IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Player v. Janssen-Ortho Inc.,*
2014 BCSC 1122

Date: 20140620
Docket: 10-3561
Registry: Victoria

Between:

**Estate of Wade Robert Player,
Desiree Marine Player, Estate of Daniel Charles
Pollock and Elaine Mills**

Plaintiffs

And:

**Janssen-Ortho Inc.,
Ranbaxy Pharmaceuticals Canada Inc.,
Ratiopharm Inc.,
Sandoz Canada Incorporated, and
Teva Canada Limited**

Defendants

Before: The Honourable Mr. Justice Bracken

Reasons for Judgment

Counsel for the Plaintiffs:	E.F.A. Merchant, Q.C. and D. Clarke
Counsel for Janssen-Ortho Inc.:	D. Neave and R. Reinertson
Counsel for Ratiopharm Inc. and Teva Canada Limited	S. Maidment and L. Parliament
Counsel for Sandoz Canada Incorporated:	O. Ilnyckyj and C. Rajotte
Place and Date of Trial/Hearing:	Victoria, B.C. October 28 - November 1, 2013
Place and Date of Judgment:	Victoria, B.C. June 20, 2014

INTRODUCTION

[1] In this proposed class action against five corporate defendants, two of the defendants, Teva Canada Limited ("Teva") and Sandoz Canada Incorporated ("Sandoz"), seek an order dismissing the action against them on a summary trial prior to a certification hearing.

[2] The claim in question involves transdermal fentanyl patches, a form of prescription painkiller where the active opioid, fentanyl, is delivered by a patch applied directly to the patient's skin. The defendants, including Teva and Sandoz, manufacture, market and distribute transdermal fentanyl patches in Canada. The plaintiffs say that fentanyl patches are defectively designed, such that they cause serious harm in ordinary use, and seek to certify a class action against all of the defendants.

[3] For the reasons set out below, I find that this matter is suitable for determination on summary trial. Based on my conclusions of fact and law, the action of the plaintiffs against Teva and Sandoz is dismissed.

BACKGROUND

The Plaintiffs

[4] Wade Robert Player died on August 10, 2007, at the age of 34. Not long before his death Mr. Player had suffered severe injuries in a motor vehicle accident and as a result had a prescription for pain management via a transdermal fentanyl patch. He was wearing a fentanyl patch at the time of his death, although there is some uncertainty as to the brand of patch Mr. Player was using that day. A coroner's report concluded that Mr. Player died as a result of fatal respiratory depression due to prescription drug interaction. Desiree Player is Mr. Player's widow.

[5] Daniel Charles Pollock had a prescription for transdermal fentanyl patches, which he used to treat chronic back pain. He died on June 26, 2008, at the age of

63. The post-mortem examination determined that he died of acute mixed/combined drug intoxication. He had morphine, oxycodone, and fentanyl in his system at the time of death. Elaine Mills is his widow.

Litigation History

[6] On September 1, 2010, Ms. Player commenced an action against the defendants on behalf of herself, her husband's estate, and the proposed class. Ms. Player is the proposed representative plaintiff for the resident subclass, described as all persons resident in British Columbia, including their estates, who used fentanyl patches between December 20, 1991 to the date of certification and all persons who assert a derivative claim on account of a family relationship to the deceased.

[7] Ms. Mills joined the action on August 22, 2011, as the proposed representative plaintiff for the non-resident subclass, which includes residents of other Canadian provinces or territories.

[8] The plaintiffs then applied for certification of the matter as a class action. At the same time, Teva and Sandoz advised they wished to apply for an order directing a summary trial of the claims against them pursuant to Rule 9-7 of the *Supreme Court Civil Rules*. I held a sequencing hearing in order to determine the order in which the applications should proceed. In oral reasons for judgment given on October 14, 2011, I ordered that the summary trial could proceed prior to the certification hearing.

Basis for Summary Trial Application

[9] As noted above, all of the defendants in the proposed class action manufacture, market and distribute transdermal fentanyl patches. However, according to the defendants, they actually manufacture two very distinct products. Teva and Sandoz both manufacture "matrix" drug-in-adhesive patches, where the active drug is suspended in a semi-solid state in the adhesive of the patch. The other defendants manufacture "reservoir" style patches, which have a reservoir of

liquid/gel fentanyl that is released into the patient's bloodstream through a rate-controlling membrane.

[10] Teva and Sandoz in this application ask that the court dismiss the plaintiffs' claims in respect of their particular transdermal fentanyl patch products. They say the plaintiffs' claims are over-inclusive and that their matrix style patches do not cause harm as alleged.

[11] The remaining defendants took no position on this application. Although counsel for Janssen-Ortho Inc. and Ranbaxy Pharmaceuticals Canada Inc. attended as observers, only the plaintiffs and Teva and Sandoz participated in the summary trial application.

Summary Trial or Summary Dismissal?

[12] At the hearing of this matter, the plaintiffs made an initial submission that this process was not a summary trial but rather an application for "summary dismissal", which Mr. Merchant described as a type of summary judgment where Teva and Sandoz were required to establish that "their product could not have caused any harm."

[13] Teva and Sandoz submit that the matter was clearly understood to be a summary trial pursuant to Rule 9-7. In fact, the plaintiffs themselves referred to the process as a summary trial in an application for document discovery they filed April 26, 2012. It appears that as of that date, at least, they understood that this matter would proceed pursuant to Rule 9-7, with the onus and procedures as set by that Rule. I agree with Teva and Sandoz that this hearing was always intended and understood to be a summary trial of the plaintiffs' action against Teva and Sandoz, and I will proceed on that basis.

ISSUES

[14] The plaintiffs allege that transdermal fentanyl patches can cause serious injuries in ordinary use, including respiratory depression and death. They say that

there is a safer alternative design of patch available, and that as such the defendants' design is negligent. Further, they say that the defendants failed to warn consumers of the risks associated with use of their products. In this action brought under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50, they claim in negligence, negligent misrepresentation, breach of warranty, and breach of fiduciary duty. They also claim that, in marketing and selling a defective product to consumers, the defendants are in breach of the *Food and Drugs Act,* R.S.C 1985, c. F-27, the *Competition Act*, R.S.C. 1985, c. C-34, the *Sale of Goods Act*, R.S.B.C. 1996, c. 410, and the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2.

[15] There are two preliminary issues that must be addressed prior to any determination of the merits of these claims. First, the court must determine the correct scope of inquiry in a summary trial for a pre-certification class proceeding. As the parties have not yet gone to certification, there is no "class" of litigants before the court. Only the named plaintiffs are parties to this matter at this point. Generally speaking, in an individual action, only facts relating to the named plaintiffs could be considered. However, the plaintiffs say that the status of this matter as a proposed class action changes matters, and that the Court should consider the claims of the entire proposed class. Before proceeding, then, I must determine whether this court should consider facts relating to potential class members, or only those relating to the named plaintiffs.

[16] Second, the court must determine whether this matter is suitable for determination by way of a summary trial. The plaintiffs say it is not, on the basis that a full trial is required for a full appreciation of the facts. Teva and Sandoz say that I can find the necessary facts in the evidence as tendered and that it can be fairly and justly dealt with by way of a summary trial.

[17] If the matter is found suitable for summary trial, Teva and Sandoz (collectively, the "applicant defendants") request judgment on the following issues:

1. Are the applicant defendants strictly liable to the plaintiffs?

2. Did the applicant defendants breach a duty of care to the plaintiffs by distributing a product that was defectively designed?

3. Did the applicant defendants breach a duty of care to the plaintiffs by failing to provide a reasonable warning of the risks associated with transdermal fentanyl patches?

4. Did the applicant defendants make any negligent misrepresentation to the plaintiffs with respect to the use of their transdermal fentanyl patch products?

5. Did the applicant defendants breach any express or implied warranty owed to the plaintiffs in respect of their transdermal fentanyl patches, either at common law or by operation of the *Sale of Goods Act*?

6. Did the applicant defendants owe a fiduciary duty to the plaintiffs, and, if so, did they breach that duty?

7. Did the applicant defendants engage in any unlawful, unfair or deceptive trade practices within the meaning of the *Competition Act*?

8. Did the applicant defendants make any false or misleading representations regarding their transdermal fentanyl patch products, contrary to s. 9 of the *Food and Drugs Act*?

9. Did the applicant defendants breach any of the provisions of the *Business Practices and Consumer Protection Act*?

[18] I will begin by discussing the scope of inquiry in a pre-certification class proceeding, as it is necessary to conclude that point before reviewing the evidence. For the reasons set out below, I have concluded that in British Columbia, the Court should consider the facts applicable to the members of the proposed class in addition to those concerning the individual plaintiffs. With that in mind, I will then review and assess the evidence presented by the parties. I then turn to the question

of whether this matter is suitable for summary determination. Finally, I will apply the law to the facts I as I find them following my review of the evidence.

SCOPE OF INQUIRY IN A PRE-CERTIFICATION CLASS PROCEEDING

[19] In most Canadian provinces, a pre-certification class proceeding is treated as an individual action: see *Ragoonan Estate v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (Sup. Ct. J.), and *Hughes v. Sunbeam Corp. (Canada) Ltd.* (2002), 61 O.R. (3d) 433 (C.A.). Those decisions establish that there must be a representative plaintiff with a cause of action against each defendant. Where the named plaintiffs have no personal or direct cause of action against a defendant, or the defendant can successfully establish a defence to the individual plaintiff's claim, the action must be dismissed.

[20] That is not the case in British Columbia. In *MacKinnon v. Instaloans Financial Solutions Centres (Kelowna) Ltd.*, 2004 BCCA 472 at para. 33, our Court of Appeal said as follows:

> I think it is also clear that an action commenced under the *Class Proceedings Act* is, even before the certification application, more than just "any old action": it is an action with ambition.

[21] In *MacKinnon* the proposed class action involved allegations that payday loan companies in the province were charging a criminal rate of interest. A number of the defendant companies applied to have the claims against them struck out on the basis that they disclosed no cause of action, as Mr. MacKinnon, the representative plaintiff, had only borrowed money from (and thus only had a cause of action against) the other defendants. The court refused to dismiss the claim against the applicant defendants, concluding that it was not necessary that the representative plaintiff have a cause of action against each defendant: "while the Act requires a cause of action against each named defendant, that cause of action must be held by [potential] class members, not necessarily the representative plaintiff" (para. 51). An application to strike a claim must be "considered in the context of its stated ambition to be a class proceeding" (para. 38).

[22] Subsequent cases have applied the principles from *MacKinnon* in the context of other rules of court. In *Birrell v. Providence Health Care Society et al.*, 2006 BCSC 1814 at para. 9, aff'd 2009 BCCA 109, on an application to add plaintiffs, both the chambers judge and the Court of Appeal took into account the potential prejudice to the proposed class members if the court refused the application. The chambers judge commented that, following *MacKinnon*, "a proposed class proceeding is subject to the ordinary *Rules of Court*, but those rules are to be applied in the context of considering its potential future as a class action" (para. 9). The Court of Appeal held that although the ultimate limitation period had expired for the proposed representative plaintiffs in their claim against the hospital defendants, they should still be added "as parties to the class action … in order to preserve any cause of action members of the putative class may have that is not time-barred against the hospitals" (para. 29).

[23] The plaintiffs in this case submit that *MacKinnon* applies to alter the ordinary approach to summary trials under Rule 9-7. They say that the court cannot narrow its evidentiary focus to the circumstances surrounding the deaths of the named plaintiffs, but must instead consider the claims of the proposed class as a whole.

[24] In Alberta, when this same issue arose, the court held that the chambers judge did "not have to engage in an investigation into possible worlds which might contain class members whose claims might not be proscribed. We need only consider the facts of these two [named] Plaintiffs" (*Kowch v. Gibraltar Mortgage Ltd.*, 2013 ABQB 317 at para. 45). Alberta does not follow the *MacKinnon* line of authority, however. I think the situation here must be different.

[25] It is clear that in British Columbia, a pre-certification class proceeding cannot be dismissed solely on the basis that the representative plaintiff does not have a claim against any particular defendant. In my view, on that basis, the plaintiff is correct to say that the court on this summary trial hearing must go beyond the evidence relating to the claims of the individual plaintiffs, and consider any properly admissible evidence relating to the claims of potential class members. This could

take the form of evidence from proposed class members themselves, or expert opinion evidence establishing that Teva or Sandoz's products are defective in their design and thus in breach of a duty of care to Canadian consumers.

[26] A summary trial pursuant to Rule 9-7 is a true trial of the action, in the sense that "judgment may be granted in favour of any party, regardless of which party has brought the application," so long as the court concludes that it can find the necessary facts to decide the issues and is of the view that it would be just to decide the issues in that manner: *Gichuru v. Pallai*, 2013 BCCA 60 at para. 23. That statement is complicated somewhat by the extended evidentiary focus just discussed, however.

[27] Obviously, I cannot issue judgment against Teva and Sandoz on the basis of evidence concerning persons who are not parties to the action; doing so would violate the rules of natural justice and the foundational principles of our adversarial system of justice. Pre-certification class action proceedings cannot be used as a vehicle for persons who are not parties to the proceeding to prosecute a claim against the defendants: see *Birrell* (S.C.) at para. 11. Thus, I can only issue judgment in favour of the plaintiffs if they are able to prove their claims as individuals. The question is, then, what role can evidence related to potential class members play in a summary trial?

[28] Considering the principle articulated in *MacKinnon*, and the law applicable to Rule 9-7, I conclude that evidence relating to the proposed class can be considered in determining whether it would be unjust to decide the issues on the application. If the plaintiffs fail to prove the claims of the individual plaintiffs, but there is evidence that Teva and Sandoz have breached a duty of care to the Canadian users of their transdermal fentanyl patches, I should refuse to issue judgment on the summary trial and allow the claim against Teva and Sandoz to continue to the certification hearing.

REVIEW OF THE EVIDENCE

[29] The evidence tendered in this matter consisted of affidavits from Desiree Player and Elaine Mills, the plaintiffs; a number of affidavits from legal assistants and associates employed by the parties' counsel; and extensive expert opinion evidence, that I will discuss in more detail below. The majority of these deponents were cross-examined and transcripts of those examinations were provided to the court. For the reasons given above, I will review all of the evidence, not just that related to the claims of the individual plaintiffs.

[30] Before setting out the evidence presented in the affidavits, I will briefly lay out the law of products liability in Canada. Although I intend to discuss the law in more detail later in the judgment, some comment on the law of negligent design and failure to warn is necessary to put the evidence in context.

[31] There is no question that all the defendants in this matter owe a duty of care to the end users of their product. They have a duty to take reasonable care in the design, manufacture and distribution of transdermal fentanyl patches, so as to eliminate any unreasonable risk or foreseeable harm inherent in the use of that product. To escape liability, they must produce a "reasonably safe" product.

