IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *I.F. v. Gilead Sciences, Inc.,*
2024 BCSC 480

Date: 20240322
Docket: S214133
Registry: Vancouver

Between:

I.F. and P.S.

Plaintiffs

And

Gilead Sciences, Inc. and Gilead Sciences Canada Inc.

Defendants

Before: The Honourable Mr. Justice Brongers

Reasons for Judgment

Counsel for the Plaintiffs:	D. Klein N.C. Hartigan B.D. Ryan
Counsel for the Defendants:	R. Sutton K. Smiley P.S. Prosterman L.A. Wilson
Place and Date of Hearing:	Vancouver, B.C. September 26-28, 2023
Place and Date of Judgment:	Vancouver, B.C. March 22, 2024

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I. OVERVIEW

[1] I.F. and P.S. (the "Plaintiffs") are patients who took certain medicines to treat HIV/AIDS. They seek to have a proposed class action certified against the manufacturers of these medicines, the defendants Gilead Life Sciences, Inc. and its Canadian affiliate, Gilead Sciences Canada Inc. (collectively referenced as "Gilead").

[2] The Plaintiffs' theory of the case concerns Gilead's development and marketing of two pharmaceuticals: (1) tenofovir disoproxil fumarate ("TDF"); and (2) tenofovir alafenamide fumarate ("TAF"). TDF is effective in the management of HIV/AIDS but can damage patients' kidneys and bones. While it was developing TDF, Gilead was also working on TAF, an allegedly safer and more effective treatment for HIV/AIDS than TDF. Gilead nevertheless chose to first market TDF-based drugs and delay the development of TAF-based drugs. The Plaintiffs allege that Gilead did this to maximize profits from TDF-based drugs while they were still patent protected from competition, needlessly depriving HIV/AIDS patients from earlier access to the less harmful TAF-based drugs. The Plaintiffs say that Gilead ought not to have sold TDF drugs in Canada given that Gilead knew that TAF was a safer alternative to TDF and that Gilead should therefore be found liable in negligence for its negligent design of TDF drugs.

[3] Gilead disputes the Plaintiffs' theory. It says that both TDF and TAF effectively treat HIV/AIDS and that both received approval from government regulators even though they have different risk/benefit profiles and their development occurred on different timelines for legitimate reasons. TDF-based drugs and TAF-based drugs are still marketed and safely used today. As TDF is not defective and Gilead provided warnings about its side effects, Gilead cannot be held liable for negligence in selling TDF-based drugs regardless of how, why, and when TAF was developed.

[4] The primary issue before the court is whether the Plaintiffs' proposed claim discloses a reasonable cause of action and a genuine issue for trial. If it does not,

the claim must be dismissed at this stage. If it does, then the secondary issue of whether the claim should be certified as a class action must be addressed.

[5] For the reasons set out below, I find that the Plaintiffs have set out a reasonable cause of action for negligent design that raises genuine issues for trial. The Plaintiffs have also met all of the statutory requirements for certification. While the Plaintiffs' claim may ultimately be dismissed when it is fully addressed on its merits, it deserves to be certified as a class proceeding at this time.

II. BACKGROUND

A) Procedural Background

[6] The Plaintiffs filed their original notice of civil claim on April 19, 2021. They also prepared a notice of application for certification of their proposed class proceeding dated July 5, 2022.

[7] Gilead responded to the Plaintiffs' proposed class action by preparing an unfiled response to civil claim and an application to dismiss, both of which were dated December 7, 2022. The application to dismiss is based on Rule 9-5 (the application to strike rule) and Rule 9-6 (the application for summary judgment rule). Gilead also prepared an application response to the Plaintiffs' certification application dated February 21, 2023. The Plaintiffs answered by preparing an application response to Gilead's application to dismiss dated August 14, 2023.

[8] On August 22, 2023, the Plaintiffs filed an application for leave to file an additional affidavit. Gilead's application response indicates that Gilead takes no position on whether such leave should be granted.

[9] The three applications – the Plaintiffs' certification application, Gilead's application to dismiss, and the Plaintiffs' leave to file an additional affidavit application – were heard together over three days from September 26 to 28, 2023.

[10] The parties' joint application record includes a total of 15 affidavits prepared by the following 13 individuals:

a) I.F.: I.F. is a plaintiff. I.F. deposes to first using a TDF-based drug and then switching to a TAF-based drug. I.F. also deposes to a willingness to serve as a representative plaintiff.

b) J.F.: J.F. is a putative class member. J.F. deposes to first using a TDF-based drug and then switching to a TAF-based drug. J.F. also deposes to a willingness to serve as an additional representative plaintiff.

c) Dr. Vincent Covelli: Dr. Covelli is a medical doctor and infectious diseases physician who was retained by the Plaintiffs to prepare an expert report. Dr. Covelli's report contains opinion evidence regarding TDF and TAF, notably in relation to the mechanisms by which they work, the medical conditions for which they are prescribed, and their efficacy, toxicity, and side effects.

d) Dr. Richard Sutton: Dr. Sutton is a medical doctor and professor of infectious diseases at Yale University who was retained by the Plaintiffs to prepare an expert report. Dr. Sutton's report contains opinion evidence regarding what was known prior to 2010 on the risks of using TDF and whether TDF remains a first-line treatment now that TAF is available.

e) Dr. Jack Finchman: Dr. Finchman is a pharmacist and professor at the University of Arizona who was retained by the Plaintiffs to prepare an expert report. Dr. Finchman's report contains opinion evidence regarding the regulatory approval process in the United States for pharmaceutical medications such as TDF and TAF.

f) Stanley North: Mr. North is a pharmaceutical regulatory affairs consultant who was retained by the Plaintiffs to prepare an expert report. Mr. North's report contains opinion evidence regarding the regulatory approval process in Canada for pharmaceutical medications such as TDF and TAF.

g) Eduardo Tanjuatco: Mr. Tanjuatco is a paralegal employed by the Plaintiffs' law firm. Mr. Tanjuatco prepared two affidavits based on information and belief in respect of this proceeding, which include publicly available

documents related to the Plaintiffs' action against Gilead that are attached as exhibits. As Mr. Tanjuatco's second affidavit was made after the applicable deadline set out in my case plan order of September 9, 2022, leave for its late filing is being sought by the Plaintiffs.

h) Dr. David Pitrak: Dr. Pitrak is a medical doctor and retired professor of medicine at the University of Chicago who was retained by Gilead to prepare an expert report. Dr. Pitrak's report contains opinion evidence on the history of the HIV/AIDS epidemic and treatment options, including TDF and TAF.

i) Karen Feltmate: Ms. Feltmate is a pharmaceutical product development and business strategy consultant who was retained by Gilead to prepare an expert report. Ms. Feltmate's report contains opinion evidence regarding the regulatory approval process in Canada for pharmaceutical medications, including TDF and TAF.

j) Dr. Robert Dow: Dr. Dow is a pharmaceutical executive who was retained by Gilead to prepare an expert report. Dr. Dow's report contains opinion evidence regarding the development of TDF and TAF.

k) Dr. Brian Conway: Dr. Conway is a medical doctor, president and medical director of the Vancouver Infectious Diseases Centre, and a professor at Simon Fraser University who was retained by Gilead to prepare an expert report. Dr. Conway's report contains opinion evidence on the nature and history of treatment and management of HIV, including the use of TDF and TAF.

l) Sheila Kutty: Ms. Kutty is the head of regulatory affairs and senior director at Gilead Sciences Canada Inc. Ms. Kutty prepared two affidavits containing information about Health Canada approvals of Gilead's TDF and TAF drugs, as well as information about TDF and TAF prescriptions and sales.

m) Robin Cardillo: Ms. Cardillo is a paralegal employed by Gilead's law firm. Ms. Cardillo's affidavit attaches as exhibits documents from the regulatory files of Gilead Sciences Canada Inc.

[11] Counsel for both parties prepared helpful written submissions in respect of the contested matters of certification and dismissal. The Plaintiffs' material also contains a draft amended notice of civil claim ("ANOCC"). While this new pleading has not been formally filed, the certification and dismissal applications proceeded with the parties' common understanding that the Plaintiffs' proposed class action is as pleaded in the ANOCC.

B) Factual Background

[12] The factual background to this matter that is set out here is drawn from the ANOCC and the affidavits filed by the parties, all of which I have considered. They include the tardy second affidavit of Mr. Tanjuatco for which leave to file is being sought by the Plaintiffs. That affidavit contains relevant information that was not discovered until after the filing deadline set out in my case plan order had expired, and Gilead is not opposed to its admission. I am therefore satisfied that such leave should be granted.

1. The Plaintiffs

[13] I.F. is the first named plaintiff in the ANOCC. I.F. made an affidavit stating that I.F. is a resident of British Columbia who was diagnosed with human immunodeficiency virus (HIV) in the early 1990s. I.F. was on several antiviral medications before being prescribed a TDF drug manufactured by Gilead called Truvada in or around 2007. I.F. continued to take Truvada until early 2020 when I.F.'s prescription was changed to a TAF drug manufactured by Gilead called Biktarvy. This was due to concerns about I.F.'s long-term kidney health. I.F. has agreed to act as a representative of the proposed class for this proceeding. I.F. wishes to be identified using initials because I.F. has suffered discrimination as a result of being diagnosed with HIV and acquired immunodeficiency syndrome (AIDS).

[14] P.S. is the second named plaintiff in the ANOCC. Unlike I.F., P.S. did not make an affidavit in support of this application. There is therefore no evidence before the court to substantiate the Plaintiffs' pleading that P.S. has HIV, initially took a TDF drug, and then switched to a TAF drug since P.S. was suffering from decreasing kidney function. There is also no evidence regarding what role P.S. intends to play in this litigation, or why P.S. has been identified by initials rather than by name.

[15] Instead, the Plaintiffs tendered an affidavit made by J.F. It states that J.F. is a resident of Ontario who was diagnosed with HIV in October 2003. J.F. was on several antiviral medications before being prescribed a TDF drug manufactured by Gilead called Atripla in June 2009. J.F. continued to take Atripla until August 2018 when J.F. followed a doctor's recommendation to switch to Gilead's TAF drug Biktarvy in order to improve bone health and reduce bone resorption. J.F. deposes to a willingness to serve as an additional representative plaintiff if the court is of the view that this would be appropriate. The affidavit is silent on why J.F. is identified by initials rather than by name.

