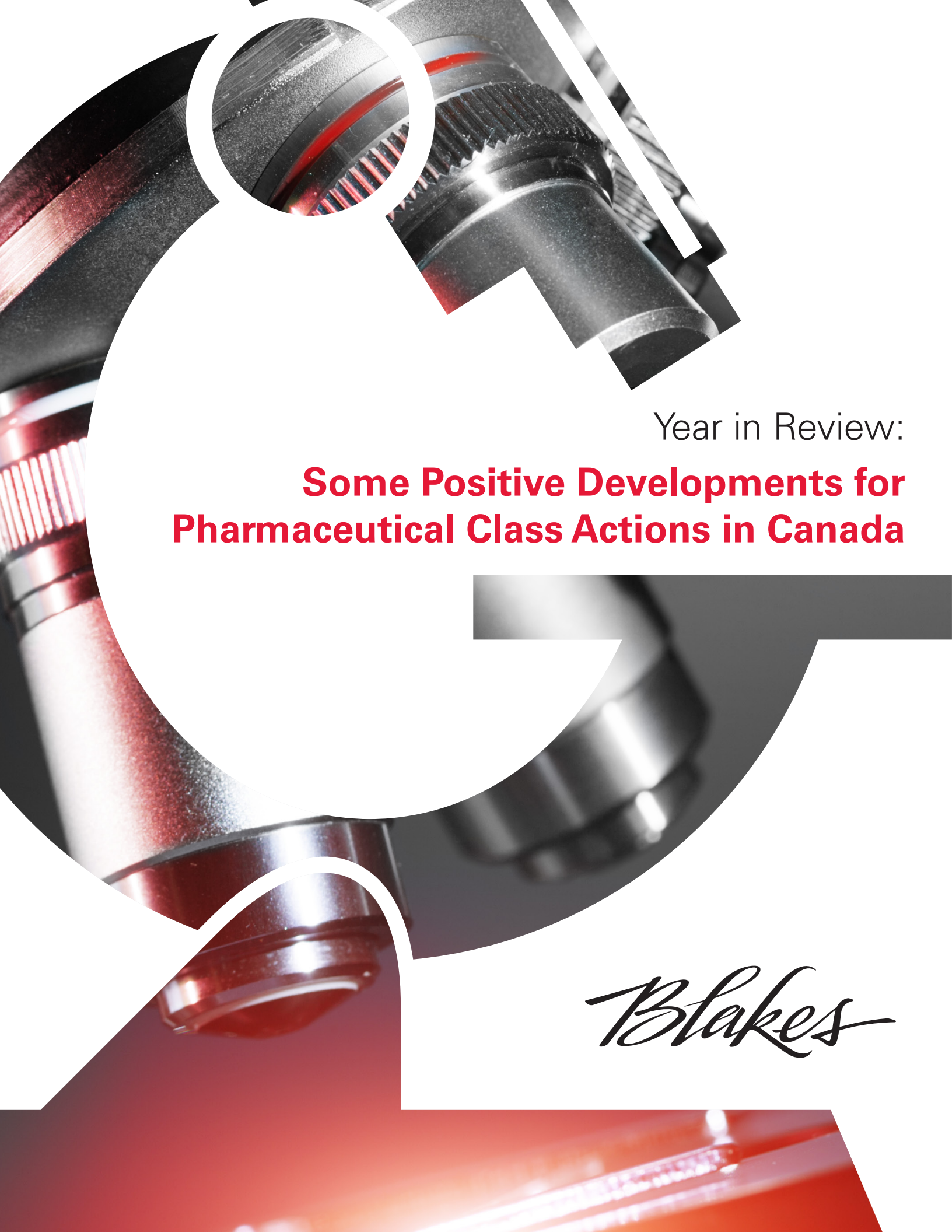

Year in Review:

Some Positive Developments for Pharmaceutical Class Actions in Canada

Blakes

The end of 2016 brought with it some good news for the defence in respect of pharmaceutical class actions, including a successful defence verdict in the first pharmaceutical product liability common issues trial in Canada. In 2016, Canadian courts also signalled a willingness to embrace summary judgment as a potential tool for early resolution of class proceedings and confirmed once again that an innovator (brand name) manufacturer does not owe a duty of care to generic users of the medicine. Defendants also achieved significant successes in resisting certification of proposed pharmaceutical class actions, despite the frequent certification of such actions in Canada. The key decisions from 2016 in respect of pharmaceutical class actions are briefly summarized below.

1 SUMMARY JUDGMENT AS A POTENTIAL TOOL IN CLASS PROCEEDINGS

Two decisions in 2016 show the Ontario courts embracing the cultural shift called for by the Supreme Court of Canada in *Hryniak v. Mauldin*, and the move away from the conventional trial, in the interests of fairness and proportionality.

