Court of Appeal File No. A-138-22
(Court File No. T-549-20)

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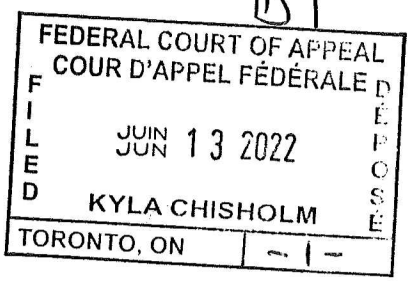
FEDERAL COURT OF APPEAL



BETWEEN:

SANDOZ CANADA INC.

Appellant
(Defendant)

- and -

JANSSEN INC. and ACTELION PHARMACEUTICALS LTD.

Respondents
(Plaintiffs)

NOTICE OF APPEAL

TO THE RESPONDENTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellant. The relief claimed by the appellant appears below.

THIS APPEAL will be heard by the Court 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 appellant. The appellant requests that this appeal be heard at Toronto.

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, if the appellant is self-represented, on the appellant, **WITHIN 10 DAYS** after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order 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 613-992-4238) 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.

June 13, 2022

Issued by: VANESSA GEORGE
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APPEAL

THE APPELLANT, SANDOZ CANADA INC. ("SANDOZ"), APPEALS to the Federal Court of Appeal from the Judgment of The Honourable Madam Justice Pallotta (the **"Trial Judge"**) dated May 12, 2022 in Federal Court File No. T-549-20 (the **"Judgment"**).

THE APPELLANT ASKS that this Court:

1. allow this Appeal;

2. set aside the Judgment;

3. order that the action in Federal Court File No. T-549-20 be dismissed (the **"Action"**);

4. require the Respondents (Plaintiffs in the Action), Janssen Inc. and Actelion Pharmaceuticals Ltd. (collectively, **"Janssen"**), to forthwith return any costs paid by Sandoz in respect of the Action;

5. award costs of this Appeal and costs of the Action to Sandoz; and

6. grant such further and other relief as this Honourable Court deems just.

THE GROUNDS FOR THIS APPEAL are as follows:

A. The Action

7. Janssen commenced the Action pursuant to s. 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***"PM(NOC) Regulations"***), alleging that the making, constructing, using, or selling of Sandoz's macitentan tablets (the **"Sandoz Tablets"**) in accordance with Sandoz's Abbreviated New Drug Submission No. 234136 (the **"Sandoz ANDS"**) would infringe and/or induce infringement of certain claims of Canadian Patent No. 2,659,770 (the **"770 Patent"**).

8. Sandoz had conceded, solely for the purposes of the Action, the infringement of Claims 21-31 (the **"Asserted Claims"**) of the 770 Patent by Sandoz's macitentan tablets which were the subject matter of the Sandoz ANDS (the "**Sandoz Tablets**").

9. In defence, Sandoz had alleged that the Asserted Claims were invalid on the grounds of obviousness, lack of utility/lack of sound prediction, insufficiency of disclosure, and overbreadth.

B. The Judgment

10. On May 12, 2022, the Trial Judge allowed the Action, granting the relief sought by Janssen, as reported in *Janssen Inc. v. Sandoz Canada Inc.*, 2022 FC 715 (the **"Reasons"**).

C. The 770 Patent

11. The 770 Patent is Janssen's third Canadian patent relating to macitentan. The other two patents are Canadian Patent Nos. 2,437,675 (the **"675 Patent"**, which expired December 4, 2021) and 2,621,273 (the **"273 Patent"**).

12. The 770 Patent explicitly admits that the compound at issue, macitentan, was disclosed in PCT publication WO 02/053557 (**"WO557"**, which issued in Canada as the 675 Patent), including its chemical structure, that it is an endothelin receptor antagonist (**"ERA"**), and its use for the treatment of "various diseases wherein vasoconstriction is involved (i.a. [*sic*] heart failure, angina pectoris, pulmonary and systemic hypertension and erectile dysfunction)."

13. WO557 highlighted macitentan as a preferred compound by: (1) including macitentan in a group of (explicitly) "preferred" compounds; and (2) including macitentan in an enumerated list of compounds in a patent claim.

14. The 273 Patent also includes a similar admission, namely that macitentan "is an endothelin receptor inhibitor and useful as endothelin receptor antagonist" whose chemical structure and preparation thereof is disclosed in WO557.