2. The Defendants

[16] Gilead Sciences, Inc. is an American biopharmaceutical company that works to discover, develop, and commercialize treatments for various human diseases and conditions, including HIV/AIDS. While it is incorporated under the laws of Delaware, its headquarters are in Foster City, California.

[17] Gilead Sciences Canada Inc. is the Canadian affiliate of Gilead Sciences, Inc. While it is registered under the laws of New Brunswick, its headquarters are in Mississauga, Ontario.

3. The Pharmaceuticals

[18] In 1991, Gilead obtained the patent rights to tenofovir. It is a drug that inhibits HIV enzyme replication and is a critical component in several antiretroviral medication therapies for HIV.

[19] Tenofovir is available in two prodrug formulations: (1) TDF; and (2) TAF. A prodrug is a compound that is metabolized or converted within the body into a pharmacologically active drug.

[20] The manner by which these two prodrugs convert to tenofovir is different. TDF is converted to tenofovir in the plasma outside of cells. TAF is converted to tenofovir intracellularly.

[21] Gilead obtained the patent rights to TDF in 1997. Gilead developed and brought to market five TDF-based drugs in Canada, as follows:

a) Viread: A drug that contains only TDF. Viread was approved for use in Canada in 2003 subject to conditions that were subsequently removed in 2005.

b) Truvada: A drug that contains TDF and another Gilead antiretroviral drug known as FTC/Emtriva. Truvada was approved for use in Canada in 2006.

c) Atripla: A drug that contains TDF and an anti-HIV drug made by Bristol-Myers Squibb known as EFV/efavirenz/Sustiva. Atripla was approved for use in Canada in 2007.

d) Complera: A drug that contains TDF, FTC/Emtriva, and rilpivirine (a drug similar to EFV/efavirenz/Sustiva). Complera was approved for use in Canada in 2011.

e) Stribild: A drug that contains TDF, FTC/Emtriva, elvitegravir (similar to rilpivirine and EFV/efavirenz/Sustiva), and cobicistat. Stribild was approved for use in Canada in 2012.

[22] Gilead's patent for TDF gave it exclusivity over TDF-based drugs until 2017, at which point generic manufacturers were permitted to market TDF-based drugs as well.

[23] In or around 1998, Gilead began research on TAF. In 2004, Gilead announced publicly that it was discontinuing its development of TAF. In 2010, however, Gilead reported publicly that it was proceeding to develop TAF once again.

[24] Gilead ultimately developed and brought to market four TAF-based drugs in Canada, as follows:

a) Genvoya: A drug that contains TAF, FTC/Emtriva, elvitegravir, and cobicistat. It is a similar drug to Stribild but contains TAF instead of TDF. Genvoya was approved for use in Canada in 2015.

b) Descovy: A drug that contains TAF and FTC/Emtriva. It is a similar drug to Truvada but contains TAF instead of TDF. Descovy was approved for use in Canada in 2016.

c) Odefsey: A drug that contains TAF, FTC/Emtriva, and rilipivirine. It is a similar drug to Complera but contains TAF instead of TDF. Odefsey was approved for use in Canada in 2017.

d) Biktarvy: A drug that contains TAF, FTC/Emtriva, and bictegravir. Biktarvy was approved for use in Canada in 2018.

[25] Both of Gilead's prodrugs - TDF and TAF – deliver tenofovir to the human body in a manner that inhibits HIV replication effectively in patients. However, TAF's intracellular conversion method leads to lower circulating plasma levels than TDF's conversion method which occurs outside of the cells. Accordingly, the TAF conversion method reduces a patient's exposure to kidney and bone toxicities when compared to the TDF conversion method. On the other hand, there are indications that TAF use may be associated with greater weight gain and higher levels of blood cholesterol in patients as compared to TDF.

[26] On July 22, 2023, the online edition of the New York Times posted an article titled "How a Drugmaker Profited by Slow-Walking a Promising H.I.V. Therapy". The article refers to Gilead's internal documents that had been produced in tenofovir

litigation in the United States, documents that can be accessed publicly through the article's online links. The documents include material suggesting that Gilead may have stopped the development of TAF in the early 2000s in order to not hurt sales of its TDF drug Viread. They also suggest that Gilead was aware that continuing or restarting the development of TAF could effectively result in extended patent protection for Gilead's tenofovir drugs.

III. ANALYTICAL FRAMEWORK

[27] The procedural law principles that apply to the two contested applications that are before the court are not in dispute.

[28] The Plaintiffs' certification application is subject to the legislative framework set out in the *Class Proceedings Act,* R.S.B.C. 1996, c. 50 [*CPA*]. Section 4(1) of the *CPA* sets out the five conditions that must be present for a proposed class action to be certified. It is written in mandatory terms which do not allow for judicial discretion to refuse to grant certification if all of the requirements are met. Its specific wording is:

> 4(1) Subject to subsections (3) and (4), the court must certify a proceeding as a class proceeding on an application under section 2 or 3 if all of the following requirements are met:
>
> (a) the pleadings disclose a cause of action;
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> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
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> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
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> (e) there is a representative plaintiff who
>
> (i) would fairly and adequately represent the interests of the class,
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> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
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> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[29] The first condition for certification (set out at s. 4(1)(a) of the *CPA*) is that the pleadings disclose a cause of action. The test to be applied is the same one that is used on an application to strike, where all facts pleaded are assumed to be true. The plaintiffs will satisfy this condition unless it is plain and obvious that their claim cannot succeed: *Pro-Sys Consultants Ltd. v. Microsoft Corporation,* 2013 SCC 57 at para. 63 [*Pro-Sys Consultants*].

[30] For the remaining four conditions for certification (set out at ss. 4(1)(b) to (e) of the *CPA*), the Plaintiffs must demonstrate that there is "some basis in fact" for a finding that the conditions have been met. While this demonstration does not entail an assessment of the merits of the proposed claim, it must be done through evidence and not simply on the basis of the pleadings: *Hollick v. Toronto (City),* 2001 SCC 68 at para. 25 [*Hollick*].

[31] With respect to Gilead's application to dismiss, as has already been noted, there are two facets to it.

[32] The first facet is an application to strike based on an assertion that the Plaintiffs' proposed class action discloses no reasonable claim as per Rule 9-5(1)(a) of the *Supreme Court Civil Rules,* B.C. Reg. 168/2009 [*Rules*]. In *BNSF Railway Company v. Teck Metals Ltd.,* 2016 BCCA 350 at para. 2, our Court of Appeal set out the applicable test for such applications as follows:

> [2] It is settled law that an application made by a defendant to have a plaintiff's pleadings struck is brought on the basis that the action(s) asserted therein cannot succeed as a matter of law. The chambers judge considers only the plaintiff's pleadings, and assumes them to be true. The threshold to be met by the plaintiff is a low one; an order striking out pleadings is made only in "plain and obvious" cases. (*See A.G. of the Duchy of Lancaster v. London & North Western Railway Co*. [1892] 3 Ch. 274; Hunt v. Carey Canada Inc. 1990 CanLII 90 (SCC), [1990] 2 S.C.R. 959; *International Taoist Church of Canada v. Ching Chung Taoist Association of Hong Kong Ltd.* 2011 BCCA 149 at para. 9.) Courts are enjoined not to rule out pleadings merely because the cause of action asserted is novel. If the claim is arguable, or can be amended to be so, it should be permitted to proceed: see *R. v. Imperial Tobacco Ltd.* 2011 SCC 42 at para. 21.

[33] The second facet is an application for summary judgment based on an assertion that the Plaintiffs' proposed class action does not give rise to a genuine issue for trial as per Rule 9-6 of the *Rules.* In *Beach Estate v. Beach,* 2019 BCCA 277 at paras. 48-49 our Court of Appeal set out the applicable test for such applications as follows:

> [48] Rule 9-5 is a challenge on the pleadings. Rule 9-6 is a challenge on a limited review of evidence. A defendant can succeed on a Rule 9-6 application by showing the case pleaded by the plaintiff is unsound or by adducing sworn evidence that gives a complete answer to the plaintiff's case: *B & L Holdings Inc. v. SNFW Fitness BC Ltd.*, 2018 BCCA 221 at para. 46, quoting *Progressive Construction Ltd. v. Newton* (1981), 1980 CanLII 493 (BC SC), 25 B.C.L.R. 330 at 335; *International Taoist Church of Canada v. Ching Chong Taoist Association of Hong Kong Ltd.*, 2011 BCCA 149 at para 14. Such evidence generally is adduced in the form of an affidavit. If the court is satisfied that the plaintiff is bound to lose or the claim has no chance of success, the defendant must succeed on the Rule 9-6 application: *Canada v. Lameman*, 2008 SCC 14 at paras. 10–11. Conversely, if the plaintiff submits evidence contradicting the defendant's evidence in some material respect or if the defendant's evidence in support of the Rule 9-6 application fails to meet all of the causes of action raised by the plaintiff's pleadings, the application must be dismissed: *B & L Holdings Inc*. at para. 46, quoting *Progressive Construction Ltd.* at 335.
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> [49] Although an application under Rule 9-6 invokes the court's consideration of evidence, it is not a summary trial: *Century Services Inc. v. LeRoy,* 2015 BCCA 120 at para. 32. The judge is not permitted to weigh evidence on a Rule 9-6 application beyond determining whether it is incontrovertible: any further weighing may only be done in a trial: *Tran v. Le,* 2017 BCCA 222; *Skybridge Investments Ltd. v. Metro Motors Ltd.*, 2006 BCCA 500 at paras. 8-12.

