Court File No. A- 21-23 id 1

FEDERAL COURT OF APPEAL
COUR D'APPEL FÉDÉRALE
FILED 2-FEB-2023 DÉPOSÉE
P Karambelas
TORONTO, ON -1-

**FEDERAL COURT OF APPEAL**

BETWEEN:

**JANSSEN INC.**

Appellant

and

**ATTORNEY GENERAL OF CANADA**
**THE MINISTER OF HEALTH**

Respondents

# NOTICE OF APPEAL

**TO THE RESPONDENTS:**

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

**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 341 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 order appealed from, you must serve and file a notice of cross-appeal in Form 341 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.**

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## Appeal

**THE APPELLANT APPEALS** to the Federal Court of Appeal from the Judgment of the Honourable Mr. Justice Manson dated January 5, 2023 (the "Judgment"). The Federal Court dismissed Janssen Inc.'s application for judicial review of the Minister of Health's decision denying data protection to the innovative new drug, SPRAVATO (the "Decision").

**THE APPELLANT ASKS THAT**:

(a) The Judgment be set aside;

(b) The Decision be set aside;

(c) SPRAVATO be declared an "innovative drug" for the purposes of section C.08.004.1 of the *Food and Drug Regulations* (the "*Regulations*");

(d) SPRAVATO be declared eligible for data protection under section C.08.004.1 of the *Regulations*, effective July 1, 2020, with the period of data protection commencing on May 20, 2020, the date that SPRAVATO received its first notice of compliance ("NOC");

(e) The Office of Patented Medicines and Liaison, Therapeutic Products Directorate of Health Canada ("OPML") be compelled to grant SPRAVATO data protection under section C.08.004.1 of the *Regulations* and to add it to the Register of Innovative Drugs, effective July 1, 2020;

(f) The words "and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph" in the definition of

the term “innovative drug” in section C.08.004.1 of the *Regulations* be declared *ultra vires* and be read out of that definition; and

(g) The appellant be awarded its costs in this Honourable Court and the Federal Court.

**THE GROUNDS OF APPEAL are as follows**:

1. This appeal relates to the eligibility of SPRAVATO for data protection.

2. This appeal also relates to the proper interpretation of the term “innovative drug” as found in section C.08.004.1 of the *Regulations*.

**SPRAVATO is a New and Innovative Drug**

3. SPRAVATO is a new and lifesaving innovative drug. It is the first fundamentally new drug for treating major depressive disorder (“MDD”) in 50 years. It was approved by Health Canada in May 2020, but Health Canada refuses to protect the data generated and submitted to obtain that approval.

4. The medicinal ingredient in SPRAVATO is esketamine. Esketamine is an enantiomer of racemic ketamine. Ketamine has been previously approved in Canada (for use as an anesthetic), but esketamine has never been previously approved in Canada. The innovative aspects of SPRAVATO that differentiate it from ketamine include:

(a) SPRAVATO offers a novel therapeutic mechanism for MDD (an indication for which ketamine is not approved) that revolutionizes treatment of MDD in patients who have not adequately responded to two or more antidepressants;

(b) SPRAVATO differs from ketamine in many areas, including but not limited to the therapeutic class targeted; the indication; the route of administration; the dosage form; the dose; and the target receptor binding affinity;

(c) The extensive clinical development program required to establish the safety and efficacy of SPRAVATO in treating patients suffering from MDD involved 29 clinical studies in thousands of patients with MDD, a clinical study program that was wholly independent of the data relating to any previously-approved ketamine products; and

(d) Esketamine and ketamine were developed and sold by different drug companies. Janssen Inc. did not develop any ketamine products, nor did it rely on any ketamine data in seeking approval for SPRAVATO.

**Data Protection is Intended to Protect Innovative Drugs Like SPRAVATO**

5. The purpose of data protection is to encourage the research and development of new medicines that improve the health of Canadians. Patients can only benefit from the discovery and development of new medicines after the information and data generated in extensive pre-clinical and clinical trials demonstrate the drug's safety and efficacy. Canada's data protection regime addresses this issue by providing time-limited protection for data to encourage the development of new drugs.

6. Canada's data protection regime is found in section C.08.004.1 of the *Regulations*. The data protection regulations are empowered by the *Food and Drugs Act*, which gives the Governor in Council the authority to enact regulations

implementing the data protection rights that Canada agreed to provide under international treaties. In other words, Canada's data protection regulations are not unique, nor are they something Canada spontaneously decided to do. They are part of what Canada specifically agreed to in treaties with its major trading parters across the globe.

**The Data Protection Regime Under NAFTA**

7. Prior to July 1, 2020, two international treaties governed Canada's data protection regime: *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States* ("NAFTA") and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS"). There were two requirements for data protection under NAFTA and TRIPS: (i) the drug must contain a "new chemical entity"; and (ii) the data filed to obtain approval must have required considerable effort to generate.