[32] Determining whether something is "reasonably safe" requires the court to undertake a risk-utility analysis. Factors to consider in this balancing include the utility of the product, the risk of injury inherent in the product, the availability of a safer design, the potential for designing or manufacturing the product so it is safer but remains functional and reasonably priced, and, among others, the plaintiff's ability to avoid injury with careful use of the product. Much of the conflicting evidence in this case focuses on two of these factors: first, the risks inherent in the use of transdermal fentanyl patches; and, second, the availability of a safer design.

[33] Even where the design itself is not negligent, so long as there is some danger associated with the use of the product, the manufacturer and distributor of that product has a duty to warn those who use the product about those dangers. The

warnings must be reasonably communicated and must clearly describe any specific dangers arising from the ordinary use of the product.

Evidence of Named Plaintiffs and Proposed Class Members

Death of Robert Player

[34] In September 2006, Mr. Player was in a motor vehicle accident where he suffered a severe head injury. Beginning in December 2006, he was prescribed fentanyl for pain relief. Mr. Player's treating physician also prescribed a number of other drugs following the injury, including a sedative, an anticonvulsant, an anti-inflammatory, an antidepressant, and a drug for neuropathic pain.

[35] At the time, Ms. Player was in training as a registered nurse. She was responsible for applying Mr. Player's fentanyl patches. She says she did so according to the instructions, and that she was always careful to remove the old patch before applying a new one. She was also responsible for organizing and administering his other medications.

[36] On August 9, 2007, Ms. Player was going to be away from home overnight and so arranged for Mr. Player to spend the night at her mother's house. She did not return to her mother's home until late in the afternoon on August 10. Mr. Player was last seen alive by a family member around 6:30 a.m. that morning, asleep on a sofa. When Ms. Player arrived around 3:00 p.m., she discovered Mr. Player lying dead on the same sofa.

[37] Ms. Player provided a copy of the coroner's report issued following Mr. Player's death. The report lists the cause of death as fatal respiratory depression due to a prescription drug interaction. A toxicology examination revealed the presence of Fentanyl, Trazodone, Carbamezepine, Gabapentin, Celecoxib, Citalopram, and Olanzapine in Mr. Player's bloodstream. The report notes that all seven of these drugs are respiratory depressants, and concludes that "[t]he combined effect of these medications caused hypoventilation, or respiratory depression." The investigative findings in the report indicate that several

prescription medications were found by Mr. Player's body and that several doses were missing, suggesting that he may have taken extra doses of some of his medications prior to his death.

[38] During cross-examination, Ms. Player admitted that Mr. Player had accidentally over-medicated on a number of occasions prior to his death, but said that as the majority of the medications were in blister packs, it was not possible to determine whether he had over-medicated on the day of his death. She also acknowledged that while Mr. Player had prescriptions for six of the seven drugs found in his system, he did not have a prescription for Trazodone, a sleeping pill. He instead had a prescription for Zoplicone, likewise a sleep aid. Ms. Player herself did, however, have a prescription for Trazodone. She said that she thought Mr. Player had probably found the Trazodone at her mother's house and taken it in error, thinking it was one of his own medications. I note that the toxicology examination shows that Mr. Player did not have any Zoplicone in his bloodstream at the time of his death.

[39] According to Ms. Player, Mr. Player had used both ratio-FENTANYL and Duragesic brand patches during the course of his treatment. As noted above, ratio-FENTANYL is a matrix drug-in-adhesive style patch manufactured by Teva, while Duragesic is a reservoir patch manufactured by one of the other defendants. Ms. Player was not certain which patch Mr. Player was using when he died, but deposed that she believed it was "most likely" ratio-FENTANYL. She did not provide any basis for this belief. Nor did she provide prescription records or any other supporting documentary evidence that might have established the brand of fentanyl patch used by Mr. Player in August 2007.

[40] Ms. Player stated that she had read the information leaflet and warnings included with the fentanyl patches used by Mr. Player and understood that there were risks associated with the use of fentanyl. In particular, she noted that she and Mr. Player felt a "great deal of apprehension" over a warning that those sleeping in

the same bed with a person using a fentanyl patch could be injured or even die, if the patch detached and adhered to the other person's skin.

[41] However, Ms. Player also said that at the time of Mr. Player's death she was not aware that fentanyl could cause respiratory depression, or that the patches could release more of the active drug than intended. She was also not aware that mixing fentanyl with a sedative, such as a sleeping pill, could be fatal. In her view, she was not accurately informed of the risks associated with the use of fentanyl. She said that if she had been aware of the dangers, she would not have allowed Mr. Player to use fentanyl patches.

[42] During cross-examination, Ms. Player reviewed the patient information provided with transdermal fentanyl patch products and agreed that it did mention the risk of respiratory depression. She stated that she could not recall if she had read that section of the information leaflet at the time of Mr. Player's death. She also acknowledged that the leaflet advises that fentanyl may have potentially harmful interactions -- including drowsiness, depressed breathing, low blood pressure or coma -- when mixed with other medications, particularly sleeping pills or other sedatives. Ms. Player testified that she did not understand from the leaflet that depressed breathing could cause death.

The Extended Coroner's Report

[43] As noted above, Ms. Player attached a copy of the coroner's report to her affidavit. She did not include a copy of the autopsy report or toxicology report completed following his death. Both documents were instead tendered by the applicant defendants, who, it appears, received these additional documents when they requested a certified copy of the full coroner's report from the coroner's office. It is not clear from the evidence whether Ms. Player received either document from the coroner's office.

[44] These documents provide a number of further details from Mr. Player's post-mortem examination. The autopsy report indicates that at the time of death,

Mr. Player was wearing two fentanyl patches, one on each arm. Ms. Player stated in cross-examination that she would not have put a second patch on Mr. Player without removing the first one. She believes he must have put the second patch on himself.

[45] The report does not suggest that the first patch was still active when Mr. Player put the second patch on. Nor does it suggest that the use of two patches resulted in a fentanyl overdose. The toxicology report includes a somewhat cryptic comment that suggests otherwise, as it says "[b]lood level of fentanyl as found after regular application of patches." Neither party presented any evidence from the forensic toxicologist, post-mortem examiner or the coroner and there was no expert opinion tendered interpreting the coroner's report or the additional documents.

[46] The plaintiffs objected to the admission of the autopsy and toxicology reports on a number of bases. They say that they were deliberately withheld by the applicant defendants until the last possible moment, and then sprung upon Ms. Player at cross-examination in a form of prohibited "trial by ambush"; that they were filed too late, after the agreed deadline for filing evidence; and that they were inadmissible hearsay. At the summary trial the reports were filed as exhibits to an affidavit from Andrew Aguilar, a lawyer with counsel for Teva. In the affidavit Mr. Aguilar indicates that he received the report from the coroner's office.

[47] According to the plaintiffs, the reports could not be received for the proof of their contents unless the coroner swore an affidavit. Even if the coroner did so, the plaintiffs submit that the resulting affidavit would also be inadmissible as the coroner is not a doctor and cannot give an opinion as to cause of death.

[48] As the plaintiffs point out, in a summary trial deponents must swear to evidence from personal knowledge, not evidence based on information and belief. The plaintiffs rely on *Huron-Perth Children's Aid Society v. C.H.*, 2007 ONCJ 744, where the court stated that a party seeking to rely on hearsay evidence in an affidavit should explain why the person who tendered the information could not swear an affidavit of their own and be made available for cross-examination. Further, in *British Columbia (Public Guardian and Trustee of) v. Egli*, 2003 BCSC

1716, this court held that medical records expressing an opinion as to the mental capacity of a patient were inadmissible for the truth of their contents where the person giving the opinion did not provide an affidavit.

[49] In submissions on this matter, the plaintiffs also addressed the evidentiary value of the original coroner's report, which, as I have indicated, was filed as an attachment to Ms. Player's affidavit. They say that they did not submit it as proof of the contents of that report, but only in support of the evidence of Ms. Player. According to the plaintiffs, the report is only relevant to show that Mr. Player was taking fentanyl at the time of his death, and that therefore his claim to be a member of the potential class is not baseless. They say that it is not, and cannot be, evidence that Mr. Player died or was otherwise injured because he was taking fentanyl.

[50] Given the context, that submission is somewhat surprising. In her affidavit Ms. Player deposes that Mr. Player's cause of death was fatal respiratory depression. She also says that he died while using fentanyl patches for pain relief. This is not sufficient to establish -- nor does it even suggest -- that Mr. Player's death was caused by his use of fentanyl transdermal patches. If the coroner's report is not tendered for the truth of its contents, there is no admissible evidence to link Mr. Player's death with his use of fentanyl.

Conclusion on Evidence Relating to Mr. Player

[51] In the circumstances, I cannot place any reliance on the details of Mr. Player's death as evidence of the plaintiffs' claims. The plaintiffs have not put forward any admissible evidence establishing fentanyl as a cause of Mr. Player's death and the resulting injuries to his estate and Ms. Player. They relied on Ms. Player's affidavit, which establishes the fact of his death and the fact that he was using fentanyl at the time. The affidavit does not permit me to conclude that Mr. Player was using a matrix-style patch at the time of his death, as at best, Ms. Player can only say, without corroborating evidence, that it was "most likely" the ratio-Fentanyl patch.

[52] The affidavit included a coroner's report that lists the cause of death as fatal respiratory depression due to a prescription drug interaction. It appears that fentanyl was one of the drugs in Mr. Player's system at the time of death, but as the plaintiffs themselves submitted, there is no expert evidence that would allow me to determine what role, if any, fentanyl played in his death. In addition, I accept that a coroner's report, without some expert interpretation, cannot prove cause of death. Evidence from the toxicologist, post-mortem examiner, or an expert interpreting the autopsy and toxicology findings would be necessary to prove causation.

[53] The best that can be said on the facts of Mr. Player's death is that at the time of his death he was wearing two fentanyl patches and using other drugs and that death *likely* resulted from an interaction of the drugs found in his system upon post-mortem examination. This sort of evidence cannot be dispositive at a summary trial. As I have said, a summary trial is a true trial of the action. The onus remains with the plaintiff and the rules of evidence apply as they do at a full trial.

[54] I conclude that the evidence concerning Mr. Player's death is not sufficient to prove it was more likely than not that Mr. Player died as a result of his use of a matrix fentanyl patch manufactured by either Teva or Sandoz. Therefore, the evidence does not support the claim by the Estate of Robert Player or Ms. Desiree Marine Player against Teva or Sandoz. Given this conclusion, there is no need for me to comment further on the admissibility of the additional two reports.

Death of Daniel Pollock

[55] Daniel Charles Pollock, whose estate and widow, Elaine Mills, are also named as plaintiffs, died while using fentanyl transdermal patches. However, as Dr. Mills acknowledges in her affidavit, Dr. Pollock was prescribed and used the Duragesic fentanyl patches, which utilized the reservoir design. While Dr. Pollock's injuries are relevant to the claim against the other defendants, they do not have any bearing on the question of whether the matrix-style patches manufactured by Teva and Sandoz cause injuries as alleged. As a result, I will not say any more about Dr. Mills' evidence.

Reported Injuries to Members of the Proposed Class

[56] Ruel Mugot, a legal assistant employed at Merchant Law Group LLP, deposed that he spoke via telephone with eight potential class members in the proposed fentanyl class action. It appears that these individuals were identified after they entered their contact information into an online database that plaintiffs' counsel has access to respecting fentanyl litigation.

[57] Mr. Mugot says that each of the individuals he spoke with identified themselves as a current or former fentanyl patch user, or as a family member of a person who had died while using fentanyl patches. During his conversations with these individuals Mr. Mugot asked them to identify the brand and dosage of fentanyl patch used, the dates of use, and any adverse events experienced while using the patches. He also asked them whether they, or their relative, had ever misused or misapplied fentanyl patches. He deposed that "[e]very individual with whom I spoke indicated that in their case the fentanyl patches had always been used as directed."

[58] Melissa Coghill, a legal researcher at Merchant Law Group, also deposed that she spoke by telephone with 24 potential class members. She repeated the same questions used by Mr. Mugot and stated that all the respondents had all indicated that their fentanyl patches had always been used as directed.

[59] The persons interviewed by Mr. Mugot and Ms. Coghill reported the following adverse events:

- twelve people reported that their relatives died while using fentanyl patches;
- five people reported dermal irritation, defined as skin rashes, hives, or open sores;
- thirteen people reported that they or their relatives suffered cognitive impairment, defined as including dizziness, drowsiness, nervousness, hallucinations, anxiety or depression;

- eighteen people reported experiencing respiratory difficulties, such as respiratory arrest, difficulty breathing, weak or shallow breathing, or shortness of breath; and

- two people did not report any adverse events.

[60] A number of the people interviewed could not recall what brand or dosage of fentanyl transdermal patch they or their relative had used. The others reported use of a variety of brands, including patches manufactured by both Teva and Sandoz.

[61] The applicant defendants object to the admissibility of this evidence, on the grounds that it is hearsay. While the affidavits list the names of the persons interviewed, none of those people provided affidavits of their own and were as a result not available for cross-examination. They say that the plaintiffs could, and should, have provided evidence directly from the potential class members.

[62] At a summary trial, evidence must be based on personal knowledge, not on information and belief: see *L.E.W. v. United Church of Canada*, 2005 BCSC 564 at para. 7. The plaintiffs acknowledged that in their own submissions with regards to the coroners' report.

[63] I find that the evidence of potential class members is not admissible as proof to support the plaintiffs' claims upon this summary trial. However, bearing in mind the principle established in *MacKinnon, v. Instaloans, supra* the evidence can be considered and may be a factor in determining whether it is just to determine this matter on a summary trial. However, I agree with Teva and Sandoz that it would have been possible for the plaintiffs to provide affidavits from these proposed class members themselves. As such, given the hearsay nature of the information provided, it is only entitled to minimal weight, even for this limited purpose.

Adverse Event Reports

[64] Ms. Coghill also swore an affidavit in which she says that she examined publicly available data about adverse events experienced by the users of fentanyl

transdermal patches in Canada. In particular, she examined the Canada Vigilance Adverse Reaction Online Database, a site maintained by Health Canada. The reports in the database are submitted to Health Canada by health professionals, consumers, or drug manufacturers and distributors. Health Canada issues a number of caveats about the use of the reports, stating that the reported clinical data is often incomplete and that the reports cannot be used to establish that the health products in question caused the reported reaction.

[65] Ms. Coghill acknowledged that the reports cannot establish a causal link between a drug and a specific adverse event, but stated that they do indicate a temporal relationship between the use of a drug and a reported adverse advent. In the case of fentanyl users, reported adverse events included respiratory difficulties, cognitive impairment, dermal irritation, and death. Other reports indicated that the patient complained that the drug was ineffective for its prescribed purpose.