[34] There is no question that Gilead's application to dismiss can be presented at the same time as the Plaintiffs' certification application: *Dussiaume v. Sandoz Canada Inc.,* 2023 BCSC 795 and *Pantusa v. Parkland Fuel Corporation,* 2022 BCSC 322. Indeed, there is considerable logic in doing so given that Gilead takes the position that the Plaintiffs' proposed class proceeding does not disclose a valid cause of action, and because this issue is relevant to both the first condition for certification (s. 4(1)(a) of the *CPA*) and the application to strike (Rule 9-5(1)(a) of the *Rules*). Furthermore, if Gilead's application to dismiss is allowed, there will then be no proposed class action left to consider and the Plaintiffs' certification application will necessarily have to be dismissed.

[35] Accordingly, the analytical framework for these applications will be as follows.

[36] First, I will analyze the Plaintiffs' proposed cause of action as set out in the ANOCC in order to properly characterize it.

[37] Second, I will consider the question of whether it is plain and obvious that the Plaintiffs' claim cannot succeed and, if the answer is no, the question of whether the Plaintiffs' claim raises no genuine issue for trial. The former question will be assessed by reference to just the ANOCC, while the latter question will entail consideration of the parties' evidence. If either of these two questions are answered in the affirmative, the Plaintiffs' claim will be dismissed.

[38] If both questions are answered in the negative, however, this will mean that I am satisfied that the first condition for certification – a viable cause of action - has been met. I will then proceed to the third and final stage of the analysis. This will entail a consideration of the four remaining conditions for certification: (1) identifiable class, (2) common issues, (3) preferable procedure, and (4) suitable representative plaintiff and litigation plan. If all four are established on the evidence, then the proposed class action will be certified.

IV. THE PROPOSED CAUSE OF ACTION

A) Characterization of the Proposed Cause of Action

[39] The Plaintiffs submit that the ANOCC sets out a reasonable cause of action in negligence generally and for negligent design in particular.

[40] Specifically, the Plaintiffs allege that Gilead was negligent in designing, testing, manufacturing, marketing, labelling, promoting, distributing, importing and selling TDF drugs. The Plaintiffs say that Gilead introduced these drugs into the stream of commerce in Canada knowing that the adverse effects related to these drugs would cause foreseeable injury to the Plaintiffs and class members. In addition, Gilead is said to have known at the time the TDF drugs were commercialized in Canada that TAF was a safer alternative to TDF. Yet Gilead

distributed, marketed, and sold the TDF drugs in Canada while withholding the TAF drugs, whose alternative design made TAF drugs safer than TDF drugs.

[41] While Gilead takes issue with whether the Plaintiffs' proposed claim is reasonable and well-founded, Gilead does not dispute that the Plaintiffs are attempting to advance an action for negligent design in respect of Gilead's TDF drugs.

[42] I also agree with the Plaintiffs' characterization. Their proposed cause of action is a negligence tort claim in respect of Gilead's alleged negligent design of the TDF drugs that were marketed to and used by the Plaintiffs and others in Canada.

B) The Law of Negligence and Negligent Design

[43] There are four elements that a plaintiff must establish in order to succeed in a negligence claim: (1) that the defendant owed a duty of care to the plaintiff; (2) that the defendant breached that duty by failing to observe the applicable standard of care; (3) that the plaintiff sustained damage; and (4) that such damage was caused, in fact and in law, by the defendant's breach: *1688782 Ontario Inc. v. Maple Leaf Foods Inc.,* 2020 SCC 35 at para. 18.

[44] Canadian jurisprudence has also recognized that for negligence claims directed at product manufacturers, there are certain specific factors that must be considered. These factors will depend upon the "category" of product liability negligence claim that is being advanced. In *Wise v. Abbott Laboratories, Limited,* 2016 ONSC 7275 at para. 339, Justice Perell of the Ontario Superior Court identified four such categories:

1) defective product claims (e.g., *Donoghue v. Stevenson,* [1932] A.C. 562 (H.L.));

2) duty to warn of inherent product use danger claims (e.g., *Hollis v. Dow Corning Corp.,* [1995] 4 S.C.R. 634);

3) negligent design claims (e.g., *Kreutner v. Waterloo Oxford Co-operative Inc.* (2000), 50 O.R. (3d) 140 (C.A.) at para. 8); and

4) pure economic loss claims for the cost of repairing dangerous products (e.g., *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co. Ltd.,* [1995] 1 S.C.R. 85).

[45] The proposed class proceeding in the case at bar falls within the third category: negligent design claims.

[46] Our Court of Appeal very recently had occasion to comprehensively set out the legal principles applicable to negligent design claims in *Ding v. Canam Super Vacation Inc.,* 2024 BCCA 102 [*Ding*]. Writing for a unanimous division, Justice Fisher explained them as follows at paras. 30-35:

> [30] The legal principles applicable to a claim in negligent design are not disputed. A manufacturer has a duty of care to avoid safety risks and to make products that are reasonably safe for their intended purpose. The mere fact that a manufacturer could have used a safer design does not automatically result in liability. A design must be one that is reasonable in the circumstances; a manufacturer is required to use reasonable care to eliminate any unreasonable risk of foreseeable harm: *St Isidore Co-op Limited v. AG Growth International Inc.*, 2020 ABCA 447 at paras. 20, 22; *Daishowa-Marubeni International Ltd. v. Toshiba International Corporation*, 2010 ABQB 627 at para. 38.
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> [31] To succeed in a claim for negligent design, a plaintiff must identify a design defect and establish that (1) the defect created a substantial likelihood of harm, and (2) there exists an alternative design that is safer and economically feasible to manufacture: *Valeant Canada LP/Valeant Canada S.E.C. v. British Columbia*, 2022 BCCA 366 at para. 116; *Kreutner v. Waterloo Oxford Co-Operative Inc*. (2000), 50 O.R. (3d) 140 at para. 8 (C.A.). These requirements are the essential ingredients of a claim in negligent design of a product, which guide a determination of whether a design is reasonable in the circumstances, and more particularly, whether a manufacturer has met the standard of care by using reasonable care to avoid an unreasonable risk of foreseeable harm.
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> [32] In determining whether a design is reasonable, the court is to apply a "risk utility" analysis, in which the risks inherent in the product as designed are balanced against the risks inherent in a safer, alternate design, considering the utility and cost of each. Factors to be considered in conducting this exercise include the utility of the product, the nature of the product in terms of the likelihood it will cause injury, the availability of a safer design, the potential for designing and manufacturing a safer product that

remains functional and reasonably priced, the ability of the plaintiff to have avoided injury with careful use of the product, the degree of awareness of the potential danger of the product that reasonably can be attributed to the plaintiff, and the manufacturer's ability to spread any costs related to improving the safety of the design: *St Isidore* at para. 21; *Daishowa-Marubeni* at para. 39; *Burr v. Tecumseh Products of Canada Limited*, 2023 ONCA 135 at paras. 57–58; *Tabrizi v. Whallon Machine Inc.*, 1996 CanLII 3532 at para. 36 (B.C.S.C.).

[33] The harm must be reasonably foreseeable. A manufacturer can only be held liable if the product in question had a design defect based on a safety risk the manufacturer either knew or ought to have known about at the time of manufacture (or a risk that when later discovered, was not addressed): *St Isidore* at para. 23; *Burr* at para. 59. In making this assessment, the court will consider the state of knowledge and technology at the time the product was manufactured and should hold the manufacturer to the same level of knowledge as an expert in its field: *St Isidore* at para. 23.

[34] Finally, whether a manufacturer has created an unreasonable risk of harm is measured by the facts of each case and includes consideration of the likelihood of a known or foreseeable harm, the gravity of the harm, and the burden or cost that would be incurred to prevent the harm. External factors such as industry and regulatory standards may also be relevant, but are neither determinative nor co-extensive: *Ryan v. Victoria (City)*, [1999] 1 S.C.R. 201 at paras. 28–29. As Justice Major stated in *Ryan*:

> [29] Legislative standards are relevant to the common law standard of care, but the two are not necessarily co-extensive. The fact that a statute prescribes or prohibits certain activities may constitute evidence of reasonable conduct in a given situation, but it does not extinguish the underlying obligation of reasonableness … Thus, a statutory breach does not automatically give rise to civil liability; it is merely some evidence of negligence. … By the same token, mere compliance with a statute does not, in and of itself, preclude a finding of civil liability … Statutory standards can, however, be highly relevant to the assessment of reasonable conduct in a particular case, and in fact may render reasonable an act or omission which would otherwise appear to be negligent. This allows courts to consider the legislative framework in which people and companies must operate, while at the same time recognizing that one cannot avoid the underlying obligation of reasonable care simply by discharging statutory duties.
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> [Emphasis added.]

[35] *Ryan* did not involve a claim of negligent design but these principles apply equally to such claims. Prévost, as a manufacturer of motor coaches, has a duty to minimize the harm that may result from accidents and to design its vehicles to make them reasonably crashworthy. I would endorse this statement made by Justice Linden in *Gallant v. Beitz* (1983), 148 D.L.R. (3d) 522 at 525 (Ont. H.C.J.):

> … Since motor vehicle manufacturers know or should know that many of their vehicles will be involved in collisions and that many people will be injured in those crashes, they must turn their minds to this matter during the process of planning the designs of their vehicles and they must employ reasonable efforts to reduce any risk to life and limb that may be inherent in the design of their products.

[47] Based on *Ding* and the jurisprudence cited therein, I conclude that in order for a pleading to set out a reasonable cause of action in negligent design, the pleading must set out material facts to show that:

a) the defendant manufacturer owed a duty of care to the plaintiff;

b) the defendant manufacturer breached that duty by failing to observe the applicable standard of care because:

   i. the manufacturer knowingly marketed a product that has a design defect;

   ii. the design defect created a substantial likelihood of harm;

   iii. there existed an alternative design that was safer and economically feasible to manufacture; and

   iv. based on a risk-utility analysis, the foreseeable risks associated with the product's design outweighed the utility of the chosen design;

c) the plaintiff sustained damage; and

d) such damage was caused, in fact, and in law, by the defendant manufacturer's breach of the duty of care.

C) Reasonableness of Proposed Cause of Action

[48] On my review of the ANOCC, there is no question that it sets out the necessary material facts to establish the first, third, and fourth elements of a reasonable negligence claim for negligent design as identified in the preceding paragraph.