15. The 770 Patent is directed towards the use of macitentan in combination with a compound having phosphodiesterase type 5 inhibitory properties (**"PDE5-I"**) in the treatment of diseases wherein vasoconstriction is involved. The 770 Patent defines "diseases wherein vasoconstriction is involved" to include [systemic] hypertension, pulmonary hypertension (**"PH"**) (including pulmonary arterial hypertension (**"PAH"**)), diabetic arteriopathy, heart failure, erectile dysfunction, or angina pectoris.

16. The 770 Patent also explicitly admits that PDE5-Is had already been disclosed in certain patent documents relating to PDE5-I inhibitors and use thereof for the treatment of hypertension, PH, heart failure, erectile dysfunction, and angina pectoris (collectively, the **"PDE5-I Patents"**).

17. The Asserted Claims are produced below.

> 21. A use of the compound of formula (I) as defined in claim 1, or a pharmaceutically acceptable salt of said compound of formula (1), in combination with at least one compound having PDE5-inhibitory properties, or a pharmaceutically acceptable salt thereof, for treating a disease wherein vasoconstriction is involved.
>
> 22. The use according to claim 21, wherein the compound having PDE5-inhibitory properties is sildenafil, vardenafil, tadalafil or udenafil.
>
> 23. The use according to claim 22, wherein the compound having PDE5-inhibitory properties is sildenafil or tadalafil.
>
> 24. The use according to claim 23, wherein the compound having PDE5-inhibitory properties is sildenafil.
>
> 25. The use according to claim 23, wherein the compound having PDE5-inhibitory properties is tadalafil.
>
> 26. The use according to claim 21, wherein the disease is selected from hypertension and pulmonary hypertension.
>
> 27. The use according to claim 26, wherein the disease is pulmonary hypertension.

28. The use according to claim 27, wherein the disease is pulmonary arterial hypertension.

29. The use according to claim 28, wherein the compound having PDE5-inhibitory properties is sildenafil or tadalafil.

30. The use according to claim 28, wherein the compound having PDE5-inhibitory properties is sildenafil.

31. The use according to claim 28, wherein the compound having PDE5-inhibitory properties is tadalafil.

D. The Trial Judge's Reasons for Judgment and Errors Therein

18. The Trial Judge found the following:

19. ***The Skilled Person.*** The Trial Judge agreed with Sandoz that the skilled person would not be limited to PH/PAH specialists. She found that the skilled person would be a specialist physician or researcher, who would have knowledge of systemic and pulmonary hypertension, the physiologic pathways involved in these diseases, and the drugs and therapies to treat them. The skilled person would have an understanding of the pre-clinical and clinical research and experiments used to develop drugs for systemic and pulmonary hypertension.

20. ***Claim Construction.*** The Trial Judge accepted the construction proposed by the parties.

21. ***Obviousness.*** The Trial Judge found that the hypotheses of trying combinations of ERAs and PDE5-Is to treat PAH had been generated, and the results of retrospective case studies that reported on the co-administration of two or more PAH drugs to patients would have been noteworthy. Despite this, she found that this would not have been accepted as the common general knowledge (**"CGK"**) of the person of ordinary skill in the art (**"PSA"**) due to the "quality" of the scientific evidence at the time.

22. ***Lack of Demonstrated or Sound Prediction of Utility.*** The Trial Judge correctly determined that the utility of the Asserted Claims was not demonstrated as of the Canadian filing date. However, the Trial Judge found that the utility was soundly predicted. The Trial Judge found that the PSA, considering the CGK together with the test results disclosed in the 770 Patent, had the factual basis and sound line of reasoning to predict that macitentan in combination with a PDE5-I would be useful to treat "diseases wherein vasoconstriction is involved", as that term was defined in the 770 Patent.

23. ***Overbreadth.*** The Trial Judge held that the Asserted Claims were not overly broad by reason of a lack of utility of some of the area covered by the Asserted Claims.

24. ***Insufficiency.*** The Trial Judge found that there was sufficient disclosure.