[66] Again, Teva and Sandoz oppose the admission of this evidence. They point out that the reports are double hearsay: Health Canada simply reports the information provided by other parties. The plaintiffs in their own submissions regarding the admissibility of the autopsy report relied on *Rosetim Investments Inc v. BCE Inc*, 2011 SKQB 253, where the court ruled that reports downloaded from the Internet were inadmissible because the affiant had no personal knowledge of the contents and there was no way to establish the reliability of the reports. That principle seems equally applicable here.

[67] Further, the applicant defendants argued that even absent the concern about hearsay, no weight for any purpose can be given to the adverse event reports as they contain incomplete or misleading information. Both Teva and Sandoz sought to demonstrate that the reports do not contain all of the relevant information regarding the alleged adverse event. Teva provided a record of their own submissions to Health Canada corresponding to two vigilance reports that listed “death” as an adverse event and indicated that the patient had been using a Teva fentanyl patch. In both cases Teva’s records indicate that the deaths were associated with drug

abuse. In one, Teva received information from a police officer that a woman was found dead with a fentanyl patch in her mouth. She did not have a prescription for the product. Similarly, in the other incident, police reported a death involving suspected drug abuse; the decedent did not have a prescription for fentanyl.

[68] Sandoz also provided its own adverse event case files for two vigilance reports listing "death" as an adverse event in association with use of a Sandoz fentanyl product. In one case the reporting doctor indicated that the patient died of prostate cancer and that the reported opioid toxicity cleared up prior to death. In addition, the reporting pharmacist indicated that while the patient was taking fentanyl, it did not appear that fentanyl played any role in the opioid toxicity, which was registered as a reaction to Sandoz Opium and Belladonna. It was not clear what brand of fentanyl the patient was using.

[69] In the second case, the patient presented at a hospital with confusion and delirium and was found to be wearing two Sandoz Fentanyl patches, which she had unintentionally left on for 7 days. The patient's delirium resolved after treatment in the hospital; she died approximately five days later from metastatic cervical cancer. There was no evidence that the death was in any way related to the patient's use of fentanyl.

[70] These examples highlight the danger of relying on the Health Canada reports, either as evidence of injuries caused by fentanyl transdermal patches or as of risks associated with those products. I agree with Teva and Sandoz that no weight can be given to this evidence as proof of the plaintiffs' claims or in considering whether the case is appropriate for determination on summary trial.

EXPERT AND SCIENTIFIC EVIDENCE

[71] The parties to this summary trial application filed extensive evidence. The plaintiffs relied on an expert opinion from Dr. Bozena Michniak-Kohn, an American scientist specializing in the area of transdermal and topical drug delivery. She is currently a tenured professor of pharmaceutics at Rutgers University and she is the

Director of the Center for Dermal Research and the Laboratory for Drug Delivery of the New Jersey Center for Biomaterials.

[72] Teva provided affidavits from Paul Stojanovski, the Executive Director of Quality and Compliance at Teva, and W. Bruce Valliant, Director of Pharmacovigilance with Teva. Pharmacovigilance is an umbrella term that describes a company's drug safety practices, including the detection, assessment, monitoring and prevention of adverse drug affects. Sandoz similarly provided affidavits from Nathalie Fortier, their Drug Information and Pharmacovigilance Manager, and Jo-anne Soltesz, Manager of the Regulatory Competency Centre for Sandoz. Generally speaking, the evidence they provided dealt with the regulatory regime governing pharmaceutical products in Canada, the quality control and assurance practices at each company, and their respective pharmacovigilance records.

[73] Teva also provided two expert opinions. Dr. Brenda Lau, a licensed British Columbia physician with a specialty in pain medication, provided an opinion on the utility of fentanyl transdermal patches and the risks associated with their use. Dr. Lau works at Surrey Memorial Hospital and St. Paul's Hospital and is the Chair of the Regional Pain Services Division, where she oversees the development of pain management services for hospitals in the Fraser Health Authority.

[74] Dr. Marianna Foldvari provided an affidavit as an expert in the area of transdermal drug delivery systems. She is a professor of pharmaceutical sciences at the University of Waterloo and the Canada Research Chair in Bionanotechnology and Nanomedicine. She provided her opinion with regards to the design of Teva's matrix transdermal fentanyl patches relative to the risks associated with their use.

[75] Sandoz provided an expert opinion from Dr. Philippa Hawley, a licensed physician specializing in the area of pain management and palliative care. She currently does clinical work at the British Columbia Cancer Agency, based in Vancouver. Beginning in 1997, she initiated and developed the Cancer Agency's Pain and Symptom Management/Palliative Care Program, a clinical program

providing medical services to patients with a cancer history who present with pain as their primary problem. She is currently the Provincial Medical leader of that program. She estimates that between 2011 and 2013 the clinic has treated 900-950 patients, of whom she has personally treated between one-third and one-half. She is also the head of the Division of Palliative Care at the University of British Columbia. Dr. Hawley provided an opinion with regards to the role of transdermal fentanyl patches in cancer pain management and the risks associated with transdermal fentanyl use.

[76] As will become apparent in the review of the scientific evidence, there were a number of conflicts between the expert opinions. Each expert provided response affidavits addressing their concerns with the other opinions. The parties also challenged the admissibility and weight to be given to some of the opinions. I have attempted to clearly set out the information provided and highlight the points of conflict and concern, although this task was made more difficult by the "she said - she said" nature of the battling affidavit evidence. I have left the questions of admissibility and weight for discussion following the review of the scientific evidence.

Fentanyl and the Pharmaceutical Context

Fentanyl Transdermal Patch Technology in Canada

[77] Fentanyl is a member of the opioid family. It is a potent drug and, along with morphine, hydromorphone, oxycontin, methadone and tapentadol, is categorized as a "strong opioid." In Canada it is authorized for use for the treatment of moderate to severe pain. It is only available by prescription.

[78] Unlike the other strong opioids, fentanyl is fat soluble, and as a result can permeate a patient's skin. It can therefore be administered transdermally, in the form of a patch. Generally speaking, these transdermal patches are designed to release a constant flow of fentanyl into the patient's bloodstream over a 72-hour period.

[79] Transdermal fentanyl patches have been available in Canada since 1991, when Health Canada granted Janssen-Ortho Inc. authorization for the sale of Duragesic brand patches. Duragesic manufactures "reservoir" type transdermal fentanyl patches. As an innovator drug, Duragesic was initially protected by patent, so that no other companies were permitted to sell transdermal fentanyl patches prior to 2006. Once the drug entered the "off-patent" period, a number of other companies applied for authorization to release generic versions of the product.

[80] Among the pharmaceutical companies that successfully received Health Canada authorization for sale of generic transdermal fentanyl patches were Ratiopharm Inc., Novopharm Ltd., and Sandoz. Ratiopharm manufactured the ratio-FENTANYL patch, Novopharm the Novo-Fentanyl patch, and Sandoz the Sandoz Fentanyl patch. Health Canada authorized the sale of ratio-FENTANYL in July 2006, Novo-Fentanyl in August 2008 and Sandoz Fentanyl in June 2009.

[81] As a result of corporate mergers, Teva is now the successor company to both Ratiopharm and Novopharm. The ratio-FENTANYL patch is still available in the market but the Novo-Fentanyl patch has subsequently been rebranded as the TEVA-Fentanyl patch.

[82] All the patches manufactured by Teva and Sandoz are matrix drug-in-adhesive style patches. As I will discuss in more detail below, generic drugs are not required to match the innovator products exactly. They only need to be "bioequivalent," so that the same level of active ingredient is released from the generic product at the same rate as it is released from the innovator product. The generic versions may therefore differ from the innovator product in their delivery mechanisms or other design elements.

The Regulation of Pharmaceuticals in Canada

[83] Health Canada is the independent federal agency responsible for regulating the sale, safety and efficacy of drugs in Canada. In particular, the Health Products Food Branch ("HPFB") is responsible for the regulation of pharmaceuticals. A drug

cannot be sold in Canada until it receives market authorization from the HPFB, which requires that an applicant organization demonstrate a drug's safety and efficacy in accordance with Health Canada regulations.

[84] The process for demonstrating drug safety and efficacy is a complicated one, particularly where the drug is an "innovator", or the first of its kind. I summarize it here as follows:

- The applicant must conduct pre-clinical studies, which involve in vitro (test tube) and in vivo (animal) testing for the performance of the drug and any potential toxic effects.

- The applicant may then apply to HPFB for authorization to conduct a clinical trial on human subjects. The purpose of the clinical trial is to verify the pharmacological effects of the drug, identify any adverse events, study the absorption, distribution, and metabolism of the drug, and ascertain its safety and efficacy. The HPFB regulates the design of clinical trials and ascertains that they do not expose participants to any undue risk. The clinical trials for innovator drugs are performed both with healthy volunteers and with the patients who are the target subjects for the drug.

- If the clinical trial indicates that the drug has a therapeutic value that outweighs any risks associated with its use, the applicant can file a New Drug Submission ("NDS") with HPFB. This form contains information about the product's safety, efficacy and quality, relying on the results of the pre-clinical and clinical trials. It also details the production method for the drug and its packaging and labelling, including the product monograph. The HPFB reviews this information and, if satisfied that the benefits of the drug outweigh the risks, issues a Notice of Compliance and Drug Identification Number, both of which are required prior to any sale in Canada.

- The approval process for generic drugs is streamlined, as it relies on much of the data put forward in the original NDS. The applicant for a generic drug files an Abbreviated NDS ("ANDS") with the HPFB. The ANDS is focused on demonstrating that the generic drug is bioequivalent to the innovator drug. Bioequivalence, as discussed above, assures that the same level of active ingredient is released from the generic product at the same rate as from the innovator product. HPFB proceeds on the assumption that so long as the drugs are bioequivalent, the generic drug has the same safety profile as the innovator drug. As a result, no further safety and efficacy testing is required.

- The manufacturers of generic drugs conduct clinical studies in testing for bioequivalence. The company administers the proposed generic drug to a group of healthy volunteers and also administers the innovator drug to the same group of volunteers. From there, the company can sample how quickly each drug enters the bloodstream and how much total drug enters the bloodstream over the dosage period. Unlike the innovator drug, generic drugs are not tested in clinical trials with diseased or injured patients.

[85] As discussed, both Teva and Sandoz manufacture generic versions of Duragesic, the innovator product. They were granted authorization for sale after establishing bioequivalence with that product.

[86] Dr. Foldvari reviewed the ANDS for both ratio-FENTANYL and Teva-Fentanyl, which included records of the bioequivalence studies conducted for both drugs. In Dr. Foldvari's opinion, both Teva patches were tested for safety and efficacy in accordance with all applicable industry standards. She deposed that the studies in question were done in accordance with Good Clinical Practice ("GCP"), an international ethical and scientific quality standard used in designing, conducting, recording and reporting clinical trials on human subjects. Health Canada, like other

national drug regulators, has adopted GCP as the required standard for use in clinical trials.

Quality Control for Teva and Sandoz Patches

[87] Both Teva and Sandoz provided information about their manufacturing and quality control processes. Ratio-FENTANYL matrix patches are manufactured in Germany, while Novo-Fentanyl and the subsequent TEVA-fentanyl matrix patches are manufactured in Florida. Sandoz Fentanyl patches are manufactured in Germany.

[88] Mr. Stojanovski and Ms. Soltesz, who monitor quality control and regulatory compliance at Teva and Sandoz respectively, said that the drug manufacturers are required to test the products for compliance with Health Canada specifications as well as with each company's own quality control specifications. In this process the manufacturers take representative samples from each lot and test them for potency, purity, and content uniformity. The manufacturers then issue Certificates of Analysis, which certify that the patches in each lot meet the chemical composition specifications approved by Health Canada. They also issue a Certificate of Manufacture, which certify that the patches in the lot were manufactured in accordance with Health Canada's approved manufacturing processes. These materials are reviewed by quality assurance staff upon arrival at Teva's and Sandoz's Canadian facilities.

[89] Mr. Stojanovski deposed that as far as he is aware, neither Ratiopharm, Novopharm nor Teva has ever released a fentanyl patch in Canada that was non-compliant with Health Canada quality control specifications. Similarly, Ms. Soltesz states that she is not aware that any non-compliant Sandoz Fentanyl patch has ever been released into the Canadian marketplace.

Evidence on Negligent Design Claim

Medical Utility of Transdermal Fentanyl Patches

[90] According to Dr. Lau, who specializes in pain medication, opioids are "the cornerstone therapy for moderate to severe tissue injury pain." Fentanyl, and in particular the patch dosage form, provide a number of unique benefits in use for pain management. First, fentanyl is up to 100 times more potent than morphine, another common opioid, so that effective pain relief requires lower concentrations of the active drug, thus reducing side effects and improving patient tolerance. Dr. Lau notes that fentanyl is the preferred strong opioid for use in patients with renal failure as many of the other drugs can have adverse effects on the kidneys. In addition, she states that fentanyl does not cause histamine release and is the preferred opioid for use in those who are susceptible to hypotension from histamine effects. As it can be delivered via patch, it is the only opioid treatment for severe pain in patients who cannot tolerate drugs taken by oral, intravenous or rectal administration. "Accordingly," Dr. Lau states, "there are certain categories of patients for which fentanyl is the only opioid available to physicians for the management of severe pain."

[91] Dr. Hawley provided a similar opinion, stating that transdermal fentanyl patches have "a unique and very valuable place in the management of cancer pain," particularly with patients who have digestive or swallowing difficulties. She noted that the patch dosage form also allows for treating physicians or caretakers to control the risk of abuse and monitor drug compliance more easily than with injection or oral-dose medications. She indicates that fentanyl is currently the only publicly-funded transdermal opioid available in Canada.

[92] Both doctors agreed that transdermal fentanyl patches have a number of practical benefits. Transdermal patches provide a constant dose over a period of time, thereby maximizing pain relief and avoiding patient overdose by diminishing the effect of erratic or inconsistent dosing. A patch also provides a benefit to pain sufferers because it can be used at home, rather than in a hospital setting, as it is

easy to administer. Dr. Hawley states that the benefits of fentanyl patches for patients and caregivers include a reduction in opioid-induced constipation; reduction in caregiver burden due to reduced frequency of administration; sleep improvements from stable dose flow at night; improved patient independence with less need for medication assistance; and improved patient confidence, self-esteem and dignity, as a result of the other listed benefits. In a palliative context, she notes that a reduced caregiver burden allows patients to rely on hospice care, which is inexpensive in comparison with a hospital bed in a palliative care unit.

