

**ONTARIO
SUPERIOR COURT OF JUSTICE**

B E T W E E N :

BENNY MIGNACCA, and ELAINE MIGNACCA

Plaintiffs

and

MERCK FROSST CANADA LTD., MERCK FROSST CANADA & CO.
and MERCK & CO., INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

REPLY

1. The plaintiffs admit the allegations contained in paragraphs 7, 10, 11, 15, 16, 17, 20, 27, 35, 48, and 63 of the statement of defence.
2. The plaintiffs deny the allegations contained in paragraphs 4, 6, 12, 13, 18, 22- 26, 29, 32-34, 36, 38, 40-47, 49-52, 55, 58-62, and 64-101 of the statement of defence and put the defendants to the strict proof thereof.
3. The plaintiffs have no knowledge in respect of the allegations contained in paragraphs 14, 19, 20, 21, 28, 30, 31, 37, 39, 41, 53, 54, 56, and 57, of the statement of defence.
4. In reply to paragraphs 44 to 47, the plaintiffs admit that in 2002 information was added to the Product Monograph for Vioxx. The plaintiffs allege that the information was insufficient, inaccurate and/or misleading and that the defendants, in effect, had failed to warn or failed to adequately warn of the increased risk of, *inter alia*, cardiovascular and cerebrovascular adverse events that they knew or ought to have know were associated with Vioxx use, at various times over the term of Vioxx's availability on the Canadian market.
5. In paragraph 64 of the statement of defence, the defendants state that the Expert Advisory Panel, convened by Health Canada in June 2005 to review the data on cardiovascular safety of selective COX-2 inhibitors, voted 12 to 1 that the information

available at the time justified the continued marketing of Vioxx in Canada. The defendants fail to state that the Expert Advisory Panel acknowledged that Vioxx carried a cardiovascular risk. Dr. Andreas Laupacis, who headed the Panel, stated "[t]here is no question Vioxx increases cardiovascular risk compared to placebo".

6. In paragraph 65 of the statement of defence, the defendants state that Health Canada's report of June 2006, based on the recommendations of the Panel, noted that the cardiovascular safety concerns associated with COX-2 selective NSAIDs applied to traditional NSAIDs and the evidence did not allow a ranking of risk within the NSAID class. However, the defendants fail to state that Health Canada recommended that Vioxx remain off the market unless and until a new drug submission was received and approved by Health Canada and furthermore that the COX-2s that were permitted to remain on the market, could do so only with a revised label, warning of the increased risk of cardiovascular adverse events and also a suggestion that these drugs be used "at the lowest effective dose for the shortest possible duration of treatment". The plaintiffs rely on this recommendation of Health Canada.

7. In reply to paragraph 82, wherein the defendants claim there was a failure to disclose accurate or adequate information regarding the representative plaintiff and/or class members' medical conditions, the defendants were provided with medical records and medical directions which enabled them to obtain whatever medical information they deemed necessary, for the representative plaintiff and for a number of other class members. The defendants utilized these directions and collected a substantial further amount of medical information with respect to these claimants' Vioxx use and their medical backgrounds more generally. In addition, cross-examinations were conducted prior to certification, in respect of these medical records.

8. In reply to paragraph 99 and the defendants' concerns of spoliation and the unavailability of medical records, the delays from first filing the statement of claim to the certification hearing and later to the implementation of the Notice of Certification, were in part due to the defendants' own actions, such as, *inter alia*, changing counsel with the requirement that additional time be provided for new counsel to be informed of the file; filing

last minute motions for stays of proceedings and other matters, and pursuing fruitless appeals well beyond deadlines.

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