Court File No. ~~23-A-~~ A-66-23
(Court File Nos. T-1831-22 and T-1842-22) ID:1

FEDERAL COURT OF APPEAL

BETWEEN:

BOEHRINGER INGELHEIM (CANADA) LTD. and BOEHRINGER INGELHEIM INTERNATIONAL GMBH

Appellants
(Plaintiffs)

and

SANDOZ CANADA INC. and SUN PHARMA CANADA INC.

Respondents
(Defendants)

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellants. The relief claimed by the appellants appears on the following page.

THIS APPEAL will be heard by the Federal Court of Appeal at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellants. The appellants request that this appeal be heard at Ottawa, Ontario.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the *Federal Courts Rules* and serve it on the appellant's solicitor, or where the appellant is self-represented, on the appellant, WITHIN 10 DAYS of being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the judgment appealed from, you must serve and file a notice of cross-appeal in Form 341B prescribed by the Federal Courts Rules instead of serving and filing a notice of appearance.

Copies of the *Federal Courts Rules*, information concerning the local offices of the court and other necessary information may be obtained on request to the Administrator of this court at Ottawa (telephone 613-996-6795) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

February 27, 2023

Issued by: _____
Registry Officer

Address of local office: Federal Court of Appeal
Thomas D'Arcy McGee Building
90 Sparks Street
Ottawa, Ontario K1A 0H9

TO: The Administrator
Federal Court of Appeal
Thomas D'Arcy McGee Building
90 Sparks Street
Ottawa, Ontario K1A 0H9

AND TO: **FINEBERG RAMAMOORTHY LLP**
1 St Clair Ave W, Suite 1102
Toronto, ON M4V 1K6

Neil Fineberg / Ben Wallwork / Belle Van

Tel: 647-795-8635 / Fax: 647-795-8634

neil@fineberg.legal
ben@fineberg.legal
belle@fineberg.legal

Solicitors for the Respondent, SANDOZ CANADA INC.

AND TO: **FINEBERG RAMAMOORTHY LLP**
1 St Clair Ave W, Suite 1102
Toronto, ON M4V 1K6

Kavita Ramamoorthy / Judith Robinson / Kristin Marks

Tel: 647-795-8635 / Fax: 647-795-8634

kavita@fineberg.legal
judith@fineberg.legal
kristin@fineberg.legal

Solicitors for the Respondent, SUN PHARMA CANADA INC.

THE APPELLANTS APPEAL to the Federal Court of Appeal from the Order of Mr. Justice Fothergill of the Federal Court in Ottawa, Ontario, dated February 17, 2023 by which the Court found, as a question of law applicable in these proceedings, that the Respondents (the Defendants) may counterclaim by right against patent claims not asserted by the Plaintiffs in actions commenced under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*.

THE APPELLANTS ASK that this Court:

(a) Allow the appeal;

(b) Set aside the Order of Mr. Justice Fothergill that decided the question of law raised by the Plaintiffs' motion for summary judgment in the Defendants' favour, and concluded as a matter of law that the Defendants may counterclaim by right against the Non-Asserted Claims in the actions commenced by the Plaintiffs under subsection 6(1) of the *PM(NOC) Regulations*.

(c) Decide, as a question of law and via summary judgment, that paragraph 6(3)(a) of the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*") does <u>not</u> permit, as of right and without leave of the Court, a counterclaim for a declaration of non-infringement and/or invalidity in respect of patent claims beyond those asserted by the Appellants in these proceedings made under subsection 6(1) of the *Regulations*;

(d) Award the Appellants their costs of this appeal and of the motion below; and

(e) Grant such further and other relief as this Honourable Court may permit and deem just.

THE GROUNDS OF APPEAL are as follows:

Background

1. This appeal relates to two underlying proceedings commenced by the Appellants/Plaintiffs ("Boehringer"), both on September 8, 2022. Each proceeding is an action for patent infringement brought under subsection 6(1) of the *PM(NOC) Regulations* (a "6(1) Action").

2. Six patents are asserted by Boehringer in the underlying actions. At present, Boehringer asserts infringement of 102 of the 121 claims contained in these patents (the "Asserted Claims"). The Asserted Claims define the scope of the underlying 6(1) Actions.

3. The Defendants filed materially identical Statements of Defence and Counterclaims on October 19, 2022. The Counterclaims filed by the Defendants each seek:

    a. a declaration pursuant to subsection 60(1) of the *Patent Act* that **each and every claim** of each of the six patents are and always have been invalid, void and of no force and effect; and

    b. a declaration pursuant to subsection 60(2) of the *Patent Act* that **each and every claim** of each of the six patents have not been infringed or induced to be infringed by the Defendants.