[49] The first element is the existence of a duty of care. The Plaintiffs plead that they are HIV-positive, were prescribed TDF-based drugs manufactured by Gilead, and that they took these drugs. There can be no doubt that Gilead owes a duty of care to persons who were prescribed and consumed medicine that Gilead

manufactures. This is properly conceded by Gilead in its unfiled response to civil claim. The first element of the Plaintiffs' proposed negligence claim is present.

[50] The third and fourth elements are the sustaining of damages by a plaintiff caused by a defendant manufacturer. Here, the Plaintiffs plead at para. 32 of the ANOCC that they suffered injuries by consuming TDF manufactured by Gilead:

> 32. As a result of taking the TDF, the plaintiffs and Class Members suffered harm and injuries, including, but not limited to decreased kidney function, renal failure, end-stage renal disease, renal insufficiency/impairment, chronic kidney disease, tubular dysfunction, chronic kidney disease, Fanconi syndrome, reduced bone density, bone breaks/fractures, bone malformation, and tooth loss.

[51] Assuming that this assertion is true, as I must, the Plaintiffs have shown that the third and fourth elements of their proposed negligence claim are present as well.

[52] The remaining element to be established is the second one: a breach of the duty of care owed to the Plaintiffs. Paragraphs 2-4 and 16-26 of the ANOCC contain specific pleadings of material fact that address Gilead's alleged breach:

> 2. In 1991, Gilead Sciences, Inc., acquired the exclusive rights to develop, manufacture, distribute, and sell tenofovir based medication for the treatment of HIV/AIDS. Between 1997 and 2001, Gilead Sciences, Inc. developed medications containing the prodrug TDF which converts to tenofovir (the active compound in the treatment of HIV/AIDS) once in the body. Starting in 2001, Gilead Sciences, Inc. brought TDF based medication to market in the US. Beginning in 2003, Gilead Sciences, Inc. and Gilead Sciences Canada Inc. brought the medications to market in Canada.
>
> 3. In and around 1998 while developing TDF, Gilead Sciences Inc. discovered and began developing another formulation called tenofovir alafenamide fumarate ("TAF") which at that time was referred to as GS-7340. Like TDF, TAF was a prodrug that converted to tenofovir within the body. Gilead Sciences, Inc. discovered that TAF was a safer alternative to TDF. TAF was more efficacious and less toxic to kidneys and bones. Despite knowing of the disparity in safety and effectiveness between TAF and TDF, Gilead Sciences, Inc. and Gilead Sciences Canada Inc. delayed and withheld the development, marketing and sale of TAF medications in order to maximize profits on the existing TDF patents.
>
> 4. The defendants had a duty to provide patients with the safest drug available, but deliberately chose to withhold TAF and instead sell inferior TDF medications first and for an extended period of time. Shortly before the TDF patent expired, the defendants sought to retain their market share of tenofovir based therapies by strategically applying for approval of TAF medications

and brought the patented formula to market as “new” and “novel” drugs in Canada starting in 2016. As a result of the defendants’ actions, patients in Canada were exposed to the more toxic and dangerous form of the drug for over a decade. These patients, including the plaintiffs, unwittingly and needlessly suffered permanent, debilitating, and sometimes fatal kidney and bone damage as a result.

...

16. The risks associated with tenofovir were well known to Gilead from the early stages of development. At the time Gilead began developing and testing the compounds, they were aware of tenofovir’s propensity to cause renal and bone injuries because of its biochemical similarity to at least two other antiretroviral drugs developed by Gilead – cidofovir and adefovir. Those drugs, like tenofovir, belong to the molecular class of acyclic nucleoside phosphates and are highly nephrotoxic.

17. Initial studies conducted by Gilead from approximately 1993 through 2001 demonstrated that while TDF was converted into tenofovir following oral ingestion, the amount of active tenofovir absorbed into the bloodstream was disproportionately low compared to the dose of TDF administered. Gilead determined that a 300-milligram dose was the lowest amount of TDF that could be administered to achieve the desired inhibition of HIV replication. This resulted in abnormally high concentrations of active tenofovir in the kidneys, which inhibited the kidneys’ ability to function properly and contributed to mineral losses that precede bone and tooth loss.

18. By the time TDF began being marketed in Canada in 2003, Gilead knew or should have known that TAF was a safer prodrug form of tenofovir with the same antiretroviral effectiveness. TAF produced significantly lower concentrations of active tenofovir in the kidneys, which in turn decreased the risk of renal injuries, as well as bone and tooth loss, when compared to TDF.

19. Between 2001 and 2004, Gilead conducted Phase I/II human studies of TAF. Results confirmed that TAF had a greater potency than TDF and was less toxic. It was clear that TAF could replace TDF. When Gilead Canada was formed in 2003 for the purposes of seeking regulatory approval, marketing, distributing, and selling tenofovir based drugs in Canada, it was aware or should have been aware of this knowledge.

20. In 2004, after completing Phase I/II studies, Gilead opted to delay and withhold the commercial development of TAF by discontinuing human testing. Meanwhile, Gilead secured patents related to TAF use in combating HIV.

21. Gilead delayed human testing of TAF based medications until 2011, approximately 4 years before the TDF patent was set to expire. In 2012, Gilead resumed Phase II testing of TAF, and began Phase III testing in 2013. In 2015, Gilead submitted the first commercial formulation of TAF to the US Federal Drug Administration.

22. To maximize profits on tenofovir-based antiretroviral medications, Gilead and Gilead Canada intentionally, knowingly, willfully, recklessly, and carelessly devised a scheme whereby they abandoned the immediate testing and commercial development of TAF in favor of the less effective, less safe TDF.

> 23. From 2004 until 2015, Gilead and Gilead Canada monopolized the market for tenofovir-based antiretroviral medications in Canada by designing, manufacturing, marketing, distributing, and selling five different TDF medications in Canada:
>
> a. Viread (approved for use in Canada in March, 2003);
>
> b. Truvada (approved for use in Canada in January, 2006);
>
> c. Atripla (approved for use in Canada in October, 2007);
>
> d. Complera (approved for use in Canada in September, 2011); and
>
> e. Stribild (approved for use in Canada in November, 2012).
>
> 24. Gilead Canada patented TDF in Canada and sought regulatory approval from Health Canada for each of these drugs, except Atripla which was submitted by Gilead Sciences, LLC.
>
> 25. During this period, Gilead and Gilead Canada continued to generate and receive data further corroborating their knowledge that TDF is highly nephrotoxic in comparison to TAF, and is more likely to cause significant renal, bone, and tooth injuries. Yet Gilead and Gilead Canada did not resume commercial development of TAF based medication until 2011.
>
> 26. Gilead and Gilead Canada knew that the safer medication would cut into sales of TDF in Canada; if TAF was available for sale, fewer people would purchase the less-safe TDF. Gilead and Gilead Canada sought to maximize profits by delaying the commercial development of TAF until the TDF patent was close to expiring.

[53] When the ANOCC is read as a whole with particular reference to these specific paragraphs, it is apparent that the pleading sets out sufficient material facts that, if proven, would show that Gilead breached its duty of care to the Plaintiffs.

[54] In particular, the facts as pleaded indicate that Gilead knew that TDF - its first prodrug for administering tenofovir - has a “design defect” that creates a substantial risk of harm to persons who take TDF. This is because the mechanism by which TDF converts into tenofovir has a propensity to cause such persons kidney, bone, and tooth damage. At the same time, Gilead also knew of an alternative design for its tenofovir prodrug, namely, TAF. The alternative TAF design does not give rise to the health risks posed by TDF.

[55] Furthermore, the Plaintiffs’ pleading sets out facts indicating that the alternative TAF design allows for the manufacture of a safer yet economically feasible tenofovir prodrug when compared to the TDF design. Based on a risk-utility

analysis, these facts arguably show that the utility of Gilead's TDF prodrug design does not outweigh the foreseeable risk it posed to the Plaintiffs and the proposed members of the class.

[56] In sum, I find that the Plaintiffs have set out in their ANOCC a reasonable cause of action in negligence against Gilead regarding the allegedly negligent design of its TDF-based drugs. It is also not plain and obvious that the Plaintiffs' negligent design claim is bound to fail.

[57] In reaching these conclusions, I have considered Gilead's arguments to the contrary. In my respectful view, however, they are not persuasive.

[58] The primary basis upon which Gilead submits that the Plaintiffs have not proposed a viable negligence claim is the Plaintiffs' acknowledgement in the ANOCC that the TDF drugs were effective in treating HIV/AIDS, and that the TDF drugs received government regulatory approval earlier than the TAF drugs did. Gilead therefore says that it was under no duty to refrain from marketing TDF drugs. At best, Gilead was under a duty to warn of the potential risks posed by TDF drugs, and the Plaintiffs do not allege that there was such a failure to warn. Gilead also argues that to accept the Plaintiffs' theory would mean that Gilead was legally required not to introduce a breakthrough treatment for HIV, leaving patients to contend with deficient alternative drugs. This is said to be contrary to Canadian negligence law and would undermine drug development by pharmaceutical manufacturers generally.

[59] The difficulty with Gilead's argument is that it does not accord with the analytical framework for adjudicating a negligent design case as has been authoritatively set out by our Court of Appeal in *Ding.* This is not a defective product case or a duty to warn case. As such, the issue is not whether the TDF drugs are defective *per se*, or whether adequate warnings of their side effects were provided. The issue is whether, given Gilead's apparent knowledge of an allegedly safer and economically feasible alternative design for the tenofovir prodrug (i.e., TAF), Gilead should be held liable for nevertheless marketing a tenofovir prodrug with a design

defect that created a substantial likelihood of harm (i.e., TDF). While Gilead may be able to demonstrate on the evidence that imposing such liability is unjustified in this case, the Plaintiffs' pleading adequately sets out a reasonable cause of action in negligent design for the purposes of Rule 9-5(1) of the *Rules* and s. 4(1)(a) of the *CPA.*

[60] I also do not agree with Gilead's suggestion that government regulatory approval of TDF negates the possibility that Gilead could be found liable for negligent design. This point is made generally in *Ding* at para. 34 by reference to the Supreme Court of Canada's decision in *Ryan v. Victoria (City),* [1999] 1 S.C.R. 201 at para. 29. It is also made in the specific context of the pharmaceutical regulatory regime administered by Health Canada in *Stanway v. Wyeth Canada Inc.,* 2011 BCSC 1057 at paras. 47 and 73; aff'd 2012 BCCA 260 [*Stanway*].