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In *Wise v. Abbott Laboratories Limited (Wise),* the representative plaintiff brought a proposed class action against Abbott Laboratories (Abbott) alleging that AndroGel™, a testosterone replacement therapy for the treatment of hypogonadism (testosterone deficiency) in men, caused serious cardiovascular events, such as heart attacks and strokes, and that AndroGel was sold by Abbott as a remedy for "LowT", despite having no therapeutic benefits. Abbott denied all claims of negligence and brought a motion for summary judgment in advance of certification to dismiss the action on a number of grounds including that the plaintiff could not prove general causation, a constituent element in all product liability claims. Ultimately, Justice Perell of the Ontario Superior Court of Justice granted the defendant's motion, concluding, among other reasons, that there was no genuine issue requiring a trial because there was insufficient evidence of general causation.

2016 also saw plaintiffs embracing summary judgment on the general causation issue. In *Levac v. James (Levac)*, the Ontario Superior Court of Justice not only certified the action, but also granted the plaintiff partial judgment against the defendant doctor. While not a pharmaceutical case, the motion has potential application in that context. The action arose from an infectious disease outbreak at a clinic where the defendant doctor administered epidural injections. The representative plaintiff alleged that the doctor, who was personally colonized with the bacteria, was responsible for the outbreak and was negligent because he implemented substandard infection prevention and control practices.

On the summary judgment motion, the court found that the doctor owed a duty of care to class members, that he breached this duty and that general causation had been established for all class members. On the evidence, there was no dispute that the doctor's breach of the duty of care could be a source of harm to patients, making

the case appropriate for summary judgment. The Ontario Superior Court of Justice not only found that general causation had been established for all class members, but that specific causation had also been established for those class members who were infected with the same bacteria as the doctor — a finding that was made in the absence of individual issues trials.

Both *Wise* and *Levac* suggest that we can expect to see greater use of summary judgment motions in the pharmaceutical class action context.

2 REJECTION OF INNOVATOR LIABILITY FOR GENERIC USE

In the 2016 decision in *Brown v. Janssen (Brown)*, the Ontario Superior Court of Justice confirmed *Goodridge v. Pfizer Inc. (Goodridge)* — that an innovator brand name drug manufacturer owes no duty of care to consumers of generic versions of the drug manufactured and sold by a generic competitor. The decision is one of the few cases in Canada to date to consider innovator liability.

> "An innovator brand-name drug manufacturer owes no duty of care to consumers of generic versions of the drug manufactured and sold by a generic competitor."

In *Brown*, the plaintiffs' proposed class action alleged that the antipsychotic medicine Risperdal® caused gynecomastia, a condition of male breast growth, and that the defendants failed to adequately warn consumers of both Risperdal and generic risperidone about the risk of developing gynecomastia. The plaintiffs pleaded that the defendants knew or ought to have known that manufacturers of generic risperidone "would be bound by Health Canada's regulations to reproduce exactly in the product monographs for generic risperidone the safety data in the product monographs for Risperdal, such that prescribers and consumers of generic risperidone would necessarily be relying on safety data presented by the defendants in the product monographs for Risperdal."

The innovator defendants in *Brown* argued that *Goodridge* and other cases had already refused to impose a duty of care on a manufacturer for products manufactured by others, and that even if the court wished to reconsider the question of innovator liability, no such duty of care should be recognized. Among other arguments, the defendants argued that allowing such liability would make brand name manufacturers *de facto* insurers for the whole industry, and that this involved policy choices more appropriately within the legislative domain. The court in *Brown* ultimately granted the defendants' request to strike all allegations of innovator liability in the plaintiffs' amended claim on the grounds that the plaintiffs' claims relating to generic risperidone had no reasonable chance of success.

A similar victory in favour of innovators was also obtained this past year at a trial in Quebec. In *Brousseau c. Laboratoires Abbott ltée (Brousseau)*, the first pharmaceutical product liability common issues trial in Canada (discussed below), the Superior Court of Québec affirmed that individuals who consumed generic versions of a drug have no claim against the manufacturer of the innovator drug under Quebec civil law.

3 OPPOSING CERTIFICATION

2016 also saw important defence verdicts in respect of proposed class certification. While pharmaceutical class actions are frequently certified in Canada, three proposed class actions were denied certification in 2016. In *Batten v. Boehringer Ingelheim (Canada) Ltd. (Batten)*, the plaintiffs sought certification of a class action related to the anticoagulant drug, Pradaxa®. The plaintiffs alleged that Pradaxa® carried the risk of excessive bleeding and that Boehringer breached its duty to warn that there was no antidote for the drug. At the certification motion, the Ontario Superior Court of Justice rejected this claim, finding on the evidence that there was no basis in fact to conclude that the absence of an antidote was a danger in the ordinary use of the medicine, and even if the absence of an antidote was a danger in ordinary use, there was no basis in fact to conclude that the absence of an antidote was a danger common to all class members. The proposed common causation issue also failed the commonality test because of the absence of a methodology to prove general causation. Accordingly, the court denied certification.