4. The Defendants' Counterclaims explicitly "plead[] and rel[y] on section 60 of the *Patent Act*", and assert that the Defendants are interested persons pursuant to "section 60 of the *Patent Act* and section 8.1 of the *Regulations*". Paragraph 6(3)(a) of the *PM(NOC) Regulations* is never mentioned in the Counterclaims.

5. The Defendants' invalidity cases, if permitted to carry through to trial on every claim of all six patents, will be unwieldy. For example, the Defendants each rely on alleged prior art schedules with 1342 entries.

6. Upon receipt of the Defendants' Counterclaims, the Plaintiffs asked the Defendants to: 1) restrict their Counterclaims to the Asserted Claims; 2) seek leave of the Court to proceed with their Counterclaims against the Non-Asserted Claims; or 3) confirm they were taking the position that they could "counterclaim beyond the scope of the 6(1) action as of right".

7. The Defendants refused to modify their Counterclaims and did not seek leave of the Court to Counterclaim beyond the Asserted Claims.

8. The Plaintiffs filed Replies and Defences to Counterclaims on November 18, 2022 that take issue with the scope of the Defendants' Counterclaims.

Decision Under Appeal

9. In the underlying motion Boehringer asked the Court to consider, via summary judgment, whether the Defendants were permitted to Counterclaim in respect of patent claims not asserted in the underlying 6(1) Actions by right (*i.e*. without leave of the Court).

10. The Motions Judge agreed with Boehringer that this "pure question of law" was amenable to determination on a motion for summary judgment pursuant to Rule 215(2)(b). He further noted that the parties agreed that the question of law "should be decided one way or the other in advance of trial".[1]

[1] *Boehringer Ingelheim v Sandoz*, 2023 FC 241 ("Motion Decision").

11. The decision below acknowledged the importance of paragraph 6(3)(a) of the *PM(NOC) Regulations* to the issue before the Court. Paragraph 6(3)(a) reads:

> 6(3) The second person may bring a counterclaim for a declaration (a) under subsection 60(1) or (2) of the Patent Act in respect of any patent claim asserted in the action brought under subsection (1)

12. The Motions Judge also recognized that the recent *Janssen* decision of this Court "explicitly left open the question of whether a defendant may challenge non-asserted claims "by right"" (*i.e.* the exact question at issue on this motion). The Motion Decision also confirms that the legal issue before the Court was "left unresolved" by *Janssen*.[2]

13. Indeed, this Court *distinguished* the question advanced by Boehringer in the motion below from the question being decided in that case. This passage from *Janssen*, which was quoted in the Motion Decision, reads:

> To address the appellants' position, it is necessary to consider whether the Regulations permit, in the context of an action under subsection 6(1) thereof, a counterclaim on claims not asserted in the action, whether by right or with leave of the Court. I will address the question of whether such a counterclaim is permitted with leave. As did the Federal Court, I will leave for another day, the question of whether a defendant in an action under subsection 6(1) may make such a counterclaim by right. [Emphasis in *Janssen*]

14. Despite the distinctions drawn by this Court in *Janssen* between counterclaims brought by right versus with leave, Boehringer's motion was ultimately dismissed on the basis that *Janssen* had already decided the question at issue.[3]

15. In further detail, the Motion Judge did not conduct any statutory interpretation analysis, but rather incorrectly rejected certain of Boehringer's arguments out

---

[2] Motion Decision at paras 29 and 46; *Janssen v Apotex*, 2022 FCA 184 [*Janssen*]
[3] Motion Decision at para 54

of hand as being, in the Motion Judge's view, "foreclosed" by *Janssen*, and arguments that could not be accepted "without departing from *Janssen*".[4]

16. Other statutory interpretation arguments made by Boehringer were rejected without analysis apart from allegedly being "before the Federal Court of Appeal in *Janssen*", despite there being nothing in the *Janssen* decision suggesting this, and despite *Janssen* itself distinguishing between the "with leave" versus "as of right" scenarios.[5]

17. The Motion Decision also focuses heavily on procedural aspects of how the Defendants could bring Counterclaims beyond the scope of patent claims asserted in 6(1) Actions if such Counterclaims were not permitted as of right. Considerations of the procedural ramifications if Boehringer's motion was successful are not germane to the legal issue before the Court, but nonetheless weighed heavily on the Motion Judge's analysis.[6]

18. Further, in considering these aspects, the Motion Decision incorrectly concluded that Boehringer was attempting to "read a new procedure into the Rules, [] one that is inconsistent with existing provisions."[7] This is wrong – Boehringer does not suggest that the *Rules* need any modification.

