FCA allows defendant to amend pleadings to allege grounds of invalidity not in NOA

June 11, 2021

The Federal Court issued a decision in an action brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, (the *NOC Regulations*), allowing a defendant (second person) to amend its pleadings to include additional allegations of invalidity not found in its Notice of Allegation (NOA).[1] The plaintiff (first person) appealed the decision, and the Federal Court of Appeal (FCA) affirmed the decision.[2]

The FCA confirmed the conclusion that the *NOC Regulations*, as amended in 2017, no longer prohibit the second person from introducing new allegations of invalidity in its Statement of Defence, even if not found in its NOA to which the first person is responding. The FCA held that the Regulatory Impact Analysis Statement (RIAS), which accompanied the 2017 amendments, supports this decision.

The plaintiffs argued they made the decision to risk liability pursuant to section 8 of the *NOC Regulations* on the basis of the contents of the NOA and that it is unfair to permit the defendant to add new allegations, as they were denied the right to consider them when accepting the liability risk. They also argued that permitting such amendments would encourage generic companies to split their case.

The FCA held that the *NOC Regulations* contain checks on the generic company's incentive to withhold invalidity allegations. Section 8(6) allows the Court to consider all relevant matters in assessing the amount of compensation awarded. Further, the Court has discretion to grant or dismiss a motion to amend a pleading.

Therefore, if the Court is convinced a proposed amendment seeks to introduce invalidity allegations that the generic company was aware of when its NOA was served, the Court could refuse the amendment as not in the interests of justice. The FCA held this was sufficient to address the first person's concerns.

The first person also argued that the proposed amendments should only be permitted to be made to the counterclaim, as opposed to the Statement of Defence, as it is a distinct proceeding from the action. The first person argued that this would allow them to argue that liability from section 8 should be limited to those issues in the NOA, and not the issues raised only in the counterclaim. The FCA also dismissed this argument, agreeing with the FC that this was not the legislator's intent.

Thus, it appears that first persons/plaintiffs will not be able to rely on the contents of the NOA as defining the scope of a proceeding brought pursuant to the NOC Regulations. They may also have to be prepared to deal with all possible grounds of invalidity. Allowing these amendments once a proceeding has started will create additional pressure for the already tight time constraints in these proceedings.

[1] *Sunovion Pharmaceuticals Canada Inc. v. Taro Pharmaceuticals*, 2021 FC 37.

[2] *Sunovion Pharmaceuticals Canada Inc. v. Taro Pharmaceuticals*, 2021 FCA 113.

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