Risks with Use with Fentanyl Transdermal Patches

[93] Dr. Lau and Dr. Hawley agreed that fentanyl use, as with all opioids, carries a risk of respiratory depression. However, both doctors opined that serious injury or death from opioid-induced respiratory depression would be "extremely unlikely" as long as the transdermal fentanyl patches were properly prescribed and applied. In Dr. Lau's experience, overdose and respiratory depression "almost invariably" result from a patient using a patch incorrectly or from errors in prescription. Like Dr. Lau, Dr. Hawley opined that "[i]f transdermal fentanyl is prescribed and used appropriately, I would not expect to see any serious respiratory issues associated with its use." She bases this conclusion on her own clinical practice. She estimates that of 3,000 patients seen between 2001 and 2011, she prescribed fentanyl for 15%. She included data from the Vancouver Centre Palliative Care Database showing the incidence of fentanyl patch use among patients at the clinics since 2005 varied between 12-18%. She is not aware of any episodes of respiratory depression due to transdermal fentanyl occurring in any cancer patients at the BC Cancer Agency.

[94] Dr. Lau and Dr. Hawley defined "appropriate" use or prescription of transdermal fentanyl patches as follows:

- The patch should not be applied to broken or altered skin, used while damaged, exposed to a heat source, or applied by a patient who has a

fever. All of these factors may result in an accelerated rate of drug release.

- The patch must be used by a patient with a prescription and in accordance with the instructions as to application. Intentional misuse or abuse, as where the patient applies additional patches, consumes the patches orally, or uses the patches without a prescription, can result in overdose.

- The patient should not use the patch in conjunction with certain other drugs, particularly other opioids or sedatives, as the interaction may lead to a dangerous increase in the risk of respiratory depression. A risk of drug interaction can arise where the patient fails to inform the prescribing physician of other medications they are taking or the physician fails to adequately monitor or assess the potential for drug interactions.

- The patient should be exposed to fentanyl through the use of gradual dose titration, a process where the dose of the chosen opioid is started low and slowly increased, allowing the patient to develop tolerance to the respiratory depressant effect. The prescribing doctor is meant to monitor the patient while the appropriate dosage is determined. A patient who is exposed too quickly to too much fentanyl may be susceptible to respiratory depression.

- The patch can only be prescribed for use by a patient who is opioid-tolerant. In Dr. Hawley's view, fentanyl cannot be safely used as a first-line opioid (i.e. with patients who are opioid-naïve). She notes that physicians are aware of this limitation on the safe use of fentanyl products.

[95] Dr. Hawley noted that the potential for respiratory depression with opioid use is well-known in the medical community. She deposed that a qualified and

reasonably competent physician would, in prescribing transdermal fentanyl patches, advise the patients of the risks of respiratory depression or overdose. A physician would also rely on strategies for managing or mitigating the risk of respiratory depression, such as the gradual does titration described above.

[96] Dr. Michniak-Kohn disagreed with this view. In her opinion, fentanyl transdermal patches are dangerous in ordinary use, as individuals who use them appropriately may still die with lethal levels of fentanyl in their blood.

[97] In giving this opinion, Dr. Michniak-Kohn relied on FDA adverse event reports, reports regarding deaths and injuries in Canada associated with use of transdermal fentanyl patches, and her experience as an expert in transdermal fentanyl litigation in the United States.

[98] However, as the applicant defendants pointed out, many of these source documents do not appear to support Dr. Michniak-Kohn's conclusion. While the sources do suggest that fentanyl is dangerous, after reviewing their content I am not persuaded that they establish that fentanyl is dangerous in ordinary use. One source, the Canadian Adverse Reaction Newsletter, relies on the Health Canada adverse reaction reports discussed above. As such the article is already based on incomplete information. In addition, the adverse reactions listed appear to be the result of intentional drug abuse or overdose, misuse or misapplication of the patch, prescriptions to opioid-naïve patients, inappropriate dose titration, or reactions between fentanyl and other drugs, such as sedatives. The article concludes by saying that the safe use of fentanyl is contingent on "its use according to the conditions recommended in the Canadian product monograph."

[99] Similarly, Dr. Michniak-Kohn cites an American article for the claim that "[m]any deaths have been reported after a single patch application in ordinary use." However, the article in fact says that "rare deaths have been reported after just a single patch application" and all those cases specifically discussed involved patients who were opioid-naïve. The other deaths discussed in the article involve individuals

who did not have a fentanyl prescription or who were administered fentanyl without gradual dose titration.

[100] I will discuss Dr. Michniak-Kohn's reliance on evidence tendered in American fentanyl litigation in more detail below. At this point I will simply note that Dr. Michniak-Kohn did not provide any documentation relating to her involvement in that litigation.

The Availability of a Safer Design

Matrix Patches versus Reservoir Patches

[101] Dr. Foldvari gave the opinion that matrix patches (and in particular, Teva's patches) are "state of the art, leading technology" in the transdermal administration of fentanyl. She is of the opinion that there is no extant safer alternative delivery mechanism for the administration of fentanyl.

[102] In her view, the safety profile for a matrix-style patch is superior to a reservoir-style patch. She deposed that the design of the matrix patch protects against the sudden or inadvertent release of large amounts of active drug, known as "dose-dumping," and the consequent risk of overdose. In her view, a reservoir patch allows for dose-dumping because any issue with the structural integrity of the patch itself can allow the patch to "dump" the entire dose out of the patch unexpectedly.

[103] Dr. Foldvari provided a comparison of the key features of reservoir patches and drug-in-adhesive matrix patches. Although noting that the two products are considered bioequivalent by Health Canada, and therefore deliver a statistically similar amount of active drug over the same period of time, she states that there are "significant, functional differences" between the two types of patch, including:

- Control of drug release: In a reservoir patch the release of the drug is controlled by a rate-controlling membrane. If the membrane is pierced or damaged, the drug may flow freely from the patch, potentially resulting in overdose. The drug in a matrix patch is controlled by the

components of the matrix itself and a concentration gradient between the patch and the skin. The drug moves from an area of high concentration (the gradient) to an area of low concentration (the skin). Because there is no membrane, there is no risk of drug release due to membrane damage. There is no concentration gradient controlling release in the reservoir-style patch.

- State of the drug: the active drug in a reservoir patch is in a gel form in the reservoir compartment. If the reservoir or the membrane between the reservoir and the skin is cut, torn or punctured, the drug may leak out of the patch resulting in an overdose. In a matrix patch, the drug is dissolved in the matrix and kept in a semi-solid state. It cannot leak, even if the patch is cut, torn or punctured.

- Stability of active drug: The stability of the fentanyl in a matrix patch remains constant. In a reservoir patch, the stability is dependent on the protective backing; where it is removed or damaged, components of the drug formulation, such as ethanol, may evaporate and change the chemical composition of the drug formula in the reservoir.

[104] According to Dr. Foldvari, the risks inherent in the use of a matrix fentanyl patches are shared by all transdermal fentanyl patches. In her opinion, it is not possible to design a patch that prevents drug abuse or deliberate misuse, or one that can deliver active drug at a constant rate to both normal and compromised skin. She also says it is not possible to design a patch that is unaffected by exposure to heat.

[105] It appears that the risks inherent in reservoir-style patches have, on at least one occasion, led to a recall for those products. In February 2008, Health Canada issued a recall notice for fentanyl patches marketed and distributed by Janssen and Ranbaxy. According to an advisory released by Health Canada, 25 mcg/hr Duragesic patches were recalled “because they may have a cut along one side of the patch which could result in leaking of the fentanyl gel from the patch.” Teva was

not subject to the recall notice in February 2008 (the Sandoz product had not yet come to market). Indeed, Mr. Valliant, Teva's Director of Pharmacovigilance, says that no matrix-style fentanyl patches have ever been recalled in Canada.

[106] In her affidavit Dr. Hawley agreed with Dr. Foldvari on this point, stating that the safety profile for transdermal fentanyl patches is increased with use of a matrix-style design, as compared with a reservoir-style design, because there is no risk of gel leakage.

Matrix Patches with Rate Control Membrane

[107] Dr. Michniak-Kohn acknowledges that there is no danger of drug leaking from a matrix patch if it is torn or cut. However, in her opinion, there is a safer alternative design available. According to Dr. Michniak-Kohn, there are more than two categories of transdermal fentanyl patch designs available on the market. In addition to the reservoir and matrix products, there are patches that she describes as "matrix with rate control membrane." She notes that specific brands may vary in a number of other ways, including through the use of permeation enhancers, the amount of fentanyl in the patch, the size of the patch, the type of adhesive, and the composition of the gel.

[108] In Dr. Michniak-Kohn's opinion, "a fentanyl patch that has both a matrix and rate-control membrane is superior to a patch without such a membrane," and that, as a result, there is an alternative design of a patch safer than those manufactured and marketed by Teva and Sandoz.

[109] According to Dr. Michniak-Kohn, examples of a matrix transdermal fentanyl patch with a rate controlling membrane are commercially available in Europe, under the brand names Matrifen and Fentadur, and in the United States, from Mallinckrodt Inc.

[110] In her opinion, adding a rate control membrane to a matrix patch "significantly reduces [the] risk" of unintended or accelerated drug release where the patch is applied to broken or altered skin. Without the rate control membrane, if a patch is

applied to compromised skin, she says that "delivery of fentanyl at a rate much higher than the labeled dose is likely to occur."

[111] In support of this opinion, Dr. Michniak-Kohn cited Suneela Prodduturi *et al*, "Transdermal Delivery of Fentanyl from Matrix and Reservoir Systems: Effect of Heat and Compromised Skin" (2010) 99:5 Journal of Pharmaceutical Sciences 2357.

[112] The article itself begins by indicating that there are, generally speaking, two types of transdermal drug delivery via adhesive patch: matrix, or drug-in-adhesive, systems; and reservoir, or membrane-controlled systems. I note that the article says nothing about the possibility of a matrix system with a rate-controlled membrane. The article notes that:

> matrix and reservoir systems have different characteristics, especially with regard to dosage form design and drug release … which makes direct comparison difficult.

[113] The purpose of the study was to assess the robustness of the two design forms when exposed to variations in skin condition (elevated temperature or compromised skin). The experiments were conducted using human cadaver skin samples, some of which were "tape stripped" to compromise the epidermal surface, and then again using synthetic membranes. The authors concluded that in conditions of compromised or highly variable skin, "a matrix FTS (Fentanyl Transdermal System) may be more affected than a reservoir FTS." The authors also note that "[i]n conditions of misuse or abuse such as elevated temperature or application of heat, either of these systems may cause an overdose."

[114] In Dr. Michniak-Kohn's opinion, matrix patches without a rate control membrane also result in greater variability in drug absorption rates, and "are more likely to lead to fatal overdoses than are matrix patches with a rate control membrane." She says that with matrix patches, only a user's skin controls the absorption, leading to great variability in absorption rates. She indicates that the data on Duragesic shows that the rate-control membrane accounted for over 50% of the rate control, so that fentanyl delivery across the skin without the membrane

would encounter only half the resistance and double the delivery on average. The applicant defendants challenged this statement, pointing out that Dr. Michniak-Kohn did not cite any study, or provide any data, to support that conclusion.

[115] Dr. Foldvari also disagreed with this view. She states that it is inaccurate to say that it is only the user's skin controlling absorption with the matrix patch. In her view, the bioequivalence studies required by Health Canada for the matrix patches demonstrated that the matrix patches delivered a statistically similar amount of drug to patients over the same period of time as a reservoir patch. Teva's bioequivalence studies particularly tested the effect of skin variability, by using a direct cross-comparison of both products on the same volunteers, and found that the products released the active drug in an equivalent manner regardless of the patient's individual skin permeability.

[116] Dr. Michniak-Kohn did depose that she has provided expert opinions in numerous American court cases involving transdermal fentanyl patches. She says that in each case she gave the same opinion that she presents here: that a matrix patch without a rate control membrane is more dangerous than a matrix patch with a membrane. She says that in those cases she assessed autopsy records for 48 individuals who died while using the Mylan patch, a matrix patch available in the United States (but not available for sale in Canada). According to Dr. Michniak-Kohn, there was no reported misuse or abuse of the patches in the cases and in each, post-mortem levels of fentanyl in the bloodstream were significantly higher than the concentration the patches were intended to deliver. She says that in each case the deaths were "all ruled to have been caused by fentanyl and they had higher levels than the patch should have produced."

[117] She states the records provided in those cases supported her opinion that the monolithic matrix patches, without a rate-controlling membrane, were responsible for the decedent's deaths. Again, Dr. Michniak-Kohn did not provide records from these cases. Nor did she provide the court with any decisions released by U.S. courts.

[118] During cross-examination Dr. Michniak-Kohn acknowledged that she herself has not conducted any studies comparing the performance of monolithic matrix patches with matrix patches with a rate-control membrane.

[119] Dr. Foldvari responded to Dr. Michniak-Kohn's opinion. To begin, she challenges Dr. Michniak-Kohn's classification of transdermal fentanyl patch design into three categories, with one described as a "matrix with a rate control membrane." Dr. Foldvari deposes that the classification of fentanyl patches is subjective and that any category grouping does not mean that the patches in the category have identical characteristics, mechanisms, or designs. Further, she says it would be more appropriate to describe the Fentadur, Matrifen and Mallinckrodt products as using a "modified reservoir design." She says the fentanyl in each is contained in a reservoir, with the release controlled by a physical membrane as opposed to the form of physico-chemical control used in a drug-in-adhesive patch like those manufactured by Teva and Sandoz.

[120] She provided a copy of the patent for the Fentadur product manufactured in the United States by Lavipharm. Based on her review of the technology in the patent, she states that the rate-control membrane is essential to the proper functioning of the patch. Without the membrane, the transfer of fentanyl from patch to skin would be too variable for safe use. She deposes that the rate control membrane is not, as Dr. Michniak-Kohn states, a secondary or supplementary safety device, but rather an essential element of the safe operation for that form of patch. Dr. Foldvari's review of the in vitro and in vivo testing of the Teva patches indicated that the matrix patches achieved effective rate control without a membrane.

[121] Nor does Dr. Foldvari agree that these patches offer a superior safety profile to a drug-in-adhesive matrix patch. In her view, there is no evidence that a rate control membrane reduces the risk of accelerated absorption, particularly when used on compromised skin. She notes that there is no scientific study supporting this position and states that a higher delivery rate may occur regardless of the presence of a rate control membrane. Dr. Foldvari concludes her response by stating that

there is simply no scientific evidence that the patch brands identified by Dr. Michniak-Kohn are safer than matrix patches, or that they are less likely to produce an overdose when applied to compromised skin.

