

CANADA / JUDGMENT

James v. Johnson & Johnson Inc.

2022 BCCA 111

COURT

British Columbia Court of Appeal

DECIDED

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2022 BCCA 111 James v. Johnson & Johnson Inc. COURT OF APPEAL FOR BRITISH COLUMBIA

Citation: James v. Johnson & Johnson Inc., 2022 BCCA 111 Date: 20220328 Docket: CA47424

Between: Lakota James Respondent (Plaintiff) And Johnson & Johnson Inc. and Janssen Inc.

Appellants (Defendants) Before: The Honourable Madam Justice Dickson The Honourable Justice

Griffin The Honourable Mr. Justice Grauer On appeal from: An order of the Supreme Court of

British Columbia, dated March 18, 2021 (James v. Johnson & Johnson Inc., 2021 BCSC 488,

Vancouver Docket S165705). Counsel for the Appellant: R.L. Reinertson A. Solose P. Elahi-

Khansari Counsel for the Respondent: V.L. Medved A.D. Brine Place and Date of Hearing:

Vancouver, British Columbia March 9, 2022 Place and Date of Judgment: Vancouver, British

Columbia March 28, 2022 Written Reasons by: The Honourable Justice Griffin Concurred in by:

The Honourable Madam Justice Dickson The Honourable Mr. Justice Grauer Summary: The

respondent sues the appellant pharmaceutical companies for product liability in respect of a

hormone contraceptive patch, EVRA. The respondent suffered a severe blood clot after using this

prescription drug. The appellants applied to have her claim dismissed based on the Supreme

Court Civil Rules R. 9-5 (no cause of action based on failure to plead material facts) and R. 9-6 (no

genuine issue for trial). They appeal the dismissal of their application. Held: Appeal dismissed.

The judge properly stated and applied the correct principles. The respondent pleaded known

causes of action and any deficiencies in setting out the material facts could be cured by

amendments. It was not an error for the judge to not impose a deadline for the amendments, as

the appellants had not requested this relief. The respondent filed expert evidence regarding the

real risks associated with the product and failure to warn of these risks, and it was not an error

for the judge to conclude that this was sufficient to raise a genuine issue for trial. The basis for

appellate interference with these discretionary decisions is not made out. Reasons for Judgment

of the Honourable Justice Griffin:

- [1] When she was 24 years old, the plaintiff, and respondent on appeal, Lakota James, was prescribed the birth control hormonal patch known as EVRA. She claims that within a few weeks of using it as directed, she suffered a severe type of blood clot known as a venous sinus thrombosis ("VST")--a type of venous thromboembolism ("VTE")--leaving her with permanent injuries. She brought a product liability claim against the appellant pharmaceutical companies Johnson & Johnson Inc. ("J & J") and Janssen Inc. ("Janssen"),

claiming negligent design, negligent manufacture and failure to warn.

- [2] The appellants sought to strike the plaintiff's pleadings for failure to plead the material facts necessary to support the causes of action, pursuant to R. 9-5 of the Supreme Court Civil Rules. The appellants also sought to have the claim summarily dismissed as revealing no genuine issue for trial, pursuant to R. 9-6. The appellants refused to participate in discovery prior to the determination of their application.
- [3] In reasons indexed as 2021 BCSC 488, the judge dismissed the application, with one exception. The judge struck a claim based on the Sale of Goods Act, R.S.B.C. 1996, c. 410, pleaded at para. 16 of the notice of civil claim.
- [4] The judge's reasons made it clear that she was of the view that Ms. James' pleading had some deficiencies in setting out the material facts, but it pleaded known causes of action and any deficiencies could be cured by allowing the plaintiff to make amendments. The judge was also of the view that Ms. James' claim revealed a genuine issue for trial.
- [5] On appeal, the appellants challenge the judge's conclusions under both R. 9-5 and R. 9-6.
- [6] I would dismiss the appeal.
- [7] The judge made no error, and none is alleged, in her recitation of the legal principles that apply to R. 9-5 and R. 9-6.
- [8] On the R. 9-5 application, it is very clear from Ms. James' notice of civil claim that she is advancing claims for product liability based on recognized causes of action. The judge noted there were some weaknesses in setting out and separating the supporting material facts for each alleged cause of action, but concluded that the pleading could be remedied by amendments. This was in accord with established legal principles and it cannot be said that the judge was clearly wrong in the exercise of her discretion.
- [9] The appellants argue that the judge gave Ms. James permission to amend, rather than requiring her to do so, and did not impose a deadline on Ms. James or set out any requirements of the amendments. Respectfully, the judge made it clear that amendments were necessary. For obvious reasons, judges prefer not to dictate the language of proposed amendments, leaving the task to counsel.
- [10] Importantly, I do not see that it was necessary for the judge to impose a time limit when the appellants did not ask for one, particularly as the litigation is at an early stage and Ms. James' medical condition might still be uncertain. Counsel for Ms. James has indicated an intent to amend the notice of civil claim once this appeal proceeding has been determined. That course of action seems reasonable in the circumstances of this case.
- [11] As for the R. 9-6 application for summary judgment, the question is whether there is no genuine issue for trial. In my view, the judge was correct in concluding that a genuine issue for trial had been raised by Ms. James' expert evidence.

