COUR SUPÉRIEURE

CANADA
PROVINCE DE QUÉBEC
DISTRICT DE MONTRÉAL

N° : 500-06-000788-162

DATE : 9 janvier 2024

SOUS LA PRÉSIDENCE DE L'HONORABLE MARTIN F. SHEEHAN, J.C.S.

JOAN LETARTE
Demanderesse
c.
BAYER INC.
et
BAYER HEALTHCARE LLC
Défenderesses

JUGEMENT RECTIFIÉ SUR DEMANDE EN REJET D'UN RAPPORT D'EXPERT

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[1] **ATTENDU QUE** le soussigné a rendu un jugement écrit le 9 janvier 2024;

[2] **ATTENDU QUE** l'avocate des défenderesses a souligné au Tribunal que le paragraphe [58] du jugement écrit, octroyait trois mois à la partie défenderesse afin qu'elle puisse répondre au rapport d'expert en demande alors que la conclusion [91] octroyait seulement deux mois à la partie défenderesse pour répondre audit rapport;

[3] **ATTENDU QUE** le paragraphe [58] du jugement était conforme aux échanges avec le Tribunal qui ont eu lieu lors de l'audience du 11 décembre 2023 quant au temps requis pour répondre au rapport au besoin;

[4] **ATTENDU QU'**il y a donc lieu de rectifier le paragraphe [91] du jugement écrit le 9 janvier 2024 pour corriger l'erreur qu'il contient afin d'accorder un délai de trois mois à la partie défenderesse pour répondre au rapport d'expert en demande;

[5] **ATTENDU QU'**il y a lieu, pour les mêmes raisons, de rectifier le paragraphe [92] du jugement écrit le 9 janvier 2024 afin d'octroyer un délai de quatre mois aux parties pour la mise en état et l'inscription du dossier;

POUR CES MOTIFS, LE TRIBUNAL :

[6] **MODIFIE** les paragraphes [91] et [92] afin qu'ils se lisent comme suit :

> ***POUR CES MOTIFS, LE TRIBUNAL :***
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> [89] ***ACCUEILLE*** *en partie la demande des défenderesses en rejet partiel du rapport d'expert de maître Louis-Paul Marin daté du 8 août 2023;*
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> [90] ***DÉCLARE*** *que la demanderesse devra déposer un nouveau rapport de l'expert Marin dans les 15 jours du présent jugement dans lequel on aura retiré les passages suivants :*
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> > *<u>Page 8 :</u> "I would like to emphasize that Section 19 of the Food and Drugs Act, which deals directly with the safety of medical devices, explicitly places the obligation for the safety of the devices on the manufacturer and distributor when it says "no person shall sell" any unsafe device. This is also made very clear within the Medical Devices Regulations. No such requirements are placed upon Health Canada. Health Canada oversees or watchdogs, as is deemed required. Practically, this is why (i) Health Canada has no obligation to undertake safety and efficacy testing; and (ii) Health Canada's determination as to whether a medical device meets the applicable requirements of sections 10 to 20 of the Medical Devices Regulations is limited to a review of the evidence of safety and effectiveness as submitted by the manufacturer, who is deemed to be the expert in the field, to substantiate the demonstration of safety and effectiveness. The foregoing also explains why […]"*
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> > *<u>Page 8 :</u> "In establishing that the manufacturer must implement a risk management and a post-market surveillance process and disclose information relative to safety, the Food and Drugs Act or the Medical Devices Regulations entrust responsibilities to this expert in the field, a responsibility which comprises an obligation to appraise information collected through the pre-clinical and clinical testing phases as well as continuously through the use of the medical device in all jurisdictions where it is sold, including its use into the Canadian market. The other fact is that"*
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> > *<u>Page 9 :</u> "I believe that my mandate requires an assessment of the standard of adequacy of the information disclosed to the physicians as well as the patients. I wish to stress that the informational duty of a manufacturer of medical devices is twofold: i) the obligation to disclose information for safety as set forth in the Food and Drugs Act and the Medical Devices Regulations, and ii) the duty to warn, which obliges the manufacturer to provide the end-user (i.e., the patient or the physician) with a reasonable and adequate*

warning of the nature and potential risks inherent in the use of a product and extent of the danger that the manufacturer knows or has reason to know."

Page 10 : La section commençant par: "Despite the fact that they entrust similar complementary and coextensive obligations, adherence to the legislative requirements set forth […]" allant jusqu'au début de la section "ii. The doctrine of the "learned intermediary".

Page 18 : "However, as explained in the first section of this report, under Canadian law, manufacturers are obliged to inform end-users of the dangers inherent in the use of their products. To this end, all manufacturers of medical devices are expected to foresee risks identifiable at the time of the design. Manufacturers must disclose information relative to the risks to the users and decide what information is necessary to include in the accompanying documents in order to disclose same. Disclosure of risks must be descriptive and provide the end-users, and as need be the patients, with information necessary to understand the risks associated with the use of the medical device and to allow them to make informed choices.

But, also as explained above, the manufacturers' informational duties do not cease at the time of sale. It is a continuing obligation and they are required to monitor the occurrence of all risks related to the use throughout the product lifecycle, as they may appear over time, as and when the product is used in real-world situations and scientific knowledge or techniques evolve. As such, it is incumbent upon the manufacturer to react and when deemed appropriate, make swift changes to its medical device's IFUs accordingly to disclose same. In summary, under Canadian law, manufacturers have an obligation to communicate dangers inherent in the use of their products of which the manufacturer has, or ought to have, knowledge, throughout the product lifecycle."

[91] ***PERMET*** *aux défenderesses de produire un rapport complémentaire de leur expert monsieur Don Boyer d'ici le 12 avril 2024;*

[92] ***PROROGE*** *la date pour la mise en état et l'inscription du dossier au 10 mai 2024;*

[93] ***LE TOUT*** *avec frais de justice à suivre le sort de l'instance.*

Martin Sheehan

Signature numérique de Martin Sheehan
Date : 2024.01.09 12:36:33 -05'00'

MARTIN F. SHEEHAN, J.C.S.

Me Christine Nasraoui
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Avocate de la demanderesse

Me Sylvie Rodrigue
Me Corina Manole
Me Marie-Ève Gingras
SOCIÉTÉ D'AVOCATS TORYS S.E.N.C.R.L.
Avocates des défenderesses

Date d'audience : 11 décembre 2023