

Legal update

Quebec Superior Court dismisses the first class action tried on the merits in the pharmaceutical area

November 2016
Class actions

Take-aways

In a judgment rendered on October 19, 2016¹, the Quebec Superior Court found for the defendant, Abbott Laboratories Ltd. (Abbott), in dismissing a class action launched by Angèle Brousseau and her husband on behalf of individuals residing in Quebec who suffered, either directly or indirectly, damages resulting from side effects of psychiatric disorders induced by Biaxin® (clarithromycin), a medication manufactured, commercialized, and distributed by Abbott. The applicants accused Abbott of not having sufficiently informed users of the risk of psychiatric disorders resulting from the use of Biaxin®.

This is the first decision rendered in Quebec on the merits in a class action in the pharmaceutical area. We highlight several items of interest in the decision:

- It confirms that when the generic medication is used, there is no legal link with the original manufacturer of the medication.
- It rejects the argument that mentioning the possible side effects in the product monograph is sufficient to establish a causal link between using the medication and developing such side effects.
- It confirms that the mere possibility of a causal link (in particular, use of the medication and simultaneously suffering undesirable effects) is not sufficient to discharge the burden of evidence, which requires that the causality be likely.

Context

In September 2005, the representative was prescribed Biaxin® to cure her pneumonia. The medication's side effects mentioned by the doctor and the pharmacist did not include psychiatric disorders. Shortly after having started to use the medication, the representative started experiencing odd sensations. She spoke about this with her doctor, who confirmed that the prescribed dosage was appropriate to treat her pneumonia. The same night, the representative slit her wrists. Four other members of the class action testified at trial as to similar facts. Among the common denominators in their testimony were the absence of any warning with regard to the psychiatric side effects and the occurrence, after using the medication, of different phenomenon affecting their behaviour or their capacity to function.

The members of the class made an association between the use of Biaxin® and the psychiatric problems from which they had suffered. They argued that Abbott had failed in its duty to inform, as imposed by article 1468 of the *Civil Code of Québec* and article 53(2) of the *Consumer Protection Act* by omitting to inform consumers that using the medication was likely to cause such side effects.

Decision of the Superior Court

The lack of a connection at law for the generic medication

At trial, Abbott contested the admissibility of the claim of one member who had used a generic version of Biaxin®. The court agreed, concluding that since Abbott was not the manufacturer of the medication used by this member, it could not incur liability in that regard.

Lack of a causal link

The court noted that the class action mechanism does not modify the substantive or procedural rules applicable in civil matters, such that the applicants continue to bear the burden of proving based on a preponderance of the evidence, fault, injury and causation.

With regard to causation, the court highlighted that the *possibility* of a causal link is not sufficient, since the civil law requires that causality be *likely*. Therefore, the court rejected the applicants' claim that mentioning the possibility of psychiatric disorders in the product monograph is sufficient to establish a causal link.

The court then turned to determine the existence of a causal link between the medication and psychiatric disorder side effects.

The court rejected the method used by the applicants' experts, which was based on the case method combined with the use of the Naranjo algorithm (a survey conceived to determine the likelihood that an undesirable reaction to a medication is truly caused by the medication or if it results from other factors). The court determined that this methodology is inappropriate to conclude as to the presence of a causal link, in light of the abundant scientific literature provided discussed by Abbott's experts. The court concluded that coincidences that constitute, at most, a remote possibility of causation are no substitute for a preponderance of evidence that establishes, in a highly likely manner, the absence of a causal link.

Considering the court's conclusion with regard to the absence of a causal link between the use of the medication and the psychiatric disorder side effects, it did not rule on Abbott's duty to inform or the criteria to be applied to an award of damages.

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Footnote

¹ *Brousseau c Laboratoires Abbott ltée*, 2016 QCCS 5083, j. S. Hardy-Lemieux.

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