

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.

By

[Beverley Moore, Chantal Saunders](#)

Expertise

[Intellectual Property, Intellectual Property Litigation, Life Sciences](#)

BLG | Canada's Law Firm

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 800 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

blg.com

BLG Offices

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3
T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9
T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2
T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4
T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3
T 416.367.6000
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing unsubscribe@blg.com or manage your subscription

preferences at blg.com/MyPreferences. If you feel you have received this message in error please contact communications@blg.com. BLG's privacy policy for publications may be found at blg.com/en/privacy.

© 2026 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.