Buprenorphine and Butrans Patch

[122] Dr. Michniak-Kohn also gave the opinion that Butrans, another opioid pain patch, is as effective as fentanyl in treating pain but does not present the same risk of death due to respiratory depression. The active drug in Butrans, buprenorphine, has a "ceiling effect", where elevated levels of the drug in the bloodstream have the effect of preventing respiratory depression, rather than causing it. Butrans patches have been approved for sale in Canada since 2010. In her opinion, buprenorphine provides a safer alternative transdermal opioid formulation when compared with fentanyl.

[123] Both Dr. Lau and Dr. Hawley disagreed with this conclusion. Dr. Lau indicated that she was familiar with the Butrans patch and had prescribed it in her pain management practice. However, she emphasized that Butrans does not provide a replacement or alternative for fentanyl products, as Butrans is only approved by Health Canada for the management of moderate pain, while fentanyl patches are approved for the management of severe pain. In her clinical experience, Dr. Lau has not found buprenorphine to be generally preferable to fentanyl; in her opinion, the Butrans patches are not as effective as the available fentanyl patches. She also notes that some of her patients have had adverse reactions to Butrans (rashes, sedation, constipation, nausea) but were able to better tolerate fentanyl. On that basis, she gave the opinion that the buprenorphine patch did not provide a viable alternative for the use of transdermal fentanyl products.

[124] Dr. Hawley agreed with Dr. Lau, giving the opinion that Butrans is not a viable substitute for fentanyl transdermal patches as it is not approved in Canada in dosages sufficient to address severe pain. She also noted that it is not publicly funded and is therefore unaffordable for many patients.

Evidence on Duty to Warn

[125] In Canada, pharmaceutical companies are prohibited from communicating drug information to patients without Health Canada approval of the form and content of that communication. This information is contained in the "product monograph," a document that describes the properties, claims, indications and conditions for use of the drug, along with any other information that may be required for the optimal, safe and effective use of the drug. The monograph contains separate sections with information for health professionals and consumers. The information provided to consumers is reproduced in a patient information leaflet, which Teva includes with every package of fentanyl matrix patches sold in Canada. Sandoz also includes a patient information leaflet with every box of Sandoz Fentanyl.

[126] For generic drugs, Health Canada requires that the consumer information portion of the monograph match the form and content of the monograph for the innovator drug. Only warnings which are included with the innovator's product may be included with the generic drug's consumer information. A generic manufacturer may not unilaterally add warnings to its consumer information, or change the wording of the existing warning. The warnings for the innovator drug and the generic drugs are, as a result, identical.

[127] Health Canada, as a part of its oversight of the pharmaceutical industry, will direct changes to a drug's product monograph from time to time. As indicated by Ms. Soltesz, this is only done where the manufacturer of the innovator drug comes forward with a recommendation for a change. The generic companies cannot change warnings without Health Canada's approval.

[128] The Teva and Sandoz provided copies of all the product monographs issued for ratio-FENTANYL, TEVA-fentanyl, and Sandoz Fentanyl from launch until the date of summary trial. Both defendants also provided copies of their patient information leaflets.

[129] With regard to the risk of respiratory depression, a review of the Teva product information leaflets shows that, with some variation, the leaflets provide the following warning:

> **When [fentanyl] should not be used:**
>
> **Because life-threatening decreases in breathing rate could occur, ratio-FENTANYL should not be used:**
>
> - for the relief of pain following surgery.
> - for the relief of pain which is only mild, or expected to last less than several weeks.
> - if you have acute or severe bronchial asthma.
> - If you are having difficulty in breathing.
>
> For the same reason, do not start on ratio-FENTANYL unless you have already been taking a strong opioid medication.

[130] Two of the later leaflets, produced for NOVO-FENTANYL between 2008-2010, instead say that:

> "Fentanyl is a very strong opioid narcotic pain medicine that can cause serious and life-threatening breathing problems. Serious and life-threatening breathing problems can happen because of an overdose or if the dose you are using is too high for you" [emphasis in original].

The leaflet advises patients to seek emergency medical help immediately if they have trouble breathing, experience slow or shallow breathing or a slow heartbeat, have severe sleepiness, feel faint, dizzy, or confused, or have a seizure or hallucinations.

[131] The leaflets also address the potential for abuse, and advise patients to dispose of leftover and discarded patches by flushing the patch down the toilet, not to damage or chew the patch, and not to let anyone else use the patch. Patients are also advised that they should not exceed the dose recommended by their doctor.

[132] A number of the experts reviewed the product information provided by Teva and Sandoz and provided opinions as to the accuracy and comprehensiveness of the included warnings. Dr. Lau gave the opinion that all of the risks associated with the use of fentanyl transdermal patches are reflected in Teva's product monographs.

In her opinion, the patient information leaflets "comprehensively addresses all of the known patient safety risks relating to fentanyl patches of which the patient should be made aware" (emphasis in original). In particular, she opines that the leaflet "reasonably warns of the risk of life-threatening decreases in breathing rate."

[133] Dr. Lau also states that the patient information adequately addresses the risk of accelerated drug release through the provision of instructions designed to mitigate the potential for inadvertent acceleration of the drug release rate. The leaflets advise the patient to apply the patch to a dry, non-hairy portion of the body, and in particular, to apply to the chest, back, flank or upper arm; to clip (not shave) the hair close to the skin, in order to avoid the risk of cuts; not to put the patch on skin that is excessively oily, burned, broken out, cut, irritated or damaged in any other way; not to clean the skin in the application area with soaps, oils, or lotions which may irritate the skin; and warns not to use soap, alcohol or other solvents to remove the patch because they may increase the drug's ability to go through the skin. The leaflets state that patients should remove one patch before applying the next one and should apply the new patch in a different location on the skin, as Dr. Lau notes that applying a new patch to the same area may increase the risk of acceleration. The leaflets also state that patients should not expose the patch to sources of heat and should not be used if the patient develops a fever.

[134] Finally, Dr. Lau gave the opinion that the leaflets reasonably address the risk of interactions between fentanyl and other drugs, as the patient is warned not to use the patch while using certain other medications or consuming particular substances. The patient is advised to inform the physician if taking any other medications, while a list headed "interactions with this medication" indicates that medications such as tranquilizers and sleeping pills may, in combination with the fentanyl patch, "cause drowsiness, depressed breathing, low blood pressure and possibly coma."

[135] Dr. Hawley reviewed the product monographs issued by Sandoz in 2009-2010 and gave the opinion that they adequately identify the risks of fentanyl use for physicians, pharmacists and patients. She also reviewed the patient information

leaflet and again deposed that the leaflet clearly and accurately explains the risks of use with the Sandoz Fentanyl patch, including the statement that "Fentanyl is a very strong opioid narcotic pain medicine that can cause SERIOUS AND LIFE-THREATENING BREATHING PROBLEMS."

ASSESSMENT OF THE EVIDENCE

[136] As already noted, Dr. Foldvari, Dr. Hawley and Dr. Lau all disagreed with various aspects of Dr. Michniak-Kohn's opinion. The applicant defendants also challenged the admissibility of much of Dr. Michniak-Kohn's evidence. In their submission, she provided opinions on matters outside her area of expertise, misrepresented or overstated the factual basis for her opinion, and acted as an advocate, rather than a neutral or objective party. Essentially, they say that Dr. Michniak-Kohn's opinion is not reliable, as she has not performed any studies or tests to measure and compare the safety and performance of the two types of patch, or provided any data or studies that provide direct support for her conclusion.

Matters Outside the Witness' Area of Expertise or Lacking a Reliable Factual Basis

[137] The applicant defendants particularly challenged Dr. Michniak-Kohn's ability to give evidence that relies on the interpretation of post-mortem fentanyl blood levels. In her affidavit she indicated that "[e]xperts in forensic toxicology and forensic pathology have expressed the opinion that post-mortem fentanyl levels can be relied upon as an estimate of the fentanyl level in the decedent's blood at the time of death." She says she relied on post-mortem blood levels in reaching conclusions as to the safety of the matrix patches in the Mylan fentanyl litigation. However, as she admitted on cross-examination, she herself is not qualified as an expert in forensic toxicology or pathology.

[138] On cross-examination the applicant defendants confronted Dr. Michniak-Kohn with evidence given by toxicologists in the U.S. Mylan proceedings she referenced. In the transcripts, the toxicologists indicate that post-mortem fentanyl levels are not a

reliable indicator of the level of fentanyl in the blood at time of death or the drug release rate of the fentanyl patch in question. Dr. Michniak-Kohn then acknowledged that reliance on post-mortem fentanyl levels in determining cause of death is somewhat controversial, as there are studies that suggest it is reliable and studies that suggest it is not. She did continue to state her opinion that the evidence in the Mylan litigation, including the post-mortem fentanyl levels, established that the patches had caused injuries in ordinary use by releasing the drug at an accelerated rate.

[139] In her affidavit, Dr. Lau deposed that the difficulties in correlating ante-mortem and post-mortem drug levels are well-recognized in the scientific community -- she provided a number of studies discussing these difficulties -- and stated that accurate interpretation requires an individualized approach with communication with the decedent's physician and other medical professionals. In Dr. Lau's opinion, there was nothing in Dr. Michniak-Kohn's report, curriculum vitae, or the exhibits to her affidavit that suggest she has any proper basis for offering an opinion regarding the significance of post-mortem drug levels in determining cause of death.

[140] Dr. Lau also challenged Dr. Michniak-Kohn's ability to give an opinion as to the suitability of a particular medication (i.e. Butrans) for use in a clinical setting. She points out that Dr. Michniak-Kohn is not a licensed physician (a fact that Dr. Michniak-Kohn acknowledges) and is not qualified to prescribe opioids or treat patients for pain.

[141] On cross-examination Dr. Michniak-Kohn admitted that she is aware that buprenorphine cannot be used as an alternative for fentanyl with every patient. She clarified that her view on Butrans is that it is "possibly safer than fentanyl and could be an alternative." She says:

> … in certain cases I am sure Buprenorphine can be used. Because I read in my literature search that that could be an alternative. … So I am not the only one looking at Buprenorphine as a possible alternative.

[142] The applicant defendants say that Dr. Michniak-Kohn mischaracterized some of the studies she relied on. I have already noted some of these concerns above, with regards to sources Dr. Michniak-Kohn relies on to establish that fentanyl may cause death with ordinary use. In addition, the applicant defendants say that the Prodduturi article referred to above does not actually support the conclusion that a matrix patch is more affected by variations in skin permeability than a patch with a rate-controlling membrane. It says that the matrix patch *may* be more affected, but also acknowledges that the experiments in the study were not sufficient to indicate whether the rate control membrane could prevent an overdose in the case of heat damage to the patch.

[143] Dr. Foldvari in her affidavit also says that the findings in the article are not statistically significant as the variability in the results obtained was high enough that conclusions could not safely be drawn without a larger sample size.

[144] Finally, the applicant defendants point out that Dr. Michniak-Kohn has herself has not conducted any tests to determine how the matrix patches performed in relation to patches with an additional membrane, or how the patches might perform with the addition of another membrane. Indeed, she acknowledged that she was not aware that anyone has done direct head-to-head safety testing comparing monolithic matrix patches and matrix patches with a rate-controlling membrane.

Dr. Michniak-Kohn as an Advocate

[145] In Canadian courts expert witnesses are required to be neutral and objective, rather than advocating for a party or position. Indeed, pursuant to Rule 11-2 of the British Columbia *Supreme Court Civil Rules,* affidavits from experts must contain a statement noting that they understand that their duty is to assist the court, rather than to act as an advocate for any party.

[146] The applicant defendants say that Dr. Michniak-Kohn misunderstood her role as expert and acted as an advocate for the plaintiffs, in particular by selecting materials she felt supported her position while purposely omitting sources that did

not support her conclusion. In cross-examination, Dr. Michniak-Kohn agreed that she did not put in all the materials available to her but stated that "everything is available in the public domain and I had to support the argument I was presenting."

[147] The applicant defendants particularly point to Dr. Michniak-Kohn's reliance on a letter from Alza, a US pharmaceutical company, to the FDA, where Alza alleges that patches lacking a rate-controlling membrane may release significantly more fentanyl than those that have one. Alza's letter also argued that patches without a rate-controlling membrane may perform differently than products with a membrane when applied to compromised skin, and as such should be treated as different dosage forms. Dr. Michniak-Kohn provided this letter as an exhibit in support of her opinion that a matrix patch without a rate-control membrane is not as safe as one that has a membrane.

[148] As Dr. Foldvari points out in her response affidavit, Alza, as the manufacturer of a Duragesic-brand reservoir patch, has a direct interest in promoting its own product over matrix style patches. In her view, it is not proper scientific technique to rely on material with such an obvious bias. Further, she provided a copy of the FDA response where the agency rejects Alza's argument. In it, the FDA finds that Alza has not provided any reliable data to show that a matrix system was less safe than a patch with a rate-controlling membrane. The FDA noted that while there may be some variability in skin permeability among individuals that can affect the rate of absorption, there was no data showing that a physical control (the membrane) provides a superior protection against variations in absorption rate than a chemical (matrix) control.

[149] Dr. Michniak-Kohn acknowledged on cross-examination that she was aware that there was an FDA reply, but did not think it necessary to include in her affidavit as, in her view, the FDA simply took the position that Alza had not provided sufficient data to accept their conclusion, rather than directly dismissing Alza's point of view. When asked why she included the Alza letter in her affidavit, she responded that it demonstrated that "the main company that was and is involved in transdermal

patches … also had concerns about the rate controlling membrane." Once again, Dr. Michniak-Kohn appears to have been selective in placing material before the court that support her opinion while omitting contradictory material.

Conclusion on Dr. Michniak-Kohn's Evidence

[150] In cross-examination Dr. Michniak-Kohn clarified a number of aspects of her initial opinion. Although in her affidavit she states that the matrix with a membrane is a safer product, in her cross-examination she appeared to add a caveat, repeating that the matrix patch with a rate controlling membrane *may* be a safer product. Noting that she had not done any comparisons in the laboratory, she said that the literature suggests "that if we did those studies, we *may* get some very favourable results." She also stated that, in essence, her message is that the existing designs can be improved, and that the addition of a "rate controlling membrane would potentially improve the design of those patches … Obviously, it is always a 'may' because … we haven't done the clinical trials on it."

[151] Asked whether there is any peer-reviewed literature that addresses the risk of overdose when a patch does not have a rate controlling membrane, she responds:

> … we know that rate controlling membranes control permeability of drugs. That is well-known in the scientific literature. So if you are trying to make a matrix patch more safer … if you add this rate controlling membrane, it should help. … if you added that extra layer, I think it is not high science to say that it would prevent some problems with those patches.

She says that there is no need to do comparison testing because it is obvious that adding another barrier to release -- an additional fail-safe -- increases the safety profile.

