal analysis, because its resolution is not capable of meaningful extrapolation to assist each Class Member, and because even if the duty to warn issue was resolved favourably for the Class Members, its resolution will not form a substantial part of each Class Member's case and very substantial individual inquiries will required for each Class Member claims. Put bluntly, the duty to warn issue does not connect the dots for a common issues trial that has any utility for a class proceeding that inevitably end with individual issues trials with very significant causation issues associated with the breach of the duty to warn.

[37] Even if the Plaintiff had retained the common issue initially formulated (ie., is citalopram teratogenic?), Price J. concluded that a resolution of the general causation question would not meaningfully advance the claims of individual plaintiffs (at para 139):

> Moreover, there was very serious problems with Ms. Price's original proposal of causation issues about general causation... [S]howing that there is some basis in fact for believing that citalopram is a teratogen only shows that some birth defects may be caused by citalopram and does not help in proving that the many and different congenital malformations in children born of mother's who had ingested Celexa were caused by citalopram.

[38] This conclusion is, in essence, the position of the GSK on the question of general causation in this Action. On appeal however, the Divisional Court disagreed with Perell J. on both points. With respect to the question of whether the general causation common issue had effectively been abandoned, the Court held, at paras 28 and 30, that the question of whether the defendants breached a duty to warn that citalopram is teratogenic included, necessarily, the question of whether citalopram was teratogenic. In short, the general causation question remained embedded in the new framing of the common issue. With respect to the general causation question itself, the Court held, at paras 29-30:

> The proposed common issue of whether Citalopram can cause birth defects contains a causation question that may be common to every plaintiff and class member. That issue is whether Citalopram is teratogenic at all. Can it cause any birth defects?

> Before one gets to whether Citalopram may cause a particular type of birth defect, first it must be found capable of causing any birth defects. This issue will turn on the same scientific evidence in every case. The same basic studies that are the precursors to inquiries into specific types of injury will be relevant...
>
> [Counsel for the plaintiff] submits further that it may be efficient for the question of general causation for each different type of injury alleged to be addressed at the common issue trial too. He argues that if the plaintiffs succeed in proving at the common issues trial that citalopram is not only teratogenic, but can cause a finite number of specific types of birth defects, then only plaintiffs who claim to have suffered those proven birth defects will go on to have individualized trials of specific causation and damages. Whether this might be accomplished by sub-class recognition and trials of general causation for each sub-class with or immediately following the common issues trial or by a different method is a question best left to the parties and the case management judge.

[39] GSK argues that ***Price DC*** does not impact its prior submissions and prior reliance on ***Price SC***:

> In GSK's submission, this appeal decision does not impact GSK's prior submissions. GSK's submissions with respect to the proposed common issue were not that the proposed common issue did not raise a causation issue; instead, GSK's submissions were and remain that there is no basis in fact that teratogens can cause congenital malformations on a class wide basis such that the proposed common issue does not advance any class members' claims.

[40] This may be a correct way of describing the issue on appeal in ***Price*** in the very narrowest terms, but it ignores what seems to me to be the sound reasoning set out in ***Price DC*** paras 29-30, quoted above. A fundamental objective of class proceedings is efficiency, and in the case at bar, as in ***Price***, before one gets to the question of whether paroxetine may cause a particular type of birth defect, it must first be found capable of causing any birth defects. In the case at bar, as in ***Price***, this issue will turn on the same scientific evidence in every case.

ii. Did the Defendants breach a duty to warn?

[41] GSK argues that, as the content and adequacy of any warning will necessarily depend on the evidence relating to general and specific causation, an assessment of the duty to warn will necessarily vary between class members. They cite ***Price (SC)*** at para 132:

> Commonality does not exist in the case at bar because congenital malformations present a broad range of potential hazards ranging from the risk of minor human body imperfections of a cosmetic nature to major imperfections that destroy the quality of a person's life or destroy that life itself.

[42] GSK further contends that changes to the product monograph over time mean that a determination of the adequacy of the warning received by one plaintiff at one point in time will

not inform the adequacy of the warning another plaintiff received at a different point in time[21], and that that Smith J's decision to certify the duty to warn common issue in ***Bartram*** is distinguishable:[22]

> Unlike in *Bartram*, where the Court was prepared to accept that GSK Canada's knowledge of the cardiovascular risk was a threshold question common for all class members who sustained cardiovascular injuries here, GSK's knowledge and responding duty to warn (if any) will have to be assessed with respect to each specific birth defect. As Dr. Scialli noted, birth defects included in the proposed class definition continue to not be referred to in the product monograph because the data does not indicate any connection between gestational exposure to Paxil and a risk of these outcomes.