[61] Finally, I cannot accept Gilead's implicit *in terrorem* argument to the effect that a refusal to strike the Plaintiffs' claim will have a chilling effect on pharmaceutical companies' willingness to develop beneficial medications for patients. This is pure speculation and is not relevant to the question of whether the ANOCC sets out a reasonable cause of action based on binding principles of negligence law.

D) Existence of a Genuine Issue for Trial

[62] I turn now to Gilead's summary judgment application and Gilead's assertion that the Plaintiffs' proposed claim does not give rise to a genuine issue for trial.

[63] Consideration of this question requires an application of the same negligent design legal principles discussed above but to the affidavit evidence tendered by the parties as opposed to just a consideration of the Plaintiffs' ANOCC. The assessment must be done by reference to the four elements of a negligent design claim enumerated at para. 47 above. If the evidence before me discloses that there is no genuine issue for trial in relation to all four elements, summary judgment dismissing the Plaintiffs' claim must be granted.

[64] The first element is the existence of a duty of care owed by Gilead to the Plaintiffs. Evidence of this may be drawn from I.F.'s uncontradicted affidavit stating that I.F. took a TDF drug, as well as the evidence of Gilead's representatives and others that Gilead developed, manufactured, and marketed TDF drugs in Canada. Most significantly, Gilead admits that it owes such a duty of care. As such, this is a "genuine issue for trial" in the sense that it is not one whose adjudication would necessarily be decided against the Plaintiffs on the evidence.

[65] The second element is the breach of the duty of care owed by Gilead to the Plaintiffs. Both parties introduced a significant volume of evidence in relation to this issue, much of which is consistent. In particular, there is a general agreement between the parties on the timelines for the development, regulatory approval, and marketing of Gilead's TDF-based drugs and TAF-based drugs. Where the Plaintiffs and Gilead part company is with respect to the following:

a) the relative efficacy of TDF-based drugs as compared to TAF-based drugs;

b) the relative safety risk posed by TDF-based drugs as compared to TAF-based drugs; and

c) the rationales for decisions made by Gilead regarding the pace at which the TAF-based drugs were developed and marketed.

[66] For example, the Plaintiffs have led evidence that while TDF and TAF have a similar efficacy profile, TAF has fewer serious side effects than TDF. Dr. Covelli opines:

> Multiple clinical studies have affirmed a similar efficacy profile of both TDF and TAF in humans in the treatment of HIV and HBV [*Hepatitis B Virus*] …
>
> As described above, lower plasma levels of tenofovir with TAF administration compared to TDF, directly result in the differences in safety profiles between the two prodrugs. Importantly, in phase 3 clinical trials, patients treated with TAF-containing regimens (compared to those treated with TDF) had significantly less laboratory evidence of kidney dysfunction and significantly smaller abnormalities in bone mineral density at the spine and hip compared to those given TDF-containing regimens.

[67] Similarly, Dr. Sutton offers this opinion:

> In summary, although in certain, specific cases the antiviral efficacy of TDF and TAF may be quite similar, the DHHS [*United States Department of Health and Human Services*] panel recommended TDF should be used with caution or avoided in patients with kidney disease and osteoporosis. When TDF is used, especially in conjunction with a pharmacologic booster, physicians should monitor for renal and bone safety during therapy. Boosters should be avoided whenever possible in patients taking TDF. I can honestly say that I prefer the use of TAF versus TDF, at VACT [*Veterans Affairs Connecticut*], which I reinforce with other faculty, all of the clinical ID fellows, other trainees, and even medical students.

[68] Furthermore, the Plaintiffs highlight a Gilead internal memorandum titled "Development Committee, Executive Report 17 April 2003" in which a Gilead executive wrote the following in relation to TAF (called GS-7340 at the time):

> NB briefly discussed the results of the 3 Apr 03 review committee meeting at which time the proposed development plan for GS-7340 [*i.e., TAF*] was discussed extensively. The recommendation of the review committee was to stop development due to the likelihood that [*TAF*] would ultimately cannibalize Viread [*a TDF drug*] regardless of its efficacy and safety profile. One reason for continuing/restarting development would be to obtain patent extension. Corporate Development has agreed to compute the NPV [*Net Present Value*] for this scenario. NB commented that if the patent extension proves worthwhile, development of [*TAF*] might resume. The program is to be reevaluated in Spring 2004.

[69] Gilead, on the other hand, has led evidence to the effect that in the early 2000s, it was unclear whether TAF had a superior efficacy or safety profile to TDF. However, Gilead's understanding of the risks and benefits of TDF evolved and by the 2010s, Gilead felt that restarting the development of TAF made sense. Furthermore, TDF remains an approved treatment for HIV/AIDS which can be effective and safe for many patients, particularly those who are younger and do not have pre-existing bone or renal issues. For example, Dr. Dow opines:

> Therefore, between the time that TDF was approved in 2003 and TAF development was discontinued in 2004, there was insufficient clinical data on which TAF approval could be considered, or to allow any conclusion that TAF had a superior efficacy and/or safety profile, let alone for long term treatment.
>
> ...
>
> It was not surprising therefore that Gilead discontinued development of TAF in 2004... TDF's efficacy was such that it was unlikely a further compound in early stage development for HIV could be shown to have superior efficacy, and safety advantages would require the study of several thousand patients

> to establish a trustworthy comparison between drugs, consistent with regulatory guidance and patient needs.
>
> ...
>
> Thus by 2010, the objective for HIV therapies had evolved. ... Given this new definition of patient need, the decision to restart TAF development with a different strategy was again reasonable in the environment at the time.
>
> ...
>
> In conclusion, the first time it was possible to have data suitable to seek approval for TAF was in 2014, when the results of these trials was published, with regulatory approval following in 2015. Once published, it was demonstrated that there was no difference in efficacy between TDF and TAF at the doses studied. Further, the large majority of patients on both treatments achieved a satisfactory outcome in terms of benefit risk.
>
> With those statements in mind, the allegation that during the period of 2003 to the present, there are no individuals for whom the benefits of the TDF Drugs outweigh the risks, given that there was at all material times a significantly safer alternative, is not one that can be supported by the facts outlined above. All of the TDF Drugs and the TAF Drugs that have been approved for prescription to PLWH [*People Living With HIV*] and are included as recommended treatments in HIV treatment guidelines. Both treatments continue to achieve a satisfactory outcome in terms of risk benefit in the large majority of patients treated.
>
> Patients and their physicians have choices to make. While I am not a practicing clinician, based on my review of the scientific literature and my experience of determining the risk benefit ratio of novel drugs during drug development, it is possible to conclude that, for a significant proportion of patients who have no pre-existing bone or renal problems, TDF remains a treatment with an adequate risk benefit profile, and a large proportion of patients will sustain benefit from treatment over many years with TDF without any bone or kidney issues which necessitate ceasing to take a TDF Drug. Older patients, particularly with age and HIV related concomitant disease, or patients with existing renal or bone disease or high risk of reduction in bone mineral density, should be considered for TAF medications. Patients who develop, on TDF treatment laboratory evidence of deteriorating renal or bone status through regular recommended monitoring, may sensibly be switched to TAF medications.

[70] Similarly, Dr. Pitrak offers this opinion:

> It is my opinion that the benefits of the TDF Products have outweighed their risks at all times since their initial approval.
>
> The impact of kidney and bone toxicities to an individual patient are generally manageable with regular monitoring. If a clinically significant adverse event is observed through monitoring, prescribers may recommend discontinuation of TDF. If TDF is timely discontinued, kidney and bone toxicities are usually reversible. And while TDF is associated with a risk of renal impairment, the risk of severe renal toxicity is low. TDF has positively impacted the lives of

> millions of people living with HIV around the world and remains a recommended option for treatment in the infectious disease community today.
>
> ...
>
> As further information on the potential for rare renal and bone adverse effects accumulated by the early 2010s, I believe the development of TAF as a treatment option for patients at risk for complications was warranted. It was not until that time, however, that providers recognized an unmet need with TDF.
>
> Another important aspect of the unmet needs was the aging of the HIV population over time, in part because of longer survival with HIV treatments like TDF. As PLWHA [*Persons Living With HIV and AIDS*] grow older they have been shown to have greater incidences of certain age-related comorbidities, including lower BMD [*Bone Mineral Density*], higher incidences of fractures, and a higher likelihood to develop chronic kidney disease. The data on aging was only emerging around 2010 and later.

[71] When reviewed holistically, this evidence does not demonstrate that there is no genuine issue for trial in respect of Gilead's alleged breach of the duty of care it owed to the Plaintiffs. It certainly does not justify the issuance of a summary judgment dismissing the Plaintiffs' claim. To the contrary, the evidence reveals that the issue of Gilead's alleged breach is one that will require a deeper assessment of the evidence than is permissible on a Rule 9-6 application. In particular, the evidence tendered on this application does not clearly show that a risk-utility analysis will necessarily lead to a conclusion that the utility of the TDF design outweighed its foreseeable risks at the relevant time, although it might. In other words, there is a genuine issue for trial with respect to the second element of the Plaintiffs' negligent design claim, that is to say, Gilead's alleged breach of the duty of care.

[72] The remaining third and fourth elements of the negligent design claim before the Court relate to damage sustained by the Plaintiffs that was caused by Gilead. I.F. deposes to being prescribed a TDF drug (Truvada) in 2007 and remaining on it until early 2020 when I.F.'s physician changed I.F.'s prescription to a TAF drug (Biktarvy) due to concerns about I.F.'s long-term kidney health. The parties have also tendered a significant volume of opinion evidence to the effect that TDF drugs manufactured by Gilead can cause damage to kidneys and bones, and Gilead has

not suggested – let alone led any evidence to show - that this statement is false. Accordingly, there is a genuine issue for trial with respect to damages and causation in this case.