- [12] As I understand it, Ms. James' theory of her case is that the EVRA patch delivers a much higher dose of estrogen and creates a much higher risk of blood clots than oral contraceptives; that the degree of risk created by the product is unnecessary such that it is inherently designed or manufactured defectively; and that the product monograph underplays the known risks of the product in comparison with oral contraceptives and does not contain an adequate warning of the risks. This theory will clearly need expert evidence at trial.
- [13] The appellants' notice of application focused on the content of the warnings given in the EVRA product monograph and provided expert evidence of Dr. Wendy Norman to the effect that the product monograph clearly warned family physicians of the risk of VTE.
- [14] In response to the appellants' R. 9-6 application for summary judgment, Ms. James filed the affidavit of Adrian Levy, Ph.D., a professor in epidemiology whose research focuses on pharmacoepidemiology and pharmacovigilance. The judge found that his evidence raised a triable issue as follows:
- [142] The plaintiff submits that if the Evra product monograph misrepresents the risk, and Dr. Levy says that it does, a triable issue very much exists.
- [143] I agree.
- [144] Dr. Levy interpreted and analyzed the data regarding the studies referenced in the Evra product monograph and delivered an opinion. The crux of his opinion was that all but one of the studies that he looked at showed statistically significant increased risk of VTE with the use of the Evra patch. That is not what is represented in the Black Box Warning of the Evra product monograph.
- [145] I agree with the plaintiff that there is a genuine issue to be tried about the adequacy of the Evra product monograph and risk. Dr. Levy's opinion is that the Black Box Warning of the Evra product monograph did not summarize or interpret the data correctly. According to Dr. Levy, although there is not a general consensus on an increased risk of VTE among women using the Evra patch compared with women using combined oral contraceptives, the available peer-reviewed studies show a statistically significant increased risk.
- [146] That is not to say that the plaintiff will succeed on this point. But, I am satisfied based on the evidence tendered and without resolving the conflicts in the evidence that the court should not take away the plaintiff's right to argue the point. [Emphasis added.]
- [15] The appellants do not take issue with the judge's finding that there was a genuine issue for trial on whether the content of the product monograph for EVRA adequately warned of the risks (although they maintain that the warning was adequate). Rather, the appellants' focus on appeal is the argument that there is no genuine issue for trial in respect of the failure to warn claim because Ms. James neither pleaded nor stated in her affidavit evidence that she read the product monograph.

- [16] On the hearing of the application, the appellants' argument was cast slightly differently: that Ms. James had not pleaded nor given evidence that she would not have used the EVRA patch had a different warning been provided (Reasons at paras. 82, 148).
- [17] A problem with the appellants' argument is that the evidence of what an adequate warning would have been requires expert evidence, and the case is still in its infancy. An affidavit from Ms. James stating that if she was warned adequately she would not have used the medication is not only self-serving, it simply raises the question: what would be an adequate warning?
- [18] On appeal, as mentioned, the appellants restate this argument. They submit that Ms. James ought to have given evidence that she read the warning that was given in the prescription drug package. They say that the failure to give this evidence is fatal to her claim, because if Ms. James did not read the warning that came with the package, she would not have read any warning, and her claim of failure to warn will inevitably fail for lack of proof of causation.
- [19] In my view, this argument ignores the context in which the application unfolded. The appellants led no evidence that required Ms. James to respond to the question of whether or not she read the product insert. The notice of application suggested that Ms. James received clear and adequate warnings in the product monograph, not that she did not read it. The appellants, as applicants, then led evidence to support their position that the product monograph contained appropriate warnings. This explains why Ms. James, in her response, focused on providing scientific evidence that showed there was merit to her claim that the product monograph did not provide an adequate warning.
- [20] The appellants also say that there was no genuine issue for trial that J & J was involved in the design, manufacture or sale of EVRA and the judge erred in not granting summary dismissal of the claim against J & J. However, the appellants simply filed one affidavit from a representative of Janssen containing a single conclusory statement to this effect, with no supporting documents or evidence from J & J and no evidence explaining the relationship between Janssen and J & J. I accept that the judge did not mention this point, but given the lack of evidence, I can understand why she did not consider it a matter of substance on the application. Based on the limited evidence filed by the appellants, and keeping in mind the pre-discovery stage of the proceeding, I would not conclude that the judge erred in declining to summarily dismiss the claim against J & J.
- [21] The onus on the R. 9-6 application was on the appellants to tender evidence that would be a complete answer to Ms. James' claims. Ms. James was not required to provide conclusive evidence of every fact that might end up being in dispute at trial, but she had to provide evidence that raised a triable issue. In the context of this case, where Ms. James' success or failure at trial will to a large extent turn on the expert scientific evidence, I would not fault her for the way in which she focused her efforts to lead evidence.

Conclusion

- [22] I see no basis for appellate interference in the judge's conclusion that the pleadings should not be struck but, rather, should be amended. I also see no error in the judge's conclusion that the evidence raised a genuine issue for trial.
- [23] I would therefore dismiss the appeal. "The Honourable Justice Griffin" I AGREE: "The Honourable Madam Justice Dickson" I AGREE: "The Honourable Mr. Justice Grauer"
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