25. In doing so, the Trial Judge made reviewable errors of law and/or palpable and overriding errors of fact, including, *inter alia*, the following:

(a) determining that none of the Asserted Claims are invalid on at least one of the bases of obviousness, lack of utility/lack of sound prediction, insufficiency of disclosure, or overbreadth;

(b) assessing the Asserted Claims collectively (and not as separate claims), including in her analysis of each ground of invalidity advanced by Sandoz;

(c) ignoring her own construction of the Asserted Claims and instead treating "diseases wherein vasoconstriction is involved" as only PH/PAH and the 770 Patent as only dealing with the treatment of PH/PAH;

(d) incorrectly narrowing the scope of her analysis to only PH and PAH, despite the 770 Patent defining "disease wherein vasoconstriction is involved" to include (but not be limited to) other diseases, e.g., systemic hypertension, diabetic arteriopathy, heart failure, erectile dysfunction and angina pectoris;

(e) improperly disregarding evidence and prior art which, despite relating to [systemic] hypertension, diabetic arteriopathy, heart failure, erectile dysfunction, or angina pectoris, did not relate to PH/PAH;

(f) misapprehending the evidence and facts of the case, misstating the evidence, and/or making factual findings that were not supported by or were inconsistent with the evidence before the Court;

(g) misstating, misapplying, and/or failing to recognize and apply the proper tests as set out in binding jurisprudence;

(h) the Trial Judge's apprehension, assessment, and/or application of the evidence was contrary to binding jurisprudence, including (but not limited to) her flawed reading and interpretations of the prior art from the perspective of a PSA (as defined by the jurisprudence);

(i) unequally treating the evidence adduced by Sandoz versus the evidence adduced by Janssen, without a proper basis, including overlooking evidence obtained on the cross-examinations of Janssen's expert witnesses and the inventor;

(j) applying inconsistent standards to her assessment of the validity of the patent, including, for example, her findings regarding obviousness versus her findings regarding utility/sound prediction;

(k) selectively reading the prior art, dismissing some parts of the prior art while simultaneously giving credence to other parts of the same prior art in a manner inconsistent with and/or unsupported by the evidence before her;

(l) reading the prior art in a critical manner, seeking failure, obstacles, and teach-aways; making findings of fact unsupported by either party's evidence;

(m) misconstruing the evidence adduced or relied upon by Sandoz;

(n) despite agreeing with the parties' construction of the Asserted Claims, applying the common meaning of "diseases wherein vasoconstriction is involved" as opposed to the 770 Patent-defined meaning of "diseases wherein vasoconstriction is involved", and thus failing to give proper consideration to the other, non-PH/PAH "diseases wherein vasoconstriction is involved", including hypertension, diabetic arteriopathy, heart failure, erectile dysfunction and angina pectoris;

(o) making inconsistent and contradictory findings, and determinations contrary to binding jurisprudence; and

(p) making inconsistent and contradictory findings of fact and misapplying those facts, contrary to binding jurisprudence.

(1) The 770 Patent, the Expert Witnesses and the Person Skilled in the Art

26. Janssen did not seek to qualify (and the Trial Judge did not qualify) its expert witnesses (Drs. Vachiery and Chakinala) as having expertise beyond PH and PAH.

27. Thus, Drs. Vachiery and Chakinala were not qualified as experts in any other "disease wherein vasoconstriction is involved" (including, but not limited to, systemic hypertension, diabetic arteriopathy, heart failure, erectile dysfunction and angina pectoris), nor was such qualification sought by Janssen. This would include the development and science of treatment of such non-PH/PAH diseases.

28. However, Sandoz's expert (Dr. Zusman) was fully qualified as having expertise in all of the "diseases wherein vasoconstriction is involved" (as defined in the 770 Patent).

29. Therefore, the Trial Judge erred in admitting and/or accepting the evidence of Drs. Vachiery and Chakinala (or, alternatively, failing to accord proper weight to their evidence), particularly in regard to diseases outside of PH and PAH. The Trial Judge further erred in comingling and conflating the evidence of Dr. Vachiery and Dr. Chakinala.

30. The errors of the Trial Judge in regard to expert evidence include:

(a) ignoring, misconstruing, or failing to properly assess the expert evidence;

(b) failing to make the appropriate evidentiary findings in light of the expert evidence;

(c) making findings on the basis of no expert evidence or on the basis of opinions from Drs. Chakinala or Vachiery who were not qualified as having the expertise necessary to provide such opinions; and

(d) making findings on the basis of opinions of Drs. Chakinala or Vachiery which were exposed as incorrect or disingenuous on cross-examination.