[73] In sum, I find that there is a genuine issue for trial with respect to all four elements of the tort of negligent design as advanced by the Plaintiffs.

E) Conclusion

[74] For the reasons set out above, I cannot grant Gilead's application to dismiss the Plaintiffs' claim. Simply put, Gilead has not met its burden to show either that the claim does not disclose a reasonable cause of action (Rule 9-5 of the *Rules*) or that the claim does not give rise to a genuine issue for trial (Rules 9-6 of the *Rules*). Gilead's application to dismiss will therefore be denied.

[75] For the same reasons, I find that the Plaintiffs have met their burden to establish that their pleadings as proposed in the ANOCC disclose a reasonable cause of action. Therefore, the first statutory condition for class action certification (s. 4(1)(a) of the *CPA*) is met. Accordingly, I will proceed to consider whether the four remaining conditions (s. 4(1)(b), (c), (d), and (e) of the *CPA*) are established as well.

V. OTHER CERTIFICATION REQUIREMENTS

A) Identifiable Class

[76] The Plaintiffs propose class definitions for (1) a "primary class members"; and (2) a "family members class", as follows:

a) "Primary Class Members": all persons who were prescribed Viread, Truvada, Atripla, Complera, or Stribild (the "TDF Drugs") in Canada and consumed one or more of those prescribed drugs; and

b) "Family Members Class": all persons who, by reason of a relationship with a Primary Class Member, are entitled to assert a claim pursuant to the *Family Compensation Act,* R.S.B.C. 1996, c. 126, the *Family Law Act,* S.B.C. 2011,

> c. 25, the *Fatal Accidents Act,* R.S.A. 2000, c. F-8, or equivalent or comparable legislation in other provinces and territories or at common law.

[77] The Plaintiffs say that the proposed class definitions are acceptable since whether a person meets them can be determined easily and objectively. Class membership does not depend on the outcome of any claim and the class definition defines all persons who will be bound by the determination of the common issues. Furthermore, the affidavit of the plaintiff I.F. and the affidavit of J.F. show that they fit within the proposed Primary Class Members, and there is evidence that another 55 persons who would be members of this proposed class have contacted counsel for the Plaintiffs as well. In addition, J.F. deposes to having a mother who provided assistance while J.F. was suffering from a leg fracture while on a TDF drug. J.F.'s mother would fall within the Family Members Class proposed by the Plaintiffs.

[78] Gilead submits that the Plaintiffs' proposed Primary Class Members definition is overly broad because it includes two categories of individuals who would not have a valid claim. The first consists of those who were prescribed and used TDF drugs but suffered no kidney or bone injuries. The second consists of those who were prescribed and used TDF drugs after TAF drugs became available in 2015.

[79] The test to be applied when considering whether the identifiable class requirement has been met is set out in *Western Canadian Shopping Centers v. Dutton,* 2001 SCC 46 at para. 38 [*Western Canadian Shopping Centers*]:

> [38] First, the class must be capable of clear definition. Class definition is critical because it identifies the individuals entitled to notice, entitled to relief (if relief is awarded), and bound by the judgment. It is essential, therefore, that the class be defined clearly at the outset of the litigation. The definition should state objective criteria by which members of the class can be identified. While the criteria should bear a rational relationship to the common issues asserted by all class members, the criteria should not depend on the outcome of the litigation. It is not necessary that every class member be named or known. It is necessary, however, that any particular person's claim to membership in the class be determinable by stated, objective criteria...

[80] In *Hollick* at para. 21, the Supreme Court of Canada also noted that this requirement is not an onerous one. There is no need to show that everyone in the

class shares the same interest in the resolution of the case. However, the party seeking certification must show that the class is not unnecessarily broad.

[81] In my view, the proposed primary class clearly identifies its members with an objective and easily identified criteria that bear a rational relationship to the Plaintiffs' negligent design claim against Gilead. There is evidence that this class has at least two members. I also find that the definition is not overbroad.

[82] Furthermore, Gilead's overbreadth argument is based on the notion that some of the individual class members may ultimately be unsuccessful because they did not develop medical problems as a result of using the manufacturer's product has effectively been made in other cases and rejected. This is because at the certification stage, class member claims need not be identical and not every class member must have a proven claim. The Plaintiffs are not required to show that all class members are likely to succeed with their individual claims or prove damages, as that would require a consideration of the merits. A relatively recent judgment to this effect is *MacKinnon v. Pfizer Canada Inc.,* 2021 BCSC 1093 at para. 82 [*MacKinnon*] (reversed in part but not on this issue in 2022 BCCA 151), where a class action in negligence was certified against a manufacturer of oral contraceptives. Justice Horsman (then of this Court) wrote:

> [82] The fact that some class members may ultimately be unsuccessful in establishing a claim against the defendants does not make the class overbroad. In any class action involving claims for personal injury, it is possible that the claims of some class members will be unsuccessful, and indeed such an outcome is "virtually ordained" by the jurisprudence that precludes merits-based class definitions: *Tiboni v. Merck Frosst Canada Ltd.*, 2008 CanLII 37911 (ONSC) at para. 78; see also: *Schwoob v. Bayer Inc*., 2013 ONSC 2207 at paras. 28-29 and *Tluchak Estate v. Bayer Inc*., 2018 SKQB 311 at paras. 102-109.

[83] The same can be said of Gilead's overbreadth argument with respect to class members who continued to take TDF even once Gilead started to market TAF. Gilead has not identified any authority for the notion that this would provide a complete defence to the Plaintiffs' negligent design claim for such patients, but even if it does, this does not make the class overbroad any more than the inclusion of

persons who may ultimately not be able to prove actual physical injuries from having taken TDF drugs.

[84] Gilead does not otherwise take issue with the proposed class definitions, including the Family Members Class. I agree that the derivative Family Members Class is also acceptable, as has been found by other Canadian courts: *Kibalian v. Allergan Inc.,* 2022 ONSC 7116 and *Greenwood v. Canada,* 2023 FC 397 at para. 38.

[85] In sum, there is some basis in fact for a finding that the Plaintiffs' proposed class is an identifiable class of two or more persons, as required by s. 4(1)(b) of the *CPA.* This second statutory condition for certification is met.

B) Common Issues

[86] The common issues proposed by the Plaintiffs are fourfold:

a) Did Gilead owe a duty of care to class members?

b) Is TAF a safer alternative to TDF?

c) Did Gilead breach the duty of care?

d) Is Gilead liable to pay punitive or exemplary damages?

[87] The Plaintiffs submit that these four issues of fact and law are common to all members of the proposed class and that similar issues have been certified as suitable for determination by other Canadian courts in class action proceedings.

[88] On the other hand, Gilead does not accept that the Plaintiffs have properly identified common issues as required by s. 4(1)(c) of the *CPA.* Gilead says that, at best, the proposed common issues are a minimal ingredient in what is at core an individual inquiry as to which of two effective and government-approved medications – TDF and TAF – are appropriate for an individual plaintiff at a specific time. These common issues are overshadowed and rendered meaningless by the individual issues that would remain to be determined even after a common issues trial.

[89] I will consider each of the proposed common issues separately.

Did Gilead owe a duty of care to class members?

[90] As noted by the Plaintiffs, whether Gilead owed the class members a duty of care is a common threshold legal question, which has been found to be appropriate for certification in similar cases (see, for example: *Felker v. Teva Branded Pharmaceutical Products R,* 2022 BCSC 1813 at paras. 220-226).

[91] In this case, however, Gilead concedes that it owes a duty of care to the class members. There is jurisprudential authority for the proposition that when there is such a concession by the defendant, it is unnecessary to certify this as a common issue: *Miller v. Merck Frosst Canada Ltd.,* 2013 BCSC 544 at paras. 177-178 [*Miller*]; aff'd 2015 BCCA 353; and *Stanway* at para. 48.

[92] In light of Gilead's reasonable concession, I decline to certify the uncontentious issue of the existence of a duty of care in this case because it is unnecessary to do so.

Is TAF a safer alternative to TDF?

[93] The Plaintiffs argue that the question of whether TAF is a safer alternative to TDF goes to the heart of each class member's claim and will materially advance the litigation. Answering the question will require assessment of complex scientific and expert evidence without requiring consideration of individual circumstances. Resolving this issue will advance the claim of each class member.

[94] Gilead submits instead that this question is overly general and does not lend itself to a single answer that will be common to all class members. Gilead says that each of the TDF drugs and TAF drugs have different risks, and which is safer may well depend on an individual class member's background and treatment needs, and which drug is most suitable given their particular circumstances.

[95] The principles to be applied when considering whether a proposed common issue should be certified were summarized by the Supreme Court of Canada in *Pro-Sys Consultants* at para. 108:

> [108] In *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, [2001] 2 S.C.R. 534, this Court addressed the commonality question, stating that "[t]he underlying question is whether allowing the suit to proceed as a [class action] will avoid duplication of fact-finding or legal analysis" (para. 39). I list the balance of McLachlin C.J.'s instructions, found at paras. 39-40 of that decision:
>
> > (1) The commonality question should be approached purposively.
> >
> > (2) An issue will be "common" only where its resolution is necessary to the resolution of each class member's claim.
> >
> > (3) It is not essential that the class members be identically situated vis-à-vis the opposing party.
> >
> > (4) It not necessary that common issues predominate over non-common issues. However, the class members' claims must share a substantial common ingredient to justify a class action. The court will examine the significance of the common issues in relation to individual issues.
> >
> > (5) Success for one class member must mean success for all. All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent.

[96] I am of the view that a determination of whether TAF is a safer alternative design than TDF – as the Plaintiffs contend – or whether both designs are acceptably safe – as Gilead contends – is one whose resolution is necessary for each class member's claim and which will avoid duplication of fact-finding and legal analysis: *Western Canadian Shopping Centres* at para. 39.