8. The term "new chemical entity" was not defined in NAFTA or TRIPS, leaving it up to the Governor in Council to introduce a definition when enacting Canada's data protection scheme. The Governor in Council chose to use the term "innovative drug", which is defined in the *Regulations* as a "drug that contains a medicinal ingredient not previously approved in a drug by the Minister of Health ("Minister") and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph".

9. On July 1, 2020, NAFTA was replaced by the *Canada-United States-Mexico Agreement* ("CUSMA").

**The Initial Request for Data Protection for SPRAVATO**

10. The eligibility for data protection for SPRAVATO was first assessed during the regulatory approval process in 2018-2019, when Canada's data protection regime was governed by NAFTA and TRIPS. In its assessment, the Minister concluded that esketamine has not been previously approved in a drug in Canada. Nevertheless, the Minister refused to grant SPRAVATO data protection because it is an enantiomer of ketamine, which had been previously approved (the "First Decision").

11. Janssen applied for judicial review of the First Decision. The Federal Court dismissed the application for judicial review. The Federal Court of Appeal dismissed Janssen's appeal, but declined to comment on the impact of CUSMA on Canada's data protection regulations and did not make any findings with respect to CUSMA.

12. After the coming into force of CUSMA, Janssen applied again for data protection for SPRAVATO.

**The Minister is Permitted to Assess Eligibility for Data Protection after Issuance of an NOC**

13. While SPRAVATO received an NOC on May 20, 2020, the *Regulations* still permit the Minister to reassess SPRAVATO's eligibility for data protection following CUSMA coming into force on July 1, 2020.

14. Subsection C.08.004.1(3) of the *Regulations* requires the Minister to consider whether data is protected at the time a generic submission, which makes a comparison to an innovative drug, is filed or approved. This is the only triggering event regarding assessment of data protection eligibility.

15. The data protection sections of the *Regulations* contain forward-looking language. They do not impose any time limits for assessing eligibility for data protection, nor do they specify that a drug's eligibility can only be assessed once.

**The Data Protection Regime Must Be Interpreted Consistently With CUSMA**

16. Following the replacement of NAFTA with CUSMA, Canada amended the *Food and Drugs Act* to enable the Governor in Council to make any regulations that are considered necessary to implement CUSMA. While the *Food and Drugs Act* empowered the Governor in Council to make regulations necessary to implement CUSMA, it did not permit the Governor in Council to implement less extensive rights than are provided by CUSMA. This is consistent with the language of CUSMA, which states that Canada may provide more extensive protection than is required under CUSMA but contains no equivalent provisions permitting less extensive rights.

17. Canada's data protection obligations changed under CUSMA, and Canada agreed to provide data protection to "new pharmaceutical products". Unlike the undefined term "new chemical entity" used in NAFTA and TRIPS, the term "new pharmaceutical product" is explicitly defined in CUSMA. It is "a pharmaceutical product that does not contain a chemical entity that has been previously approved". The *only* prerequisite under CUSMA for data protection is that a new drug does not contain a chemical entity that has been previously approved.

18. The definition of "innovative drug" in the *Regulations* must be interpreted consistently with "new pharmaceutical product" in order for Canada to actually implement the obligations it agreed to under CUSMA. "Innovative drug" therefore cannot be interpreted to automatically exclude enantiomers under CUSMA. The words

"and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph" in the definition of "innovative drug" in the *Regulations* are *ultra vires* and should be read out of that definition.

19. Since the Minister, in the First Decision, already found that the chemical entity in SPRAVATO (esketamine) has not been previously approved in Canada, SPRAVATO meets the definition of "innovative drug" as of July 1, 2020 and is entitled to data protection.

**The Decision Denying SPRAVATO Data Protection Was Unreasonable**

20. The Minister found that SPRAVATO is not eligible for data protection because it is not entitled to a reassessment of data protection eligibility and, even if it were so entitled, it is not an "innovative drug" within the meaning of section C.08.004.1 of the *Regulations*. The Decision applied section C.08.004.1 of the *Regulations* as it had been applied under NAFTA and claimed that the coming into force of CUSMA did not necessitate any change to Canada's data protection regime.

21. The Minister's decision that SPRAVATO is not entitled to a reassessment of data protection eligibility was unreasonable because:

(a) it was based on the absurd premise that Janssen requested that the term of data protection to run from July 1, 2020 instead of the date of SPRAVATO's NOC;

(b) it was based on illogical reasoning that conflated the two distinct aspects of the data protection regime, namely, the timing of assessing data

protection eligibility and the date on which data protection commences; and

(c) it was inconsistent with the principles of statutory interpretation by reading in a timing requirement into the *Regulations* based an administrative practice that is unsupported by the text and purpose of the *Regulations* and by failing to provide sufficient justification for such interpretation.