(2) Obviousness

31. The question to be answered was whether using macitentan and a PDE5-I together to treat a "disease wherein vasoconstriction is involved" (as the term is used in the 770 Patent) was obvious or, at least, obvious to try, as at the claim date. The Trial Judge erred in her determination that the subject-matter of the Asserted Claims was not obvious.

32. The Trial Judge unduly elevated the inventive concept of the Asserted Claims by requiring that the prior disclosure of macitentan includes it being a compound "to be combined with a PDE5-I".

33. The Trial Judge erred in her determination of whether this subject matter/inventive concept would have been obvious to a PSA, *by failing to give proper regard to the state of the art*.

34. The Trial Judge erred in her determination of the CGK and/or the motivation of the PSA, including, *inter alia*, the following:

(a) despite finding that a researcher would have formed part of the skilled team, the Trial Judge failed to consider and/or overlooked the evidence from the expert witnesses regarding the review and consideration of the teachings of certain prior art documents, including patent documents, which would have rendered such prior art documents as CGK or, at the very least, state of the art;

(b) the Trial Judge failed to consider those publications which the expert witnesses expressly admitted would have been part of the CGK;

(c) the Trial Judge failed to consider the prior art from the perspective of the skilled team, which she defined to include a researcher, including the researcher's review of patent documents;

(d) the Trial Judge applied an elevated standard to the prior art, including her requirement that the prior art "demonstrate" their teachings (e.g., by reporting pre-clinical or clinical trial data) instead of disclosing the information. On this basis, the Trial Judge excluded numerous pieces of prior art and their teachings regarding the use of ERAs in combination with PDE5-Is for treating "diseases wherein vasoconstriction" is involved;

(e) the Trial Judge determined that the PSA would have required *demonstrating* or *establishing* that ERAs and PDE5-Is could be combined to treat PAH, despite her earlier finding that certain prior art relied upon by Sandoz was not merely "hypothesis-generating", but the hypotheses had already been generated and they presented some evidence in support of the combination therapy;

(f) the Trial Judge imposed an elevated requirement on the prior art regarding the "quality of the [scientific] evidence". In particular, the Trial Judge required that the safety and/or efficacy of ERA + PDE5-I combination therapy for the treatment of PH/PAH be demonstrated to an acceptable level of confidence;

(g) the Trial Judge imposed an elevated requirement on the teachings of the prior art, requiring treatments disclosed to be the "standard of care" (or similar) in order to be considered CGK;

(h) the Trial Judge determined that the inclusion of statements that questions remained, or that further work needed to be done, or that trials were underway, was sufficient to disregard the teachings of the prior art and disqualify them from being considered by the PSA;

(i) the Trial Judge ascribed a meaning of "class effect" which was not consistent with the evidence;

(j) the Trial Judge failed to consider and/or dismissed evidence regarding the class effect of ERAs and PDE5-Is;

(k) the Trial Judge required that the PSA be "steered toward" the combination of an ERA + PDE5-I, that there be "a focus in the field" on that combination therapy, and/or that the field "was moving in that direction" and similar terminology, instead of accepting the disclosure of such information; and

(l) the Trial Judge dismissed and/or failed to properly consider the evidence of the expert witnesses that as at the relevant date, the combination of an ERA and a PDE5-I had been used in clinical practice to treat PH/PAH.

35. The Trial Judge erred in failing to find that even if relevant prior art were not CGK, it would have nonetheless been part of the state of the art available to the PSA. The Trial Judge went on to compound this error by failing to consider all of the relevant prior art and giving this prior art the proper weight. The Trial Judge further erred in her imposition of the following on the PSA in her obviousness analysis:

(a) requiring that the PSA be "focused on combination therapies with an ERA and a PDE5-I";

(b) requiring that the PSA "expect that any ERA could be combined with a PDE5-I" (despite, *inter alia*, the admissions of the patentee in the 770 Patent, including those admissions of the prior art relating to macitentan and PDE5-Is); and

(c) finding that the PSA "did not understand there would be a class effect for ERAs when used in combination with other drugs (including PDE5-Is", despite the teachings of the prior art.

36. The Trial Judge erred in failing to accord proper weight to the admissions of the patentee in the 770 Patent and the 273 Patent, as well as the disclosures in WO557 itself regarding macitentan and the use of the compounds of WO557.