[97] My view is not shaken by Gilead's assertion that the relative safety of TDF and TAF will be different for each individual drug and patient. While this may be true, I am satisfied on the evidence tendered that it is possible to determine generally whether or not TAF constitutes an alternative prodrug design whose safety profile is tangibly superior to that of TDF. If it is, and the Plaintiffs can establish all of the other elements of their negligent design claim, the Plaintiffs will succeed. If it is not, the Plaintiffs will fail. The basis in fact for this finding is drawn from the expert reports of Dr. Covelli and Dr. Sutton for the Plaintiffs, and those of Dr. Dow, Dr. Pitrak, and Dr.

Conway for Gilead. While their final views differ, they have each effectively provided general opinions on whether or not TAF is safer than TDF.

[98] The question of whether TAF is a safer alternative to TDF will be certified as a common issue.

Did Gilead breach the duty of care?

[99] The Plaintiffs submit that whether a defendant breached a duty of care is often certified as a common issue in product liability cases. In the case at bar, the issue focuses entirely on Gilead's knowledge and conduct and does not depend on the evidence of individual class members. As such, it is an issue that should be certified in this proceeding too.

[100] Gilead's primary argument in response echoes Gilead's general submission made in support of its application to dismiss. Gilead says that in light of TDF's acknowledged efficacy in treating HIV, the regulatory approval TDF received and maintains based on its favourable benefit/risk profile, and TDF's continued use today, there is no basis in fact for the assertion that Gilead breached its duty of care to the Plaintiffs. Of course, I cannot accept this argument at this stage in light of my conclusions set out earlier in respect of Gilead's application to dismiss.

[101] Gilead's secondary argument mirrors its assertion with respect to the suitability of certifying the question of whether TAF is a safer alternative to TDF as a common issue. It is that the question of whether Gilead breached the duty of care is not a common issue since its determination will depend on whether the TAF drugs are in fact safer alternatives for any particular patient. This, in turn, will depend on such individual determinations as:

1) when did the class member take the TDF drugs and what other HIV drugs were available at the time, including TAF;

2) what was the indication for which the particular drug was prescribed (e.g., was it for treatment of HIV, or to address another concern, such as Hepatitis B); and

3) what is the alleged side effect and how relevant is it to the particular class member.

[102] I agree with the Plaintiffs that the issue of whether Gilead breached the duty of care it owed to the Plaintiffs is a common one that warrants being certified. Recall that the four sub-elements that the Plaintiffs must prove in order to establish a breach of the duty of care identified at para. 47 of these reasons are that: (1) Gilead knowingly marketed a product that has a design defect; (2) the design defect created a substantial likelihood of harm; (3) there existed an alternative design that was safer and economically feasible to manufacture; and (4) based on a risk-utility analysis, the foreseeable risks associated with the product's design outweighed the utility of the chosen design. An assessment of these four sub-elements lends itself to common determinations that can be applied to all of the members in the class. This will avoid duplication of fact-finding and legal analysis. There is also a basis in fact for the existence of this common issue as noted above at paras. 65-71 of these reasons.

[103] I also do not accept Gilead's argument that determining whether Gilead breached its duty of care necessarily requires an assessment of each individual class member's situation. As was noted by our Court of Appeal in *Trotman v. WestJet Airlines Ltd.,* 2022 BCCA 22 at para. 59, it is not necessary at the certification stage to believe that the common issues will be answered identically for every class member. Paraphrasing the wording of that paragraph, there are four possible outcomes to a common issues trial in respect of Gilead's alleged breach of the duty of care it owes to the class: (1) a finding that the breach was committed in respect of all class members; (2) a finding that no breach was committed in respect of any of the class members; (3) a finding that there was no breach in relation to an identifiable subset of the class members; or (4) a finding that for some class

members it is not possible to determine whether there was a breach, in which case individual issues trials might be needed. However, the mere risk of individual issues trials does not preclude the certification of issues in common.

[104] This observation is particularly apposite to Gilead's argument that the viability of the Plaintiffs' claim may vary depending on what time period is examined, as Gilead's potential liability may depend on the state of knowledge of the risks and benefits of TDF and TAF in any given year. As was noted by our Court of Appeal in *Stanway* at paras. 60-61, the issue of whether there has been a breach of the duty of care can be a common one even if the duty evolves over time:

> [60] Wyeth submits that the 27-year class period is unmanageable in the context of the changing scientific knowledge regarding the risks of hormone therapy. Wyeth contends that there is no commonality because its duty of care must be assessed at a specific period of time. Wyeth submits that the evolving medical knowledge and the concomitant changing prescribing information precludes a finding of a single common standard of care for the entire 27-year class period.
>
> [61] There may well be challenges in assessing the duty of care (and the standard of care) over the 27-year class period. Similar concerns arose in *Rumley*, but the Supreme Court of Canada concluded that the common question was capable of a "nuanced answer". It is too early to say in this case what shape that answer might take, but one obvious potential solution would be the development of sub-classes defined by reference to the changing product monographs. If the class period proves to be truly unmanageable, it is open to the court to decertify the action. These are refinements that can be addressed as the litigation progresses.

[105] Accordingly, the question of whether Gilead breached the duty of care will be certified as a common issue.

Is Gilead liable to pay punitive or exemplary damages?

[106] The final common issue that the Plaintiffs propose for certification is whether Gilead should pay punitive or exemplary damages. The Plaintiffs argue that there is evidence establishing some basis in fact for their assertion that Gilead decided to develop, promote, market and sell more harmful TDF drugs when Gilead was aware that TAF was a safer alternative, and did so purely in pursuit of profit. If proven, the Plaintiffs say that this reprehensible conduct could justify an award of punitive damages. The Plaintiffs also say that this is a common issue that can be determined

without evidence from individual class members as the focus will be on the blameworthiness of Gilead's conduct.

[107] Gilead argues that the Plaintiffs' evidence does not establish a sufficient basis in fact for certification of punitive damages as a common issue. Furthermore, given that punitive damages are only awarded if compensatory damages do not adequately achieve the objectives of retribution, deterrence, and denunciation, they may only be considered after any individual issues trials are resolved. As such, punitive damages cannot be determined at a common issues trial on a class-wide basis.

[108] In *Rumley v. British Columbia,* 2001 SCC 69 at para. 34; aff'g 1999 BCCA 689, the Supreme Court of Canada approved our Court of Appeal's certification of punitive damages as a common issue. The Court of Appeal's rationale for doing so was set out at para. 48 of its decision:

> [48] The purpose of punitive damages is to punish a morally culpable defendant: see *Chace v. Crane Canada Inc.* (1997), 1997 CanLII 4058 (BC CA), 44 B.C.L.R. (3d) 264 (C.A.). The plaintiffs' pleading alleges conduct that if substantiated could be characterized as morally culpable. Any award for punitive damages should reflect the overall culpability of the defendant. It does not have to be linked to the harm caused to any particular claimant and does not require individualized assessment. A global award can be assessed for the successful class members as a group, and allocated among them as the trial judge considers appropriate. The plaintiffs would be required to succeed on a common issue related to sexual abuse as well as proving moral culpability to establish a foundation for punitive damages.

[109] Furthermore, in *Chalmers v. AMO Canada Company,* 2010 BCCA 560 at para. 31, our Court of Appeal addressed the concern raised by Gilead here regarding the suitability of determining whether punitive damages should be awarded prior to any resolution of individual issues, should that be necessary. The Court of Appeal held that this is not an impediment to having punitive damages certified as a common issue, so long as it is limited to a general consideration of whether such damages might be warranted in order to punish the defendant:

> [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.

[110] On the strength of these binding appellate authorities, I am satisfied that it is appropriate to certify as a common issue the question of whether Gilead is liable to pay punitive or exemplary damages. There is also evidence that provides some basis in fact for the Plaintiffs' assertion that Gilead's conduct may be deserving of such a sanction, especially the now publicly available Gilead internal document mentioned at para. 68 above. It is understood, however, that the actual quantification of such an award, if found to be warranted in general, will await the completion of any individual issue trials that may need to take place.

Conclusion

[111] In sum, I find that the claims of the class members raise three common issues that deserve to be certified: (1) is TAF a safer alternative to TDF; (2) did Gilead breach the duty of care; and (3) is Gilead liable to pay punitive or exemplary damages. The third statutory condition for certification, as prescribed by s. 4(1)(c) of the *CPA*, is met.

C) Preferable Procedure

[112] Section 4(2) of the *CPA* sets out a non-exhaustive list of considerations for the court to assess whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues. They are:

> 4(2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including the following:

> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

[113] The Plaintiffs argue that all five of the enumerated considerations are met.

[114] First, the Plaintiffs say that the common issues predominate over any individual issues that may remain after the resolution of the common issues. The answers on duty and breach will significantly advance the claims of each class member with only an assessment of damages being required afterwards.

[115] Second and third, the Plaintiffs note that there is no evidence that any putative class members wish to pursue these claims through individual lawsuits, and there are no other proposed class proceedings regarding the subject matter of this action.

[116] Fourth, the Plaintiffs assert that individual litigation of these claims would be expensive and repetitive, with duplicative discovery, interlocutory applications, and findings of fact.

[117] Fifth, the Plaintiffs are confident that the administration of this case as a class action will not be unduly burdensome on judicial resources. The fact that individuals may have to prove that they are members of the class and there may be a need for individual issues trials does not mean that a class proceeding is inappropriate, particularly given the Court's case management powers set out in ss. 12, 27 and 32 of the *CPA.*

[118] Gilead, however, is of the view that a class action is not the preferable procedure for the fair, efficient, and manageable resolution of the common issues that the Plaintiffs intend to raise. Focusing largely on the s. 4(2)(a) *CPA* consideration, Gilead argues that the Plaintiffs' proposed common issues do not predominate over questions affecting individual prospective class members. Those questions include whether the class member:

a) sustained a kidney injury or a bone injury that was caused by the TDF drugs;

b) was properly monitored for kidney and bone issues and therefore could have addressed and possibly reversed any injuries that occurred;

c) benefitted from the availability of TDF during the time when it would not have been possible to introduce TAF;

d) had a risk-benefit profile for TDF drugs that was beneficial as compared to the risk-benefit profile for TAF drugs; and

e) decided to switch from TDF drugs to TAF drugs once the latter became available, and how quickly this was done.