[43] In ***Bartram***, Smith J. held at paras 38 and 41:

> 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...
>
> ...
>
> All potential class members and/or their treating doctors had to rely on the same published material. If there was a point at which developing knowledge made that material incomplete, misleading or inadequate, each class member may still have to separately prove that she was pregnant after that point and that, if fully informed, she could or would have safely stopped taking Paxil. However, that does not diminish the commonality of the threshold issue.

[44] While it is correct to observe that the proposed class in the case at bar is broader than ***Bartram***, which was limited to cardiovascular defects, I do not agree that this factor alone is sufficient to distinguish ***Bartram*** as it applies to the duty to warn. The product monograph in ***Bartram***, as here, changed over time (indeed it was the same product monograph as in the case at bar). I see no reason why the reasoning in ***Bartram*** could not be extended to those specific birth defects or categories of birth defects a common issues Justice identifies as having been caused or contributed to by paroxetine exposure *in utero* in the case at bar. Moreover, as the Plaintiffs point out, a proposition underlying the Plaintiffs' position with respect to the duty to warn is that whatever changes were made to the product monograph over time, they were not in fact material

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[21] DB3 para 13 referencing October 15, 2013 Affidavit of Mark Braham, at para 15. The Plaintiffs point out that there are factual issues with the Plaintiffs' assertion in this regard and the Affidavit of Mr. Braham appears to confuse the product monograph with a separate "Advisory": PB3 para 16.

[22] DB1 para 84

and as a result the warning was insufficient in the same way over the entire period. I therefore see no reason why the duty to warn issue cannot be certified as common.

iii. Punitive damages

[45] The punitive damage claim in ***Bartram (SC)*** was certified by Smith J. at para 45. He relied, in part, upon the decision of the British Columbia Court of Appeal in ***Chalmers v AMO Canada Company***, 2010 BCCA 560, wherein the Court held at para 31:

> Although the ultimate determination of the entitlement and quantification of punitive damages must be deferred until the conclusion of the individual trials, it does not follow, in my opinion, that no aspect of the claim of punitive damages should be certified as a common issue. It is my view that the question of whether the defendants' conduct was sufficiently reprehensible or high-handed to warrant punishment is capable of being determined as a common issue at the trial in this proceeding where the other common issues will be determined. The focus will be upon the defendants' conduct, and there is nothing in this case that will require a consideration of the individual circumstances of the class members in order to determine whether the defendants' conduct is deserving of punishment. The ultimate decision of whether punitive damages should be awarded, and the quantification of them, can be tried as a common issue following the completion of the individual trials.

[46] I agree, and therefore find that the claim for punitive damages may be certified as a common issue.

(e) Preferable Procedure

[47] As I have frequently observed in past certification cases, it is a common refrain among defendants in class certification proceedings that certification should be denied because individual issues will predominate. This is an appropriate factor to consider under s.5(2)(b) of the Act, but it is not, on its own, determinative. GSK argues that the individual issues in this case pose a substantial obstacle to certification. At para 105 of DB1, GSK lists individual issues as follows:

(a) individual causation, including with reference to maternal medical history, genetic history and lifestyle habits prior to pregnancy and whether those may have caused or contributed to the alleged outcome, as well timing of exposure to Paxil, ingestion of other medications or substances, diseases and illnesses, occupational exposures, and other environmental exposures;

(b) the benefit of the drug as part of any risk/benefit analysis, in particular the medical condition(s) for which the mother was prescribed Paxil and the severity of the condition(s) and the risks of non-treatment or under-treatment, which may involve evidence of treating physicians and psychiatrists;

(c) the state of knowledge of the potential risk for each outcome at the time that Paxil was prescribed and thus what warning, if any, should have been provided;

(d) particulars of the alleged birth defects of the child, including a precise description of the alleged defect, details of any other medical conditions the child may have

encountered, information needed to evaluate potential genetic causes of the defect, including the timing, nature and dose of all potentially teratogenic exposures; and

(e) the impact of the defect, and whether the defect has resulted in ongoing medical/health issues requiring ongoing care and, if so, the details and costs of such care, including medical and economic reports.

[48] With the possible exception of aspects of (d), the individual issues GSK cites will be implicated in every class proceeding involving pharmaceutical exposure and the duty to warn. Yet, as the Plaintiffs point out, these class proceedings are certified in Canada, not necessarily as a matter of routine, but with some regularity.