37. The Trial Judge erred in her misapprehension of the alleged divergence in teachings on the impact of ETA/ETB selectivity, which resulted in the Trial Judge's determination that this would be a teach-away, including the Trial Judge's misapprehension and misreading of WO395. This error was also compounded by the Trial Judge's misapprehension and reading of WO557. The Trial Judge disregarded all of the evidence given by both parties' experts as well as Dr. Clozel (the inventor) regarding the considerations in selecting ERA candidates for further drug development.

38. In reaching her conclusion as to obviousness, the Trial Judge failed to imbue the PSA with the proper CGK and deprived the PSA of the understanding and appreciation that the PSA would have had of the state of the art.

39. The Trial Judge failed to perform the exercise of how the PSA, equipped with the CGK, would have addressed the known challenges associated with treating PH/PAH in light of the state of art. The Trial Judge applied inconsistent standards and

made inconsistent findings of fact in regard to the different invalidity allegations advanced by Sandoz. For example:

(a) the Trial Judge dismissed Sandoz's allegations of obviousness because "The skilled person would have considered the evidence insufficient to extrapolate the teachings about bosentan and sildenafil to a combination of any ERA and a PDE5-I, *based on shared mechanisms of action*";

(b) yet the Trial Judge dismissed Sandoz's allegations of lack of utility/sound prediction, stating that "the CGK provided the context and logical explanation for these observed effects (particularly the knowledge of NO and endothelin pathways that are involved in vasoconstriction and the knowledge of the way that an ERA or PDE5-I would affect steps in these pathways to modulate a vasodilatory effect" – which is entirely based on the *shared mechanisms of action* of ERAs and PDE5-Is.

(3) Lack of Utility/Lack of Sound Prediction

40. The Trial Judge was required to determine whether the utility of the subject-matter of the Asserted Claims had been demonstrated or was soundly predicted at the filing date of the 770 Patent.

41. The Trial Judge erred in applying incorrect tests in determining whether the inventor had soundly predicted utility of the subject-matter of the Asserted Claims.

42. The Trial Judge erred in misapprehending the evidence and misapplying her factual findings, including by, *inter alia*, the following:

(a) dismissing and/or misapprehending the evidence relating to the testing data and the analyses of such data underlying the examples set out in the 770 Patent;

(b) dismissing the evidence relating to the methodology of the inventor in conducting the testing to obtain the testing data and the inventor's analyses of such data underlying the examples set out in the 770 Patent;

(c) disregarding the fact that the underlying data and analyses of the data was not disclosed by the inventor;

(d) disregarding the evidence that this underlying data and analyses of the data shows that the disclosure of the 770 Patent is misleading;

(e) failing to find that the limited animal pre-clinical testing conducted by the inventor was insufficient to support the asserted utility of the entire scope of the Asserted Claims, including being insufficient to support a finding that such utility was soundly predicted;

(f) dismissing the evidence and ignoring her own earlier findings of fact (and stipulations of the parties in the joint scientific primer submitted to the Court) that angina pectoris, diabetic arteriopathy, and heart failure are not diseases of vasoconstriction;

(g) finding that the endothelin and NO pathways are pathways that operate in the vasculature throughout the body to effect vasoconstriction or vasodilation, in order to support a finding that the utility of the Asserted Claims was soundly predicted across the entire scope of "diseases wherein vasoconstriction is involved" (including those diseases which are not actually diseases of vasoconstriction);

(h) dismissing the evidence that erectile dysfunction, heart failure, angina pectoris, diabetic arteriopathy, and certain subtypes of PH and PAH are not treated using an ERA;

(i) restricting her determination of utility based solely on the examples and "ABCs" disclosed in the 770 Patent, despite the additional underlying data and analyses of the data conducted by the inventor which were omitted from the disclosure in the 770 Patent;

(j) finding that there "could be utility in a vasodilating effect, *even when abnormal vasoconstriction is not an underlying cause of a disease*" [italics added];

(k) dismissing and/or failing to consider the evidence of *lack of utility* in respect of diseases falling within the claimed scope of the Asserted Claims, including: erectile dysfunction, heart failure, angina pectoris, diabetic arteriopathy, and certain subtypes of PH and PAH and misapprehending and/or mischaracterizing the evidence regarding the same;

(l) creating a false distinction between (1) it being known that ERAs did not treat certain diseases or it not being known that ERAs could treat certain diseases; versus (2) ERAs not being useful for the treatment of those same diseases;

(m) grounding her finding that there was a sound line of reasoning to predict that the observed effects would extend to any PDE5-I based on the known mechanisms of action for PDE5-Is, yet dismissing the notion of class effects in her obviousness analysis; and

(n) basing her determination of sound prediction of utility of the macitentan + PDE5-I *combination* over the entire scope of the Asserted Claims based on the efficacy of only *one* of either macitentan or the PDE5-I.