19. *Janssen* concluded that the "intention of the Regulations is to leave to the Federal Court the discretion to permit a counterclaim under subsection 6(3) that includes non-asserted claims."[8] The Motion Decision removes that discretion. It permits defendants to counterclaim as of right, bypassing the Federal Court and removing discretion from the analysis.

---

[4] Motion Decision at paras 41 and 52
[5] Motion Decision at para 43
[6] Motion Decision at paras 44-50
[7] Motion Decision at para 47
[8] Motion Decision at para 54

20. The decision below was a judgment on a question of law determined before trial. As such, Boehringer appeals pursuant to paragraph 27(1)(b) of the *Federal Courts Act*.

The Errors Below

21. The Motion Judge erred in deciding that second persons to actions commenced under subsection 6(1) of the *PM(NOC) Regulations* are permitted to counterclaim *by right and without leave of the Court* in respect of *any* patent claim contained in the patents asserted in the 6(1) Action, and not just those patent claims asserted in the 6(1) Action.

22. The primary, and flawed, overarching basis on which the Motions Judge arrived at his conclusion on the question of law identified above was by finding that he was bound by *Janssen*. He relatedly erred by finding that the consequence of *Janssen* was the creation of an "as of right" entitlement to allow second persons to counterclaim beyond the claims asserted in the 6(1) Action.

23. If the Appellants are incorrect, and if the only interpretation of *Janssen* is as found by the Motions Judge, *Janssen* is manifestly wrong and must be clarified that it does not apply to the situation at bar, or varied or overturned pursuant to *Miller v Canada,* 2002 FCA 370.

The Specific Errors Leading to the Erroneous Conclusion of the Motion Judge

24. In finding himself bound by *Janssen*, and holding that the *Regulations* entitle a second person to counterclaim beyond the claims asserted in the corresponding 6(1) Action as of right and without requiring leave of the Court, the Motions Judge erred by:

    a. Failing to give effect to paragraph 46 of *Janssen,* where the Court expressly stated it would not be deciding whether or not a counterclaim

beyond the asserted claims was available as of right, but rather only addressing the issue of whether it was possible with leave of the Court;

b. Failing to give any effect to the express language of paragraph 6(3)(a) of the *PM(NOC) Regulations*, which limits the scope of a second person's entitlement to counterclaim within a 6(1) Action solely to claims asserted in that action;

c. Failing to undertake any meaningful statutory interpretation analysis in respect of the question at bar, for example failing to address the redundancy and "reading out" of the words "in respect of any patent claim asserted in the action brought under subsection (1)" from paragraph 6(3)(a) of the *PM(NOC) Regulations*;

d. Concluding that a second person has a right, or an entitlement, to counterclaim beyond the asserted claims despite this being directly contrary to the conclusion within *Janssen* that the intention of the *PM(NOC) Regulations* was to ensure the Court retained the *discretion* to permit counterclaims beyond the asserted claims where appropriate to do so;

e. Requiring Boehringer to justify that the existing practices under the *Federal Courts Rules* were insufficient, notwithstanding that the *Rules* apply generally to proceedings and the specific and targeted implementation of the *PM(NOC) Regulations* would take precedence as a matter of statutory interpretation;

f. Failing to account for the express language of subsection 55.2(5) of the *Patent Act*, which expressly requires the *PM(NOC) Regulations* to take precedence in the event of inconsistency or conflict with any Act of Parliament or any Regulations made thereunder;

g. Considering it the burden of the Plaintiffs to strike any expanded counterclaim made by a Defendant in a 6(1) Action, rather than properly recognizing per *Janssen* that any such expanded counterclaim can only be brought with leave of the Court;

h. Considering Boehringer's argument as "read[ing] a new procedure into the Rules, particularly one that is inconsistent with existing provisions" notwithstanding that the issue of "leave" was not at issue and was itself established by *Janssen* without any suggestion of requiring a novel procedure;