[49] In ***Markson v MBNA Canada Bank*** (2007), 85 OR (3d) 321 (CA), the Ontario Court of Appeal summarized the principles governing the question of preferability as follows:

(a) The preferability inquiry should be conducted through the lens of the three principal advantages of a class proceeding: judicial economy, access to justice and behaviour modification;

(b) "Preferable" is to be construed broadly and is meant to capture the two ideas of whether a class proceeding would be a fair, efficient and manageable method of advancing the claim and whether a class proceeding would be preferable to other procedures such as joinder, test cases, consolidation and any other means of resolving the dispute; and,

(c) The preferability determination must be made by looking at the common issues in context, meaning, the importance of the common issues must be taken into account in relation to the claims as a whole.

[50] The Defendants argue that a class proceeding will not be preferable if, at the end of the day, the class members remain faced with the same economic and practical hurdles that they faced at the outset. In ***Bartram***, Smith J. held at para 47:

> The common issues will require extensive discovery to determine the state of GSK's knowledge at various times, expert evidence on the general state of scientific knowledge and research at those same times, and expert evidence on the general causation issue. I can think of nothing that would be less efficient, more costly and more limiting of access to justice than requiring each class member to separately obtain and adduce the same evidence. Given the complexity and costliness of doing so, I doubt that the issues could be litigated in any procedure but a class action.

[51] The common issues the Plaintiffs seek to certify would be necessary and would materially advance any individual plaintiff's claim in an individual action. I agree with Smith J. that requiring individual plaintiffs adduce the evidence necessary to support the general causation and duty to warn claims framed in the proposed common issues would be inefficient and possibly prohibitively costly for individual plaintiffs. I therefore conclude that a class proceeding is the preferable procedure.

(f) Representative Plaintiff

[52] In oral argument [23], and in its DB1[24], the focus of GSK's submissions in regard to the adequacy of the PRP were on the proposed litigation plan[25] and the conduct of the MLG firm in prosecuting this action. In its DB3, GSK supplemented this argument by raising issues about the ability and willingness of the PRP, Ms. Singh, to prosecute the claim on behalf of the class.[26]

[53] With respect to the proposed litigation plan, it is correct that para 29, which addresses the individual issues claims procedure, at this point effectively fails to set out a process. This is not entirely surprising in light of GSK's position that individual claims and individual causation are the fundamental issues in this Certification Application. As Smith J. held in ***Bartram*** at para 50:

> The defendant objects to the proposed management plan, in part because it fails to fully address how the individual causation analysis is to be dealt with for each putative class member. I do not consider it either realistic or necessary to consider that issue in any detail at this stage. The individual issues will not need to be addressed at all unless the plaintiff succeeds on the trial of the common issues.

[54] With regard to the suitability of Ms. Singh as PRP, much of GSK's argument turns on the conduct of the MLG firm, which no longer represents the PRP, and on issues that arose between Ms. Singh and that firm. It appears that, at some point, Ms. Singh was of the view that her interests might be better advanced by way of an individual, rather than class proceeding. That appears no longer to be the case. In the wake of my decision in the Representation Action (2021 ABQB 316), it is now Ms. Singh's evidence that she wishes to remain as a representative plaintiff and to proceed with certification.[27]

[55] GSK further casts doubt on the ability of Ms. Singh as PRP and her Counsel to fund the class proceeding and/or any adverse costs awards. I agree with the Plaintiffs that the evidence in the substitution dispute regarding the indemnification of Ms. Singh by the Consortium provides sufficient basis in fact to permit certification. In the result, I conclude that Ms. Singh is an adequate representative plaintiff and there are no grounds to reject certification on this basis.

VI. Conclusion

[56] In the result, and based on the foregoing, the application to certify this proceeding as a class proceeding is granted. The class definition and common issues will be as set out herein at paras 1 and 2.

[57] Costs will follow the event in such amounts as may be agreed between Counsel, or as may be assess by an assessment officer under the Rules.

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[23] Jan 19 TR 81/6 – 85/11
[24] DB1 paras 114-123
[25]December 12, 2012 Affidavit of Fiona Singh, Exhibit C
[26] DB3 paras 34-42
[27] February 7, 2020 Affidavit of Fiona Singh, para 8

[58] As I will be retiring as a Justice of the Court on December 16, 2022 and will be *functus* after that, as Associate Chief Justice, I transfer case management to Justice D.B. Nixon for any matters that remain unresolved thereafter, arising out of this Decision.

Heard on the 9th day of January, 2019, with supplementary material filed on the Certification Application on June 30th, 2021 (Defendants) and July 30th, 2021 (Plaintiffs).
Dated at the City of Calgary, Alberta this 17th day of November, 2022.

J.D. Rooke
A.C.J.C.K.B.A.

Appearances:

C. Docken, M. Farrell, C Churko,
for the Plaintiffs

K. Findlay, S. Jenkins,
for the Defendants