[119] Simply put, Gilead says that each potential class member will have individual circumstances with respect to their TDF drug use that will lead to a "monster of complexity" such that class certification is not appropriate.

[120] In *AIC Limited v. Fischer,* 2013 SCC 69 at paras. 16-38, the Supreme Court of Canada set out a thorough explanation of the analytical framework for determining whether a class action is the preferable procedure for resolving the common issues. It noted in particular that all of the s. 4(2) *CPA* factors must be reviewed collectively, with no single factor being determinative. Also, the inquiry must be conducted through the lens of the three principal procedural advantages of class actions, namely: judicial economy, behaviour modification, and access to justice.

[121] I have considered the s. 4(2) *CPA* factors, the evidence tendered by the parties on this application, and the arguments of counsel. It is apparent that the only

reasonable alternative to a class proceeding for resolving the class members' claims against Gilead is individual actions. I find that it is preferable to use the procedural mechanism of a class proceeding to achieve such a resolution, as opposed to multiple individual negligent design actions.

[122] Indeed, the only real argument Gilead has presented to the contrary is the extent to which there may be individual issues for specific class members that cannot be dealt with collectively in a common issues trial. In my view, however, these individual issues do not predominate or overwhelm the proposed common issues, particularly the determination of whether TAF is a safer alternative to TDF, and whether Gilead breached its duty of care to the patients who took TDF drugs.

[123] This is because it is apparent from the affidavits tendered – the expert reports in particular – that the most significant aspect of this case will be the inquiry into whether Gilead knowingly marketed TDF while the TAF alternative existed, and whether, based on a risk-utility analysis, the risk of doing so outweighed the benefits. This inquiry is likely to be complex, involving extensive scrutiny of scientific and corporate actions taken and decisions made some time ago. This complexity would deter many class members from bringing individual claims, and requiring them to do so would impose an unwarranted barrier to access to justice. On the other hand, allowing the class members to litigate collectively would promote judicial economies, and potentially encourage behaviour modification more readily than would be the case if they were required to litigate individually. This would benefit not just the Plaintiffs, but Gilead as well. This is because a collective finding that Gilead breached its duty of care would spare the class members from having to demonstrate this individually, and because a contrary finding would result in a dismissal of the claims of all class members in a single proceeding: *MacKinnon* at para. 62.

[124] Finally, I am also satisfied that there are no known individual class members who seek to bring their own proceedings against Gilead in respect of TDF drugs,

and that the Plaintiffs' proposed national class action is the only one of its kind in Canada.

[125] Therefore, I conclude that there is some basis in fact for a finding that the Plaintiffs' proposed class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, as required by s. 4(1)(d) of the *CPA.* This fourth statutory condition for certification is met.

D) Suitability of Representative Plaintiffs and Litigation Plan

[126] The Plaintiffs propose that I.F. be named as a representative plaintiff. They say that I.F. will adequately represent the class, does not have a conflict with other class members, and has developed a reasonable plan for litigating the action and providing notice.

[127] While the Plaintiffs' written submissions indicate that J.F. would also be willing to serve as a representative plaintiff and satisfies the requirements for doing so, counsel for the Plaintiffs indicated orally that, upon reflection, this is unnecessary given I.F.'s suitability for this role.

[128] The Plaintiffs also submit that their proposed litigation plan is similar to plans that have previously been approved by this Court and therefore should be acceptable for this case as well.

[129] Gilead does not take issue with the individual suitability of I.F. as a representative plaintiff. However, Gilead argues that the Plaintiffs have nevertheless not met the s. 4(1)(e) *CPA* condition since they have not put forward a workable litigation plan. They say that it is rudimentary, vague and formulaic. In particular, it does not address how causation would be assessed generally, or how the individual issues that remain after the common issues are determined would be adjudicated.

[130] I am satisfied on the basis of the uncontested affidavit evidence of I.F. and Mr. Tanjuatco that I.F. will fairly and adequately represent the interests of the class, and that I.F does not have a conflict of interest with the other class members in respect of the common issues. I am also satisfied that counsel for the Plaintiffs, Klein

Lawyers LLP, are capable and suitable to perform the role of class counsel. The only issue is whether the Plaintiffs' litigation plan sets out a workable method for advancing the proceeding on behalf of the class and notifying class members of the proceeding.

[131] It is well established that litigation plans need not be perfect, can be a "work in progress", and might require amendments as the case proceeds and the nature of the individual issues are demonstrated by class members: *Fakhri et al v. Alfalfa's Canada Inc. cba Capers,* 2003 BCSC 1717 at paras. 77-78; aff'd 2004 BCCA 549.

[132] Keeping these principles in mind, the Plaintiffs' proposed litigation plan is adequate to satisfy the requirement of s. 4(1)(e)(ii) of the *CPA,* namely, that it sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding. It is similar to plans that were approved by this Court in *Miller* and *MacKinnon v. National Money Mart Company,* 2007 BCSC 348. It may require changes as this matter proceeds, but is sufficient for this early stage of the proceedings.

[133] In sum, there is some basis in fact for a finding that there is a representative plaintiff who meets all of the requirements set out at s. 4(1)(e) of the *CPA.* This fifth statutory condition for certification is met.

E) Conclusion

[134] Since the Plaintiffs have established that all five of the s. 4(1) *CPA* conditions are met, I must certify the plaintiffs' proposed claim against Gilead as a class proceeding, and will do so.

VI. NEXT STEPS

[135] As a result of the certification of the proposed class proceeding, the Plaintiffs' action may now proceed towards trial. Of course, it will largely be up to the parties themselves to decide how this should be done, under the Court's supervision. It is also possible that the parties may wish to enter into a settlement agreement, and to present it to the Court for approval rather than proceeding to trial.

[136] That said, there are three pre-trial procedural matters that I direct the parties to consider and address forthwith.

[137] The first is formalization of the ANOCC in accordance with Rule 6-1 of the *Rules.* Since the Plaintiffs' original notice of civil claim has yet to be amended, this may be done without leave of the court (Rule 6-1(a)). I expect that this will result in the preparation of a filed version of the ANOCC that will be served upon Gilead in short order. At the risk of stating the obvious, the ANOCC that is filed must be in substantially the same form as the one contained within the joint application record, since the determination of the parties' applications has been effected by reference to this draft pleading.

[138] The second is Gilead's response to civil claim. Like the ANOCC, it has yet to be filed. I expect that Gilead will prepare, file, and serve a revised pleading after the Plaintiffs have properly filed and served their ANOCC.

[139] The third is the matter of the anonymization of the Plaintiffs' names. Counsel for the Plaintiffs have proceeded on the apparent assumption that it is permissible as of right for their clients to litigate anonymously using their initials given the private nature of the Plaintiffs' medical conditions and history. They rely on the Supreme Court of Canada's decision in *L'Oratoire Saint-Joseph du Mont-Royal v. J.J.,* 2019 SCC 35 at para. 32 to justify this approach.

[140] In my view, however, the assumption that such anonymization can be done as of right cannot be accepted following the Supreme Court of Canada's subsequent decision in *Sherman Estate v. Donovan,* 2021 SCC 25. It states unequivocally that the open court principle is a central feature of our democracy that is protected by the constitutionally entrenched right to freedom of expression, and there is a strong presumption against limiting it. All aspects of court proceedings are therefore presumptively open to the public, and an applicant who seeks to limit public access to them faces a high bar. This includes the practice of anonymizing the names of litigants and witnesses.

[141] Accordingly, if the Plaintiffs wish to continue to litigate this matter anonymously by using their initials, they will have to present a formal application for an anonymization order supported by affidavit evidence, to which Gilead may respond. Even if all parties consent, however, this will not be determinative of this issue. Given the public importance of the open court principle, the Court must make its own determination of whether the requested exception to this principle is warranted.

VII. DISPOSITION

[142] For the reasons set out above, I make the following orders:

a) The Plaintiffs are granted leave to file the second affidavit of Eduardo Tanjuatco made August 14, 2023.

b) Gilead's application to strike the Plaintiffs' action and for summary judgment in respect of the Plaintiffs' action is dismissed.

c) The Plaintiffs' action as pleaded in their draft amended notice of civil claim is certified as a class proceeding.

d) The class is defined as:

   i. "Primary Class Members": all persons who were prescribed Viread, Truvada, Atripla, Complera, or Stribild (the "TDF Drugs") in Canada and consumed one or more of those prescribed drugs; and

   ii. "Family Members Class": all persons who, by reason of a relationship with a Primary Class Member, are entitled to assert a claim pursuant to the *Family Compensation Act,* R.S.B.C. 1996, c. 126, the *Family Law Act,* S.B.C. 2011, c. 25, the *Fatal Accidents Act,* R.S.A. 2000, c. F-8 or equivalent or comparable legislation in other provinces or territories or at common law.

e) I.F. is appointed as the representative plaintiff.

f) Klein Lawyers LLP is appointed as class counsel.

g) The nature of the claims asserted on behalf of the class is in negligence, specifically, the tort of negligent design.

h) The relief sought by the class for personal injury are general damages, special damages, punitive damages, recovery of health care costs incurred under the *Health Care Costs Recovery Act,* S.B.C. 2008, c. 27 and under comparable legislation in other provinces and territories, and damages for Family Members Class under the *Family Compensation Act,* R.S.B.C. 1996, and under comparable legislation in other provinces and territories or at common law.

i) The common issues for the class are:

   i. Is TAF a safer alternative to TDF?

   ii. Did Gilead breach the duty of care?

   iii. Is Gilead liable to pay punitive or exemplary damages?

j) The manner in which and the time within a class member may opt out of the proceeding will be determined in a subsequent application.

[143] There is a strong presumption against the awarding of costs in respect of a class proceeding certification application as per s. 37 of the *CPA.* However, this presumption does not expressly apply in respect of cross-applications to dismiss claims that are proposed to be certified as class actions. If the parties are unable to agree on costs in respect of the three applications decided here, they may contact Supreme Court Scheduling within 30 days of the date of these reasons for judgment to schedule a hearing on this issue before me.

"Brongers J."