43. It is antithetical to a finding of sound prediction of utility where there is either evidence of actual knowledge of inutility or the clear absence of knowledge supporting the claimed utility.

44. The Trial Judge erred in making inconsistent findings of the applicable CGK, as set out above (see the section regarding obviousness), even though she found that there was no practical difference in the CGK during the 2006-2008 period.

45. Having regard to the errors above, the Trial Judge then went on to erroneously find that there was a factual basis and/or sound line of reasoning (including disclosure thereof) supporting sound prediction of utility over the entire scope of the Asserted Claims.

(4) Insufficiency of Disclosure

46. The Trial Judge was required to determine whether the patent specification of the 770 Patent provided sufficient information to enable the PSA to practice the invention as claimed.

47. The Trial Judge erred in admitting and/or accepting the evidence of Janssen's experts that "the skilled person would understand how macitentan and a PDE5-I work to treat diseases wherein vasoconstriction is involved, and how the invention can be used (i.e. put into practice) for the treatment of such diseases". This finding is contradictory to the Trial Judge's findings regarding the CGK and state of the art

particularly in light of the Trial Judge's determination that there were no practical differences in the prior art or the relevant skills and knowledge of the PSA at any material time between 2006 (for obviousness) and 2008 (for sufficiency).

48. The Trial Judge erred in finding that the patent specification provided sufficient information to enable the PSA to practice the invention – over the entire scope of the Asserted Claims, despite the evidence that erectile dysfunction, heart failure, angina pectoris, diabetic arteriopathy, and certain subtypes of PH and PAH are not treated using ERAs.

49. The Trial Judge erred in conflating Sandoz's submissions regarding obviousness and insufficiency. In dismissing these submissions, the Trial Judge erred in failing to apply the proper tests for obviousness and insufficiency.

50. Moreover, the Trial Judge erred because there cannot be a sufficiency of disclosure where either (1) the subject treatment is not known to be capable of treating a particular disease falling within the scope of the claim; or (2) the subject treatment is known not to be capable of treating a particular disease falling within the scope of the claim.

(5) Overbreadth

51. The Trial Judge was required to determine whether the subject-matter of the Asserted Claims exceeded the invention that was made or disclosed.

52. The Trial Judge erred in conflating utility/sound prediction and overbreadth, contrary to binding jurisprudence.

53. The Trial Judge erred in finding that the Asserted Claims were not overly broad, despite the evidence that erectile dysfunction, heart failure, angina pectoris, and

diabetic arteriopathy are not treated using ERAs as of the relevant date. In any event, the Trial Judge erred because the invention made or disclosed cannot be either (1) a treatment that is not known to be capable of treating a particular disease falling within the scope of the claim; or (2) a treatment that is known not to be capable of treating a particular disease falling within the scope of the claim. Thus, where a patent claim extends to either (1) or (2), it has claimed more broadly than the invention made or disclosed.

E. This Appeal

54. Sandoz submits that the Trial Judge committed reviewable errors, both in findings of fact and applications of the law. These factual and legal errors are such that the within Appeal ought to be allowed and the Judgment ought to be set aside.

F. Costs

55. If successful, Sandoz request its costs of this Appeal and of the underlying Action.

56. Sandoz relies on such further and other grounds as counsel may advise and this Honourable Court may permit.

57. Sandoz proposes that this appeal be heard in Toronto.

DATED at Toronto, Ontario this 13th day of June, 2022.

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Court of Appeal File No. _____
(Court File No. T-549-20)

FEDERAL COURT OF APPEAL

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Appellant
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- and -

JANSSEN INC. and ACTELION PHARMACEUTICALS LTD.

Respondents
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I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the _____ day of JUN 13 2022 A.D. 20 ____

Dated this ____ day of JUN 13 2022 20 ____

VANESSA GEORGE
REGISTRY OFFICER
AGENT DU GREFFE