> *Batten, Harrison* and *Baratto* reaffirm that certification of a pharmaceutical class action is not guaranteed and that courts will exercise an important gatekeeper function at the certification stage.

In *Harrison v. Afexa Life Sciences Inc. (Harrison)*, the British Columbia Supreme Court denied class certification in a case involving the over the counter product Cold-Fx. The plaintiff alleged that the labelling, packaging and marketing of Cold-Fx misled the proposed class of purchasers of the product into believing that the product provided "immediate relief" of cold and flu symptoms. On the evidence, however, the court found that the class definition was overly broad because not all of the Cold-Fx products sold during the relevant time contained the alleged misrepresentations. Furthermore, not all purchasers of Cold-Fx would have purchased the product for short term relief or because of the alleged representations and not all were purchasers dissatisfied with the product. Moreover, the court found that the representative plaintiff could not fairly and adequately represent the class because she appeared to be no more than a placeholder and the litigation plan for advancing the action was "boilerplate". The plaintiff has appealed the decision.

In *Baratto c. Merck Canada inc. (Baratto)*, the plaintiff sought authorization to institute a class action for all persons residing in Quebec who were prescribed Propecia® and/or Proscar® prior to November 18, 2011 for the treatment of baldness. The plaintiff alleged that the defendant failed to adequately advise class members of the health risks associated with the use of the medications, including depression and erectile dysfunction. The Superior Court of Québec refused to authorise the proposed class action, concluding that the plaintiff's allegations were purely hypothetical, including the fact that there were numerous alternative possible causes for his problems. The court further held that an analysis of the evidence of proposed members of the class could only be done on an individual basis, such that a class action would be ill-suited to advance the rights of class members. The plaintiff has appealed the decision.

The 2016 decisions in *Batten*, *Harrison*, and *Baratto* reaffirm that certification of a pharmaceutical class action is not guaranteed and that Canadian court will exercise an important gatekeeper function at the certification stage.

Despite the welcomed decisions in *Batten*, *Harrison*, and *Baratto*, the Nova Scotia Supreme Court certified a proposed class action after allowing the plaintiffs leave to file supplemental evidence on the identifiable class criterion. In *Sweetland v. GlaxoSmithKline Inc.*, the plaintiffs alleged that Avandia®, a medication for the treatment of Type 2 diabetes, caused cardiovascular events including heart failure, heart attacks and strokes, and that the defendants were liable for negligent design, negligent distribution and marketing, and waiver of tort. At the initial certification hearing in 2015, the court refused to certify the action, but "in the interests of fairness", permitted the plaintiffs to supplement evidence related to the identifiable class criterion, and to file a revised list of common issues. Furthermore, the court refused to dismiss the possibility of compensation based upon waiver of tort at the certification stage, and deferred the matter to the common issues trial. At the second certification hearing, the court held that it was satisfied that the evidence provided by the plaintiff, including two affidavits from individuals who were prescribed Avandia, remedied the deficiencies noted in the first certification decision to establish the existence of two or more class members.

Similarly in *Dembrowski v. Bayer Inc.*, the Saskatchewan Court of Queen's Bench, at the initial certification hearing, granted leave to the plaintiff to file a revised litigation plan after finding that the other certification criteria had been met. At the second certification hearing, the court certified the proposed action, concluding that with some amendments, the second litigation plan was sufficient to meet the certification criteria.

4 FIRST PHARMACEUTICAL PRODUCT LIABILITY COMMON ISSUES TRIAL IN CANADA

A report of the defence successes of 2016 in pharmaceutical cases would also be incomplete without reporting on the 2016 decision of the Superior Court of Québec in *Brousseau*. As noted above, *Brousseau* was the first ever decision of a Canadian court ruling on the merits of a pharmaceutical product liability common issues trial.

In *Brousseau*, the plaintiffs alleged that class members experienced certain psychiatric reactions while taking the drug, Biaxin®, and that Abbott Laboratories failed to sufficiently inform users of the risk of these reactions. The Superior Court of Québec dismissed the action, concluding that the plaintiffs had not met their burden of proof with respect to causation. The court held that the inclusion of side effects in the product monograph was not proof that the manufacturer believed there to be a causal link between the drug and the side effect and that the mere possibility of a causal link (e.g., evidence of case reports) was insufficient to prove general causation on a balance of probabilities. The plaintiffs requested an appeal of the decision, which was rejected by the Quebec Court of Appeal. The decision highlights that once a product liability case is certified, plaintiffs must still establish causation with credible and convincing scientific and expert evidence at trial.

Summary

The defence can be encouraged by these decisions, which suggest that certification of a pharmaceutical class action is not guaranteed. Where appropriate, the defence may also be encouraged to take cases to a merits hearing — either on a motion for summary judgment or trial. Canadian courts have made clear that plaintiffs must establish issues such as causation based on solid scientific and expert evidence in order to be successful on the merits.

For further information, please contact Robin Linley, Jessica Lam or any other member of our Class Actions or Life Sciences groups.

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