i. Finding that the necessary consequence of certain permissive language in paragraph 6(3)(a) of the *Regulations* was that a second person was entitled to bring a broader counterclaim, despite this being a misreading of the statute and despite these not being equivalent comparables. The permissive nature is not the scope of the restrictions imposed once the second person decides to commence a counterclaim but rather is the second person's choice of whether or not to bring a counterclaim instead of simply defending the 6(1) Action. In reaching this conclusion, the Court failed to account for clear law of statutory interpretation that the permissive element does not apply to the imposed limitations, but instead the optional element of whether or not to proceed with the restricted step;

j. Failing to consider that the *PM(NOC) Regulations* were enacted and enabled pursuant to subsection 55.2(4) of the *Patent Act*, which enabled the making of regulations specific to circumstances arising out of the exception to infringement provided in subsection 55.2(1). This included conferring rights of action in respect of disputes over patent rights under paragraph 55.2(4)(g) as well as restricting or excluding the application

of other rights of action under the *Patent Act* or another Act of Parliament (under paragraph 55.2(4)(h));

k. Failing to consider that the express words of Parliament within the *PM(NOC) Regulations* were to limit counterclaims solely to those "in respect of any patent claim asserted in the action brought under subsection (1)". This is intended to legislate exhaustively on the scope of permissible, as of right counterclaims to 6(1) Actions (*i.e.* as a complete code), restricting and removing any availability of broader relief. In finding that this was not the case, the Court failed to consider that the expression of limits can oust an otherwise available remedy;

l. Failing to account for binding case law (including of the Supreme Court of Canada) that requires words in a statute or regulation to be read in a manner that gives each word meaning, and therefore the Court failed to account for the fact that its interpretation of paragraph 6(3)(a) of the *PM(NOC) Regulations* made the limitation "in respect of any patent claim asserted in the action brought under subsection (1)" meaningless;

m. Failing to consider that section 6.02 of the *Regulations*, as expressly written and as interpreted by the FCA in *Apotex v Bayer*, 2020 FCA 86, precludes the joining of <u>any</u> other action during the period in which the Minister is precluded from issuing a Notice of Compliance to the second person, unless the strict statutory exceptions are met. This preclusion would prevent the joining of issues even where it would be efficient to do so, such as claims of non-infringement or invalidity of claims that were not made pursuant to paragraph 6(3)(a) of the *PM(NOC) Regulations*, but were instead brought under the *Patent Act*; and

n. Failing to consider that *Janssen* would be internally inconsistent if it stood for the position that a second person can do so as of right what *Janssen* held it could do with leave of the Court.

25. For the above reasons the Motion Decision must be overturned. As a legal issue that the Motions Judge found appropriate to decide prior to Trial, this Court is properly positioned to render a decision on the issue rather than remitting it back to the Motions Judge.

26. Boehringer relies on:

    a. *Federal Courts Act,* RSC, c F-7, ss. 27 and 52;

    b. *Federal Courts Rules,* SOR/98-106, as amended, Rules 3, 53, 215, 335-340, 342-348, 400 and 403;

    c. *Patent Act,* RSC, c P-4, s. 55.2, 60;

    d. *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133, ss. 4, 5, 6, and 8.1; and

    a. Such further and other grounds as counsel may advise and this Honourable Court may permit.

27. Boehringer requests that this appeal be heard in Ottawa, Ontario, and that it proceed on an expedited basis.

Gowling WLG (Canada) LLP
Barristers & Solicitors
160 Elgin Street, Suite 2600
Ottawa, Ontario K1P 1C3

John Norman
Alex Gloor
Alex Camenzind
Rebecca Johnston

Tel: 613-233-1781
Fax: 613-563-9869

Solicitors for the Appellants / Moving Parties

TO: Federal Court of Appeal
Thomas D'Arcy McGee Building
90 Sparks Street
Ottawa, Ontario K1A 0H9

AND TO: **FINEBERG RAMAMOORTHY LLP**
1 St Clair Ave W, Suite 1102
Toronto, ON M4V 1K6

Neil Fineberg / Ben Wallwork / Belle Van

Tel: 647-795-8635 / Fax: 647-795-8634

neil@fineberg.legal / ben@fineberg.legal / belle@fineberg.legal

Solicitors for the Respondent, SANDOZ CANADA INC.

AND TO: **FINEBERG RAMAMOORTHY LLP**
1 St Clair Ave W, Suite 1102
Toronto, ON M4V 1K6

Kavita Ramamoorthy / Judith Robinson / Kristin Marks

Tel: 647-795-8635 / Fax: 647-795-8634

kavita@fineberg.legal / judith@fineberg.legal /
kristin@fineberg.legal

Solicitors for the Respondent, SUN PHARMA CANADA INC.