[152] The opinion of Dr. Michniak-Kohn is not that the matrix patch manufactured and distributed by Teva and Sandoz is unsafe. Rather, she is of the opinion that if a membrane was added to the patch it *might* be safer. No tests have been conducted to support her opinion and thus her opinion is speculative. The evidence of Dr. Foldvari is that patches sold in Europe and the United States which Dr. Michniak-Kohn claims offer a matrix patch with an additional membrane are not a third

category of patch that is safer, but rather a patch in which the membrane is a necessary feature of the patch to control the rate of release of fentanyl.

[153] I find that Dr. Michniak-Kohn is qualified to give expert opinion evidence on some aspects of this case, however she is not qualified to give opinion evidence on the appropriateness of drugs that could be used in substitution for fentanyl. I also find that in the areas where she is qualified, her opinion that the matrix patches manufactured by Teva and Sandoz are unsafe lacks a proper factual foundation. Finally, she has chosen to ignore evidence that contradicts her opinion and has taken on the role of advocate for the opinion she is advancing contrary to Rule 11-2(1) of the *Supreme Court Civil Rules.*

[154] I find that while her evidence is admissible, it is of little weight on the critical issue of whether the matrix patches manufactured by Teva and Sandoz are unsafe when used in accordance with the manufacturers' directions.

Other Challenges to Expert Evidence

[155] The plaintiffs challenged the evidence given by Drs. Foldvari and Hawley. They say that Dr. Hawley's assessment of the patches was overly focused on their value for money, in particular the cost savings associated with the use of transdermal fentanyl patches.

[156] The plaintiffs say the form of Dr. Foldvari's affidavit -- in which she appears to express an opinion as to whether the applicant defendants met the legal standard of care -- undermines her neutrality and also deprives the court of the ability to assess credibility or make the necessary factual findings. They say she relies too much on Health Canada approvals and bioequivalence studies in establishing safety, rather than focusing on the question of whether the products in question are reasonably safe or could cause harm in the manner alleged. They also say that her answers in cross-examination regarding the role of bioequivalence in establishing safety were revealing, as she refused to say that the bioequivalency studies established that the products were equally safe.

[157] The plaintiffs also say that Dr. Foldvari, as an expert in transdermal delivery systems, should have responded to questions on cross-examination about the potential for increasing the safety profile of a matrix patch with the addition of a rate-controlling membrane. Asked whether two safety features would be better than one safety feature, she responded that adding another rate-controlling mechanism to a patch would not be "rational," as it would suggest that the first rate-control mechanism was not adequately tested or sufficiently well-designed.

[158] The defendants' experts provided clear and well supported opinions. They have deep knowledge and are experienced in their respective areas of expertise. Drs. Hawley and Lau are practising physicians in the field of pain control and have first-hand experience in the administration and monitoring of pain control using fentanyl. They acknowledge placing reliance on Health Canada regulation and approvals of fentanyl products manufactured by Teva and Sandoz. They did not present as advocates for any product and they gave opinions on products that have been approved for use in Canada by Health Canada. The products apparently favoured by Dr. Michniak-Kohn, Matrifen and Fentadur, have not been approved for use in Canada.

[159] I find the expert evidence presented by Teva and Sandoz to be admissible and credible.

SUITABILITY FOR SUMMARY TRIAL

[160] Rule 9-7 of the *Supreme Court Civil Rules* permits any party to an action to apply to the court for judgment, either on an issue or generally, by way of a summary trial. The Rule, like its predecessor, Rule 18A, is meant to expedite the early resolution of cases by allowing parties to put forward their evidence via affidavits and other written materials, rather than by *viva voce* testimony.

[161] Not all matters are suitable for determination by this process. As set out in Rule 9-7(15)(a), the court may not grant judgment in a summary trial where the

judge is unable to find the facts necessary to determine the issues, or is of the opinion that it would be unjust to decide the issues summarily.

[162] The leading case on summary trial, *Inspiration Management Ltd. v. McDermid St. Lawrence Ltd.*, [1989] B.C.J. No. 1003 sets out a number of factors for the court to consider in determining whether it would be unjust to grant judgment at summary trial:

> The chambers judge is entitled to consider, inter alia, the amount involved, the complexity of the matter, its urgency, any prejudice likely to arise by reason of delay, the cost of taking the case forward to a conventional trial in relation to the amount involved, the course of the proceedings and any other matters which arise for consideration on this important question.

[163] Subsequent cases have identified a number of additional factors, including the cost of the litigation, the time needed for summary trial, whether credibility is a critical factor in the determination of the dispute, and whether the application would result in "litigating in slices": see *Dahl v. Royal Bank of Canada*, 2005 BCSC 1263 at para. 12, aff'd on appeal 2006 BCCA 369; and *Gichuru* at para. 31.

[164] In addition, as noted in *Dahl* at para. 13, the court should not issue judgment if doing so would require findings of fact that could embarrass the court at the hearing of any subsequent issues, as may happen where there are overlapping issues or multiple defendants. See also *Bacchus Agents (1981) Ltd. v. Philippe Dandurand Wines Ltd.*, 2002 BCCA 138.

[165] In *Gichuru* at para. 35, the Court of Appeal affirmed that the onus on summary trial remains with the plaintiff, even where the defendant has brought the application. All parties must come to the summary trial hearing "prepared to prove their claim, or defence" (para. 32). In other words, there is no "respondent's veto" at summary trial: the respondents -- in this case, the plaintiffs -- cannot argue that the matter is unsuitable for summary disposition on the basis that they have put forward insufficient evidence to prove their case (see *Everest Canada Properties Ltd. v. Mallmann*, 2008 BCCA 275 at para. 34).

Positions of the Parties

[166] The plaintiffs argue that the proceedings involve complex factual issues that require full examination for discovery and a conventional trial in order to provide the court with a full appreciation of the facts. They submit that these matters are not suitable for summary trial, due to the complexity of the case and the fact that conflicts in the evidence on the central issue will require the court to assess credibility. They also say that it is inappropriate to use a summary trial process in the context of a pre-certification class proceeding, as resolving the issues prior to certification is inconsistent with the goals and principles of the *Class Proceedings Act*.

[167] Teva and Sandoz point to a number of British Columbia cases where the court has issued judgment under Rule 9-7 in a pre-certification class proceeding. They also submit that conflicts in the evidence and credibility issues are not an absolute bar to proceeding summarily: *MacMillan v. Kaiser Equipment Ltd.*, 2004 BCCA 270 at para. 22. Even if there are conflicts in the evidence, provided there is sufficient admissible evidence to allow the judge to find the necessary facts, summary trial may still be appropriate. Finally, they say that there are no conflicts in the evidence, and that the plaintiffs have failed to meet their onus, as, in their submission, the affidavits tendered by the plaintiffs are not admissible as proof of their claims.

Summary Trials and Pre-Certification Class Proceedings

[168] At the summary trial hearing a major portion of the plaintiffs' submissions were concerned with the idea that a summary trial is *prima facie* inappropriate for determining issues in a proposed class action. As Teva and Sandoz point out, relying on *The Consumers' Association et al. v. Coca-Cola Bottling Company et al*, 2006 BCSC 863, aff'd 2007 BCCA 356, and *Dahl*, there are examples of British Columbia courts hearing pre-certification summary trials on the issue of ultimate liability. However, the plaintiffs' submissions raise a question as to whether the

status of this matter as a proposed class proceeding is a factor to consider in determining whether it is suitable for summary determination.

[169] Section 40 of *Class Proceedings Act* expressly provides that the *Supreme Court Civil Rules* apply to class actions, both pre- and post-certification. There is therefore no statutory bar on this court issuing judgment under Rule 9-7 for a matter brought under the *Class Proceedings Act*. However, as discussed above, the rules may alter in application in order to recognize the class proceedings context.

[170] For the reasons set out below, I conclude that the status of this matter as an "action with ambition" is not in itself a factor that would render it unjust to issue judgment. The factors set out in *Inspiration Management* and the subsequent case law provides sufficient safeguards against injustice, just as they do in an ordinary action.

[171] To begin, I do not accept the plaintiffs' argument that summary trial is not suitable because determining the case prior to certification would be inefficient. The plaintiffs argued that, because the decision would not be binding on the proposed class, judgment against the plaintiffs would simply result in another member of the class stepping forward to pursue the claim on behalf of the class.

[172] It is true that if this Court issues judgment against the plaintiffs and dismisses the claim against Teva and Sandoz, that decision only binds the named plaintiffs. As noted in Michael Eizenga *et al*, *Class Actions Law and Practice* 2d ed. (Markham: LexisNexis Canada, 2008):

> Motions brought before the certification motion, even where successful, may not mean an end to the litigation for the defendant. The determination will not bind the potential class members, and another class proceeding may be commenced.

[173] In some cases this might be a reason to deny the application for a summary trial; see for example *Sharrock v. Moneyflow Capital Corp.*, 2010 BCSC 1219. In *Pausche v. B.C. Hydro et al.*, 2000 BCSC 1556, the court refused to issue judgment on a limitations issue argued at a pre-certification summary trial, noting that to do so

could lead to a "pyrrhic victory for the defendants" as a new action might immediately be begun by another representative plaintiff "who was not susceptible to the limitations defence" (para. 22). However, as Bauman J. (as he then was) pointed out in *Pausche*, the application did not concern an issue common to all members of the proposed class. The same is true of *Sharrock*, where the applicant defendants advanced a defence unique to the representative plaintiff.

[174] In cases where the application concerns the defendant's liability to the class a whole, the concern about a replacement plaintiff is practically, if not legally, alleviated: *Martin v. Astrazeneca Pharmaceuticals PLC*, [2009] O.J. No. 3847 (S.C.J.), noting that summary determination would likely have "the practical effect of leading to an abandonment of the claims of other class members, an early settlement or a narrowing of the issues to be tried" (para. 17).

[175] Although Teva and Sandoz have made submissions regarding the named plaintiffs, their application for dismissal is based on the position that they are not in breach of any duty in law to the users of their matrix transdermal fentanyl patches they produce. If they succeed on summary trial, it is difficult to imagine that any new representative plaintiff would step forward to re-argue these issues.

[176] As Teva and Sandoz point out, there are a number of decisions where this court issued judgments under Rule 9-7 in pre-certification class proceedings. In *Dahl*, the plaintiffs brought a proposed class action against a number of defendant banks, alleging a failure by the banks to disclose the amount they charged to consumers using their credit cards. The banks applied under Rule 18A for dismissal on a number of the statutory claims, arguing that they had properly disclosed the amounts in question as interest charges. The court found that the matter was suitable for summary trial. The court also rejected the plaintiffs' argument that there were significant overlapping issues arising out of the issue proposed for summary determination and the issues that remained to be determined in the case.

[177] *Consumers' Assn. of Canada* involved a claim by the named consumers' association on behalf of all consumers who had purchased beverages in the

province after 1997. The plaintiffs claimed that the deposits for recyclable beverage containers collected from consumers were to be held in trust until refunded to the consumer, and alleged that the various corporate defendants (beverage manufacturers and Encorp, the not-for-profit agency in charge of beverage returns and recycling) had in fact converted $70 million in deposit funds to their own benefit. The court held that the matter was suitable for summary disposition, as the claims were not factually complex, there were no significant credibility issues, and the ample affidavit evidence addressed what few questions of fact arose in the matter.

[178] In addition to *Dahl* and *Consumers' Assn. of Canada*, the following decisions also involved a summary proceeding, either under Rule 9-7 or Rule 18A, in a pre-certification class proceeding:

- *Pfeiffer v. Pacific Coast Savings Credit Union*, 2000 BCSC 1472, var'd on other grounds, 2003 BCCA 122. Both parties applied for judgment under Rule 18A, the defendant seeking dismissal and the plaintiff seeking judgment on three substantive issues. The case involved the interpretation of a mortgage contract. The plaintiff was successful at summary trial and received an individual award, with the court directing that the hearing of the certification application be heard at a later date. The Court of Appeal disagreed with the chambers' judge's interpretation of the contract and reduced the award substantially, but did not disagree with the decision to issue judgment on summary trial.

- *Royster v. 3584747 Canada Inc. dba Kmart Canada Ltd. et al*, 2001 BCSC 153. This proposed class action involved the wrongful termination of Kmart employees following the closure of a particular branch of the store. The court found that the employer had given reasonable notice, in the form of working notice and pay in lieu of notice, and dismissed the claim following the summary trial.

- *Azevedo v. Legal Services Society (British Columbia)* (1998), 49 B.C.L.R. (3d) 45 (C.A.). On a summary trial the court found in favour

of the defendant and dismissed the claim; the Court of Appeal upheld the decision. The plaintiff lawyer had brought a proposed class action on behalf of all lawyers who had acted on behalf of legal aid clients, alleging that the Society had breached the terms of a contract by refusing to pay certain hold backs from legal fees. The court found that there was no promise to repay the hold backs in the contract.

- *Blackman v. Fedex Trade Networks Transport & Brokerage (Canada), Inc.*, 2009 BCSC 201. The plaintiff alleged that the defendants were in breach of the *Business Practices and Consumer Protection Act* in the manner in which they charged customs brokerage fees to their customers. The parties agreed that the matter was suitable for disposition at summary trial; the court found in favour of the defendants and dismissed the action.

[179] I note that in each of these cases the application concerned issues common to all members of the proposed class. I conclude that the "binding" concern raised by the plaintiff is not sufficient, in itself, to find that it would be inappropriate to issue judgment under Rule 9-7.

[180] In addition, regardless of any potential inefficiency, there are legitimate policy reasons to allow for summary determination in proposed class actions. In *Consumers' Assn. of Canada*, addressing a similar argument from the plaintiffs, the court said as follows:

> [35] The fact that this is a potential class action does not militate against the use of pre-trial applications generally, or this R. 18A application specifically, as the plaintiff argues. The *Class Proceedings Act* at ss. 4 and 11 sets out a sequence which trifurcates the proceeding into certification, trial of common issues, and trial of individual issues. One probably unintended consequence of class proceedings statutes has been the transformation of certification proceedings from preliminary step to battleground; in some senses, the certification proceeding is the trial … That being the case, I view pre-trial interlocutory applications in an appropriate case as potentially streamlining an increasingly cumbersome process, particularly in cases where the pleadings are lacking in merit, yet may meet the low threshold for certification.

As stated in *Kowch* at para. 14, "[i]t is not a principle of class action law that weeds should be allowed to ripen and grow, instead of being nipped in the bud."

[181] Further, if the matter has no merit, allowing it to continue to certification will undoubtedly cause prejudice to Teva and Sandoz. Where the court can find the necessary facts through the summary process, it promotes efficiency to issue judgment at the pre-certification stage.

