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In PM(NOC) Litigation, the Pleadings Rule

Since the amendments to the *PM(NOC) Regulations* in 2017, both generic and brand side litigants have struggled with the question of whether the second person's Notice of Allegation governs the issues in the proceeding, or the Statement of Defence. The Federal Court of Appeal has answered in this week's decision in *Sunovion Pharmaceuticals Canada Inc v Taro Pharmaceuticals Inc*: it is the Statement of Defence.

This grey area arose because the amendments shifted the proceedings under the *Regulations* from applications to actions. As Justice Locke wrote for the Federal Court of Appeal, the pre-2017 *Regulations* "contemplated an application by a 'first person' for an Order prohibiting the Minister of Health from issuing a notice of compliance, in which the first person bore the burden of establishing that the allegations made in the NOA [Notice of Allegation] were not justified." A proceeding by way of application meant there were no pleadings and the Notice of Application had to respond directly to the Notice of Allegation. This is not the case in the current regime.

The Courts considered the appellant's arguments that reliance on the Notice of Allegation would allow the second person (often a generic) to split its case and that there would be general unfairness to the first person in making its decision to commence an action. The Court analyzed comments from the RIAS and provisions concerning damages available to the first person in these actions, and concluded the proper checks in balances were in place so that a first person would not be unfairly prejudiced if allegations were put forward by the second person in their Statement of Defence that did not appear in the Notice of Allegation. Both the Federal Court of Appeal and the court below concluded these checks sufficiently limited a second person's incentive to try to profit from withholding invalidity allegations in its Notice of Allegation.