[182] I am bolstered in this conclusion by the recent decision of the Supreme Court of Canada in *Hryniak v. Mauldin,* 2014 SCC 7. In that decision, Karakatsanis J. began her judgment delivered for the Court in this way:

> [1] Ensuring access to justice is the greatest challenge to the rule of law in Canada today. Trials have become increasingly expensive and protracted. Most Canadians cannot afford to sue when they are wronged or defend themselves when they are sued, and cannot afford to go to trial. Without an effective and accessible means of enforcing rights, the rule of law is threatened. Without public adjudication of civil cases, the development of the common law is stunted.
>
> [2] Increasingly, there is recognition that a culture shift is required in order to create an environment promoting timely and affordable access to the civil justice system. This shift entails simplifying pre-trial procedures and moving the emphasis away from the conventional trial in favour of proportional procedures tailored to the needs of the particular case. The balance between procedure and access struck by our justice system must come to reflect modern reality and recognize that new models of adjudication can be fair and just.
>
> …
>
> [4] In interpreting these provisions, the Ontario Court of Appeal placed too high a premium on the "full appreciation" of evidence that can be gained at a conventional trial, given that such a trial is not a realistic alternative for most litigants. In my view, a trial is not required if a summary judgment motion can achieve a fair and just adjudication, if it provides a process that allows the judge to make the necessary findings of fact, apply the law to those facts, and is a proportionate, more expeditious and less expensive means to achieve a just result than going to trial.
>
> [5] To that end, I conclude that summary judgment rules must be interpreted broadly, favouring proportionality and fair access to the affordable, timely and just adjudication of claims.

[183] While the court acknowledged that the inappropriate use of summary procedures will likely result in delays and increased costs, the view expressed

resonates in an action like this one where the process is likely to be long and expensive.

[184] No doubt Teva and Sandoz have the ability to fund this litigation, but money is not the only cost associated with a class action that calls into question the safety of a product such as fentanyl. Upon certification public notices stating that the drug is the subject of a class action and alleging the drug is unsafe and can cause death in ordinary use is likely to alarm anyone who is using or perhaps even prescribing fentanyl. On the evidence presented, the consumers of fentanyl are most likely to be people who are seriously ill and who use the drug to control serious chronic pain. That is, of course, of no consequence if there is evidence to justify the action. However, if the evidence is insufficient to support the action then the consequences associated with involvement in an extensive and expensive class action are very serious.

[185] Although I find that a pre-certification class action is not inherently unsuitable for summary determination, it is not a simple matter to determine whether this particular matter is suitable for summary determination. There are a number of factors -- the complexity of the factual issues and the voluminous nature of the filed materials, for example -- that suggest that it would not be appropriate to issue judgment. On the other hand, as the defendants point out, there are difficulties with the admissibility and weight of the plaintiffs' evidence, and the onus remains with the plaintiffs. If the plaintiffs have failed to put forward sufficient evidence to make their case, it may be that refusing judgment would be tantamount to allowing a respondent's veto.

Complexity, Conflicting Evidence and the Need for Full Appreciation

[186] The matter is not directly analogous to any of the previous summary trials held in pre-certification class proceedings. Those cases all concerned questions of contract or statutory interpretation. They involved few, if any, disputed facts, and could be determined on the basis of a minimal evidentiary record.

[187] That is not the case here. This matter requires the court to make findings of fact concerning pharmaceutical design and drug safety. The complexity of that endeavour is perhaps best demonstrated by the fact that the parties filed more than 5,000 pages in materials for this application, including affidavits, exhibits, submissions and case authorities.

[188] The summary trial procedure is not well suited to factually complex cases. In *Chu v. Chen*, 2002 BCSC 906, this court indicated that a case involving copious or voluminous affidavit materials may not be suitable for summary disposition. I note that in that case, the court refused to grant judgment when faced with less than 900 pages in materials. See also *Simon Fraser Student Society v. Canadian Federation of Students*, 2009 BCSC 1081 at paras. 17, 21; again, the court found that, due to the sheer volume of material before the court, issuing judgment would prove "difficult, elusive and not necessarily fair or just" (para. 22).

[189] The complexity in this case is exacerbated by the fact that the central issue -- the question of negligent design and the availability of a safer alternative product -- turns on conflicting expert opinion evidence. The experts disagreed about the relative safety and utility of the fentanyl transdermal patch products, the relevance and correct interpretation of scientific studies, and even, at some points, about the correct terminology to be applied to fentanyl drug dosage forms.

[190] Where there are conflicting affidavits it may not be possible for the judge to find the necessary facts. In *Inspiration Management* the court said that generally speaking, the chambers judge should not decide issues of fact or law "solely on the basis of conflicting affidavits even if he prefers one version to the other" (para. 55). Certainly, in some cases the court may resolve the conflict or find the necessary facts by looking to other admissible evidence. However, where there is a "head on" conflict in the evidence regarding an important issue, and the court cannot resolve the issue without assessing the deponents' credibility, it will not be suitable for summary determination: *Jutt v. Doehring* (1993), 82 B.C.L.R. (2d) 223 (C.A.) at para. 13.

[191] Teva and Sandoz say that there is, in fact, no conflict in the evidence here because the plaintiffs' expert evidence is inadmissible or, if admissible, should receive little to no weight. I note that in *British Columbia (Director of Civil Forfeiture) v. Nguyen*, 2011 BCSC 1792, the court commented that before a judge will find that a conventional trial is required to resolve conflicts in the evidence, the conflicts must be rooted in admissible evidence.

[192] While the materials filed in this trial are extensive, two key issues are reasonably straightforward:

1. Is there evidence to connect the matrix patches manufactured by Teva and Sandoz to the deaths of Mr. Player or Mr. Pollock? and

2. Is there sufficient evidence presented to establish that the Teva or Sandoz patches are defectively designed?

[193] As already discussed, there is no evidence to connect either the Teva or Sandoz matrix patch to the death of Mr. Pollock. As to Mr. Player, the only evidence presented is that Mr. Player died as a result of respiratory depression and that fentanyl was one of several drugs that can cause fatal respiratory depression.

[194] On the evidence, it is not known whether Mr. Player was using a fentanyl patch manufactured by Teva or Sandoz. There is no evidence available on that issue and the evidence that is available is not sufficient to conclude that Mr. Player died as a result of his use of fentanyl patch manufactured by Teva or Sandoz or that his death was caused by fentanyl. The best that can be said is that fentanyl was among several other drugs in Mr. Player's system that can cause fatal respiratory depression. The evidence is not sufficient to prove it was more likely than not that Mr. Player died as a result of fentanyl use.

[195] As to the evidence respecting defective design, again, the evidence falls short. As already stated, I am not able to give the evidence of Dr. Michniak-Kohn sufficient weight to support a finding of defective design. At best, her evidence is that there is another design or designs that might be safer. The alternate patches

identified by Dr. Michniak-Kohn are Fentadur, Matrifen and Mallinckrodt's Fentanyl Transdermal system. None have been approved for use in Canada by Health Canada and all three are described as a "modified reservoir" design. Dr. Foldvari said in her evidence that the additional membrane in those patches is an essential feature necessary to control the delivery of the drug and that it is not an additional safety feature.

[196] Dr. Foldvari's opinion is well documented and there is no evidence to show that the patches have any problem with the delivery rate of the drug that could cause injury or death in ordinary use. I accept the opinion of Dr. Foldvari that there is no known safer alternative to the matrix patches produced by Teva and Sandoz.

[197] Despite the volume of material, I do not find this action to be so complex that it would not be appropriate to deal with it on summary trial with respect to the defendants Teva and Sandoz.

[198] There are comments in the law, as in *Ho v. Ho*, 2013 BCSC 559, that the court should be hesitant to grant judgment on a summary trial where a party has not yet had an opportunity to conduct examinations for discovery and where there appears to be an issue that requires exploration by way of examinations or production of documents. Similarly, the court should be reluctant to resolve factual issues on a summary trial application in the absence of admissible evidence where the evidence "may well be tendered in admissible form at the subsequent trial" (*Farallon Mining Ltd. v. St. Eloi*, 2012 BCSC 264 at para. 31). However, in this case, the parties have conducted full examinations for discovery and cross-examinations of the respective experts. The evidence has been fully developed. The plaintiffs had a full opportunity to present evidence supporting their claims.

Overlapping Issues and the Potential for Embarrassment

[199] Where only a few of the defendants apply for dismissal in a complex, multi-party negligence case, the summary trial judge may be asked to "cross a legal minefield, not knowing where to step to avoid making decisions with unforeseen

consequences or unintended results": *Privest Properties ltd. v. Foundation Co. of Canada*, [1990] B.C.J. No. 1349 (S.C.).

[200] In my view that is not a concern in this matter, as the issues to be determined need not actually overlap with those involved with the claim against the other defendants. The products at issue in this summary trial are sufficiently distinct in their design, so as to explain why any finding of fact in this matter may not match the finding of fact in subsequent proceedings involving the other defendants.

[201] I have tried to limit my comments on the facts to avoid making any findings about fentanyl transdermal patches that might be construed as applying directly to the reservoir-style products manufactured by the other defendants. To be clear, nothing I have said or will say in this judgment is intended as a comment on whether those products are reasonably safe or not, or whether those defendants have breached a duty of care to their consumers. Although some of the evidence dealt with the safety profile of the reservoir-style product, none of the parties had argued that those products represented a safer alternative design. As such there is no need to reach any conclusion on their comparative safety or design. Similarly, although the evidence on failure to warn dealt with a product monograph shared by all the fentanyl transdermal patches, my conclusions on that point are limited to the duty to warn as it applies to Teva and Sandoz's matrix fentanyl transdermal patch products. as the other products rely on an alternative design, the same warning materials may lead to a different conclusion on the standard of care.

[202] In my view, the crux of this case was the claim that a matrix patch with a rate-controlling membrane represented a safer alternative design than that used by Teva and Sandoz. I can reach a conclusion on that point without foreclosing any future submissions that may arise in subsequent proceedings between the plaintiffs and the other defendants.

Conclusion on Suitability for Summary Trial

[203] In a summary trial, as in any trial, the plaintiffs carry the obligation to prove their claims through admissible evidence. The rules of court and applicable case authority establish that provided the facts can be found and it would not be unjust to decide the matter on summary trial, the court can issue judgment: see *Inspiration Management Ltd.,* and Rule 9-7(15) of the *Supreme Court Civil Rules.*

[204] As Levine J.A. stated in *Harrison v. British Columbia (Children and Family Development),* 2010 BCCA 220 at para. 40:

> [40] The trial judge was required to grant judgment if the evidence adduced on the R. 18A application provided the facts necessary to decide the issue of liability, and it would not have been unjust to do so. It is not a question of whether a full trial could conceivably "turn something up" or produce a different result. Rather, as stated by McEachern C.J.B.C in *Inspiration Management Ltd. v. McDermid St. Lawrence Ltd.* (1989), 36 B.C.L.R. (2d) 202 at 215 (C.A.).
>
> > Anything might happen at a trial and one can never say that the result will always or inevitably be the same. If the chambers judge can find the facts, then he must give judgment as he would upon a trial unless for any proper judicial reason he has the opinion that it would be unjust to do so.
> >
> > The test for Rule 18A, in my view, is the same as on a trial. Upon the facts being found the chambers judge must apply the law and all appropriate legal principles. If then satisfied that the claim or defence has been established according to the appropriate onus of proof he must give judgment according to law unless he has the opinion that it will be unjust to give such judgment.

[205] On the evidence before the court, I am satisfied that it is possible to find the necessary facts to decide this case on summary trial. The essential facts and issues are not as complex as the considerable material placed before the court may suggest. There are conflicts in the expert evidence, but on my findings that the opinion evidence of Dr. Michniak-Kohn is not of sufficient weight to support the allegations made by the plaintiffs, there is no credible evidence to support the plaintiffs' claim.

[206] There was a significant body of evidence placed before the court on the summary trial and the expert evidence has been thoroughly canvassed. There is no

suggestion that the plaintiffs were not able to present all of the scientific evidence available. The same is true of Teva and Sandoz. The evidence that has been presented allows a full appreciation of the facts that are essential to the determination of the plaintiffs' action.

[207] Class actions are a powerful tool. They allow an action to proceed where an individual plaintiff would find the cost of an action prohibitive as well as in actions where the research and investigation is not within the ability of a single plaintiff. However, it is not a tool where simply making an allegation against a defendant or group of defendants is sufficient. There must be evidence to warrant the expense of a full trial.

[208] In this case the evidence against Teva and Sandoz is not sufficient to warrant such an expense. The plaintiffs' expert has damaged her credibility by acting as an advocate. But perhaps more importantly, even if I accepted it, taken at its best her evidence is that Teva and Sandoz marketed a product that was defective because it did not utilize a membrane as was used in Fentadur, Matrifen and Mallinckrodt's fentanyl products. Leaving aside the fact that none of those products were approved for use in Canada at the relevant times, the expert evidence that I do accept is that those products are a different reservoir type design and not a safer matrix design.

[209] I conclude that this matter is suitable for summary determination. I turn now to discuss the application of the law to the facts.

NEGLIGENCE

[210] The law in Canada provides guidance as to the factors for consideration in deciding if a product is unsafe for consumers in ordinary use. See: *More v. Bauer Nike Hockey Inc.,* 2010 BCSC 1395, at paras. 195 and 202, aff'd by 2011 BCCA 419, *Harrington v. Dow Corning Corp.,* 2000 BCCA 605. The law was nicely summarized by Nation J. in *Daishowa-Marubeni International Ltd. v. Toshiba International Corp.,* 2010 ABQB 627 at paras. 37-40 where she said:

> [37] The manufacturer, who has the knowledge that the absence of reasonable care in the design and manufacture of its product may result in injury to the consumer's life and property, owes a duty to the consumer to take that reasonable care: *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.) at p. 599.
>
> [38] The duty of reasonable care in design rests on the principle that the manufacturer should use reasonable care to eliminate any unreasonable risk or foreseeable harm …
>
> [39] Claims in negligent design require the court to balance the risk inherent in the product as designed, considering its utility and cost, against the risks inherent in a safer, alternate product or design. One has to look at 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 the product so it is safer but 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 that can be attributed to the plaintiff and the manufacturer's ability to spread any costs related to improving the safely of the design.
>
> [40] The law does not impose strict liability on manufacturers, the onus does not require that they produce items that are accident proof or incapable of doing harm. The manufacturer is not the insurer of anyone who suffers injury while using or misusing a product.

[211] The onus is on the plaintiff to show that the item as designed was not reasonably safe as there was a substantial likelihood of harm and it was feasible to design the product in a safer manner: *Tabrizi v. Whallon Machine Inc.* (1996), 29 C.C.L.T. (2d) 176 (B.C.S.C.).

[212] It is clear from the evidence that Teva and Sandoz each complied with the appropriate regulatory standards in manufacturing their respective fentanyl matrix patches. The evidence of Drs. Hawley and Lau attest to the utility or usefulness of fentanyl in pain management and that there is no suitable alternative available. Dr. Lau said that the fentanyl transdermal patch is the only effective transdermal patch available approved for the treatment of moderate to severe pain. Even Dr. Michniak-Kohn acknowledged in cross-examination that fentanyl was required for some patients.

[213] Dr. Michniak-Kohn’s evidence is that Teva and Sandoz manufactured defective products when different design choices would have made their products safer. But the evidence of Dr. Foldvari is that the products referred to, Fentadur,

Matrifen and the fentanyl patch manufactured by Mallinckrodt Inc., are really modified reservoir patches where the so-called additional membrane is necessary to control the release of the drug rather than an additional membrane to provide extra safety benefits.

[214] I find that the matrix patches manufactured by Teva and Sandoz satisfy the requirements as required by the law in Canada. There is no satisfactory evidence to show that there is a safer alternative design or that an alternate design of the fentanyl patches was available and could have been used but for the negligence of Teva and Sandoz.

FAILURE TO WARN

[215] The plaintiffs submit that Teva and Sandoz failed to provide an adequate warning to consumers of the dangers associated with the use of fentanyl. They rely on *Hollis v. Dow Corning Corp.,* [1995] 4 S.C.R. 634 at paras. 20 - 23. In that case the court said:

> [20] It is well established in Canadian law that a manufacturer of a product has a duty in tort to warn consumers of dangers inherent in the use of its product of which it has knowledge or ought to have knowledge. This principle was enunciated by Laskin J. (as he then was), for the Court, in *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569, at p. 574, where he stated:
>
> > Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purpose for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer.
>
> The duty to warn is a continuing duty, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered; see *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189, at p. 1200, per Ritchie J. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product …

[216] The court went on to note that the rationale for the duty placed upon manufacturers can be traced to the well-known case of *Donoghue v. Stevenson.* As manufacturers who produce and distribute the drugs have a significantly greater

knowledge of the potential dangers of their products than consumers of the drugs, the manufacturers bear a duty to warn to correct the imbalance of knowledge between manufacturers and consumers so as to allow an informed choice.

[217] The higher the danger associated with the ordinary use of the product the greater is the burden upon manufacturers. A general warning will not be sufficient. A warning must be sufficiently detailed to allow the consumers of the drug and their professional advisors a full indication of the specific dangers that can arise from the use of the product: *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569. The standard is necessarily a high one for pharmaceutical products that people ingest, often when affected by serious illness. What is required is that accurate and understandable information be communicated.

[218] Fentanyl is not a product that can be purchased at a store. It is a product that is only to be used when authorized by prescription and then only when the consumer has been conditioned to opioid drugs through a period of titration under the supervision of a qualified physician.

[219] The product at issue in *Hollis* was breast implants. The defendant failed to include a warning in its product monograph respecting the possibility of unexplained ruptures of its product, a hazard it knew existed. In *Lambert* the product was a highly inflammable lacquer/sealer the defendant knew could be ignited by an open flame such as a pilot light in a furnace.

[220] The plaintiffs say that fentanyl is a highly dangerous drug that can cause decreased heart rate and fatal respiratory depression and there is a duty to provide “clear, complete and current” information to users of the drug. The plaintiffs submit the warning provided in this case were inadequate.

[221] Fentanyl is a drug that is only used under the supervision of a physician. Thus, there is a “learned intermediary” standing between the consumer of the drug and the manufacturer. The principle respecting a learned intermediary was stated in *Hollis* this way:

> [28] … Generally, the [learned intermediary] rule is applicable either where a product is highly technical in nature and is intended to be used only under the supervision of experts, or where the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product. In such cases, where an intermediate inspection of the product is anticipated or where a consumer is placing primary reliance on the judgment of a "learned intermediary" and not the manufacturer, a warning to the ultimate consumer may not be necessary and the manufacturer may satisfy its duty to warn the ultimate consumer by warning the learned intermediary of the risks inherent in the use of the product.

[222] Teva and Sandoz submit that the product monographs relevant to this action were "clear, complete and current." They are in identical form to the warnings of the innovator drug that have been approved by Health Canada. The Teva monograph that is reproduced in the evidence clearly advised physicians that fentanyl should only be prescribed by physicians knowledgeable about "…the continuous administration of opioids and the management of patients receiving potent opioids for treatment of pain and in the detection and management of respiratory depression…" Teva submits that the prescribing physician is able to assess the dangers of the drug with respect to the particular patient. It argues the physician has a duty to know the potential dangers of the medication prescribed to a patient and to exercise independent judgment about the product with respect to the patient: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.,* [1986] O.J. No. 2331 at para. 24; (1986), 54 O.R. (2d) 92 (C.A.).

[223] Part I of the Teva product monograph is directed to physicians. It warns of all of the risks associated with fentanyl that are relevant to the allegations in this case. In particular, it warns of potential deaths from hypoventilation and states "…caution must be exercised and patients carefully observed for untoward reactions."

[224] As noted above, Dr. Hawley reviewed the product monographs and said that in her opinion the product monographs are clear and that upon reviewing them the risks of fentanyl use can be readily understood by physicians, pharmacists and patients. She said the monographs addressed all of the risks associated with the use of fentanyl. Her evidence was unchallenged and there is no evidence to contradict her opinion.

[225] The plaintiffs note that the adequacy of the warnings in the product monographs is a legal question for the court. That is so, but the evidence of Dr. Hawley and Dr. Lau can inform that decision and be of assistance in reaching a conclusion. Whether a product monograph respecting a pharmaceutical product is clear, complete and current, is not likely a decision a court could make in the absence of medical evidence. In this case, I accept the evidence of Drs. Lau and Hawley and rely on it in assessing the adequacy of the warnings in the product monograph.

[226] As to the warnings in the patient monograph Ms. Player said that she was aware that only one patch should be worn at a time and acknowledged that she and her husband had reviewed the patient information received with the fentanyl patches he was using.

[227] The product monographs that contain warnings to physicians and patients included with the Sandoz and Teva matrix patches are required to be and have been approved by Health Canada. Dr. Hawley's evidence is that the monographs outline the risk of respiratory depression. She also testified that the risks fentanyl use outlined for patients in the monograph are clear and accurate and reasonably understandable by patients.

[228] Dr. Hawley also said that in her opinion the information in the patient monograph provides clear instructions on how to safely apply the patch and provides a reasonable warning about the dangers of not following the instructions. Her opinion is not contradicted by any other evidence.

[229] I find that the product monographs distributed to physicians and pharmacists as well as the product monograph in the form of a package insert for patients contain clear, accurate and understandable warnings that are sufficient to satisfy the test set out in *Hollis* at para. 20. I therefore find that Teva and Sandoz are not liable on the ground of failure to warn of the risks of using fentanyl.

ADDITIONAL GROUNDS OF LIABILITY

[230] The plaintiffs also advance several other grounds of liability. As is common, their action is cast in the broadest possible terms. Given my findings and conclusions on the product liability and failure to warn portions of the action, I do not find it necessary to deal extensively with the remaining categories of the claim.

Misrepresentation

[231] The plaintiffs claim that Teva and Sandoz misrepresented their products to consumers and say that had the true facts been known, the plaintiffs and other consumers would not have used fentanyl or would have ceased using it upon becoming aware of the true facts. The plaintiffs have issued a general pleading on this point and have not particularized the precise misrepresentations alleged. However, it is my finding that there was no misrepresentation of the facts made by either Teva or Sandoz in their product monographs. I find that the nature of the product and the risks of use were clearly stated in a readily understandable way and that there was appropriate advice given through the monographs and the advice of intermediary professionals. There is no evidence to support a claim of misrepresentation and the action on that head of damage is dismissed.

Competition Act

[232] The plaintiffs' next claim is that Teva and Sandoz engaged in unlawful, unfair and deceptive trade practices that are proscribed by the *Competition Act*. Teva and Sandoz submit that there is no evidence to support any claim under the *Competition Act.* Given my findings respecting the matrix patches manufactured and distributed by Teva and Sandoz, it follows that there is no evidence that either Teva or Sandoz are liable for a violation of the *Competition Act* or that there is any causal connection between the matrix patches and any loss or damage by the plaintiffs.

Other Statutes

[233] I have reached the same conclusion respecting the *Food and Drugs Act,* the *Business Practices and Consumer Protection Act,* and the *Sale of Goods Act*. These claims rest on a necessary finding that Teva or Sandoz breached the provisions of the statutes by manufacturing and distributing a dangerous product even under ordinary use. Upon my findings the claims must fail and they are dismissed. Likewise, there is no evidence that Teva or Sandoz breached any warranty under the sale of goods or any express or implied warranty that might arise as part of a collateral contract.

Breach of Fiduciary Duty

[234] The plaintiffs also claim that Teva and Sandoz breached a fiduciary duty owed by drug manufacturers to consumers of fentanyl. Teva and Sandoz submit that the evidence in this case does not support a claim for breach of fiduciary duty. A similar submission was made by plaintiffs' counsel and rejected in *Wuttunee v. Merck Frosst Canada Ltd.*, 2007 SKQB 29. At paras. 60-63 of *Wuttunee* the court said:

> [60] The plaintiffs acknowledge their claim based on a breach of fiduciary duty is novel to the extent they seek to extend the fiduciary relationship extant between doctor and patient to drug manufacturer and their targeted consumers. They submit that courts should acknowledge the high degree of inequality between manufacturers of drugs and doctors is comparable to the one between a doctor and a patient to the extent that drug manufacturers are subject to a fiduciary duty to make full disclosure of any deficiency in their product to doctors in their capacity as agents for patients and to consumers directly. They further argue that, without the extension of fiduciary duty, current remedies are limited to "recoverable damages" which are inadequate in the instant case.
>
> [61] The position of Merck in response may be summarized as follows:
>
> (a) Fiduciary duty exists where the defendant is in a position of power *vis-à-vis* the plaintiff. No such power exists in the instant case. See: *Lac Minerals Ltd. v. International Corona Resources Ltd.*, [1989] 2 S.C.R. 574 at pp. 598-600; *Norberg v. Wynrib, supra*;
>
> (b A fiduciary is subject to strict obligations otherwise unknown at law and is expected to act in a manner consistent with the best

interests of the beneficiary and Merck is not subject to such an obligation;

(c) There are no reported decisions opining that a manufacturer or distributor of a controlled drug owes a fiduciary duty to the consumer of its products; therefore, no cause of action based on a fiduciary duty is available against it;

(d) The plaintiffs' proposed subrogation by way of a fiduciary duty is inconsistent with the concept of fiduciary duty to the extent that it contemplates the duty owed to one person being imputed for the benefit of another.

[62] *Waters' Law of Trusts in Canada*, 3d ed. (Toronto: Thomson Carswell, 2005) summarizes the law regarding fiduciary relationships generally at pp. 41-42 as follows:

> Several relationships, in addition to the relationship between trustee and beneficiary, have been generally recognized as giving rise to fiduciary obligations. These include the relationship between partners, directors and corporations, solicitors and clients, and agents and principals. While these relationships are generally recognized as giving rise to fiduciary obligations, they do not invariably do so. Although there are categories that are generally recognized as giving rise to fiduciary obligations, the situations in which fiduciary relationships can arise are not closed. Identifying these situations can be difficult as there is no widely accepted definition of what gives rise to a fiduciary relationship. However, in *Frame v. Smith*, [[1987] 2 S.C.R. 99, 42 D.L.R. (4th) 81], Wilson J. suggested the following indicia of a fiduciary relationship that have been accepted as a "rough and ready guide:"
>
> (i) The fiduciary has scope for the exercise of some discretion or power.
>
> (ii) The fiduciary can unilaterally exercise that power or discretion so as to affect the beneficiary's legal or practical interests.
>
> (iii) The fiduciary is peculiarly vulnerable to or at the mercy of the fiduciary holding the discretion or power.
>
> [Citations omitted.]

[63] Based on the facts pled, the absence of any case authority or jurisprudential writing positing that a fiduciary relationship arises in circumstances akin to those in the instant case, and the additional reasons advanced by Merck, I conclude the plaintiffs have no arguable cause of action based on breach of fiduciary duty owed them by Merck. While it is important not to foreclose the extension of the fiduciary duties in appropriate circumstances, more than what is before the Court is required to warrant an extension of fiduciary relationships in the manner advocated by the plaintiffs,

> including detailed pleadings and a comprehensive brief of law in support thereof.

[235] Teva and Sandoz take the same position as the defendants in *Wuttunee*, and rely on *Frame v. Smith* to say the claim should be dismissed. The plaintiffs' invite the court to reconsider *Wuttunee* in light of recent developments in the law. However, the law in Canada is found in *Frame v. Smith* and not *Wuttunee*; it is not open to me to "reconsider" the law as set out by the Supreme Court of Canada. While I accept the categories of fiduciary relationship are not closed there is no evidence before me upon which I can find that Teva or Sandoz had any scope for the exercise of discretion or power that either defendant could exercise to affect the plaintiffs' legal or practical interests. Further, there is no evidence that either of the plaintiffs or a potential member of the proposed class was vulnerable to or at the mercy of the exercise of the discretion or power. I agree with the court's finding at para. 63 of *Wuttunee,* and dismiss the claim for breach of fiduciary duty.

Strict Liability

[236] The plaintiffs say the defendants in this case are strictly liable to the plaintiffs. Teva and Sandoz argue that courts in Canada have rejected the doctrine of strict liability in products liability cases. I agree with that submission. The law in Canada is as stated in *Daishowa-Marubeni International Ltd*.

CONCLUSION AND SUMMARY

[237] The action of the plaintiffs is dismissed as against Teva and Sandoz. I find that Teva and Sandoz did not breach any duty of care to the plaintiffs by selling a product that was defectively designed.

[238] I find that the product monographs to physicians, pharmacists and consumers contained information about the risk of using fentanyl patches manufactured and distributed by Teva and Sandoz contained information that was clear, complete and current and that Teva and Sandoz did not breach any duty of care by failing to provide a reasonable warning to the plaintiffs.

[239] Given my finding that the patches manufactured by Teva and Sandoz were not defectively designed, I find that there was no negligent misrepresentation to the plaintiffs respecting the Teva and Sandoz matrix patches.

[240] I also find that there was no breach of statute by Teva or Sandoz respecting the sale and distribution of their respective transdermal matrix fentanyl patches.

[241] The action by the plaintiffs against Teva and Sandoz is dismissed. Costs may be spoken to if necessary.

"J. K. Bracken, J."
The Honourable Mr. Justice Bracken