22. Additionally, the Minister's decision that SPRAVATO is not an "innovative drug" within the meaning of section C.08.004.1 of the *Regulations* was unreasonable because:

(a) it strayed well beyond the constraints of the governing statutory scheme by failing to interpret the *Regulations* consistently with CUSMA and reading in limits on the scope of data protection that are not found in the *Regulations* or CUSMA;

(b) it failed to apply a purposive construction to interpret "innovative drug" consistently with the definition of "new pharmaceutical product" in CUSMA; and

(c) it was based on an absurd premise, circular reasoning and is a results-oriented exercise aimed at justifying the continued application of the prior interpretation of "innovative drug".

23. These errors by the Minister resulted in a reading in of a timing requirement to the *Regulations* and an interpretation of "innovative drug" that cannot be justified and a Decision that is unreasonable and should be set aside.

**The Federal Court Erred in its Review of the Decision**

24. In the Reasons for Judgment, the Federal Court declined to consider the fresh evidence provided by Janssen on the application for judicial review. The Appellant is not appealing this aspect of the Judgment.

25. In the Reasons for Judgment, the Federal Court also considered whether the Decision was reasonable and, in particular:

(a) Whether the Minister erred by holding that SPRAVATO is not an "innovative drug" under subsection C.08.004.1(1) of the *Regulations*; and

(b) Whether the Minister erred by holding that the relevant time to determine data protection eligibility was at the time SPRAVATO was issued an NOC.

26. When assessing whether the Minister's decision that SPRAVATO is not an "innovative drug" under subsection C.08.004.1(1) of the *Regulations* was reasonable, the Federal Court erred in law by failing to appreciate that the Minister:

(a) neglected to properly or reasonably apply the requirements of the empowering and governing statutes for the *Regulations*;

(b) failed to apply a purposive interpretation of the *Regulations* and the definition of "innovative drug" in light of the entire governing statutory scheme; and

(c) blindly followed jurisprudence of this Court that is no longer relevant or binding, as it was decided under NAFTA.

27. The Supreme Court of Canada's decision in *Canada v Vavilov*, 2019 SCC 65 ("*Vavilov*") mandates that the above factors be considered and appropriately addressed for the decision to be found reasonable. The Federal Court erred in law by omitting these factors from its analysis or by failing to properly apply these legal principles.

28. Instead of following *Vavilov*, the Federal Court erred in law by finding that the Minister reasonably considered the context and purpose of the data protection provisions, even though the Decision did not demonstrate that the Minister was alive to the text, context and purpose of key aspects of the governing legislation.

29. Based on the Decision, the Minister did not consider the text of the statutes that implemented CUSMA into Canadian law, namely the *Canada-United States-Mexico Agreement Implementation Act* and the *Food and Drugs Act*. Instead, the Minister examined and relied on irrelevant materials, Canada-United States-Mexico Agreement – Canadian Statement of Implementation and a Regulatory Impact Analysis Statement, that are subordinate to the legislation governing Canada's data protection regime as evidence of legislative intent. Under *Vavilov*, such an approach is unreasonable and neglecting to address it constitutes an error of law on the part of the Federal Court.

30. Had the Minister considered the entire legislative context, the only reasonable conclusion would have been that the data protection articles of CUSMA were implemented into Canadian law without qualification and, consequently, the interpretation of "innovative drug" under the *Regulations* needs to be wholly consistent with Canada's obligations under CUSMA.

31. In addressing the impact of CUSMA, the *Canada-United States-Mexico Agreement Implementation Act* and the consequential amendments to the *Food and Drugs Act*, the Federal Court also erred in law in:

(a) Considering the impact of the Canada-European Union Comprehensive Economic and Trade Agreement ("CETA") on the definition of "innovative drug" in the *Regulations*, even though that treaty is legally irrelevant to that definition, or at most is subordinate to the impact of CUSMA and TRIPS;

(b) Failing to correctly apply the binding approach to statutory interpretation in the context of treaty obligations as set out by the Supreme Court in *Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30;

(c) Misunderstanding and misapplying the requirements of the *Canada-United States-Mexico Agreement Implementation Act*;

(d) Misunderstanding and misapplying the requirements of the *Food and Drugs Act*;

(e) Misunderstanding and misapplying CUSMA and the rights and obligations set out therein; and

(f) Accepting and agreeing to an interpretation of "innovative drug" in regulations that is inconsistent with the governing statutes and relevant treaty provisions.

32. The Federal Court also erred in law in failing to consider that the Minister's analysis included applying jurisprudence that is not binding under CUSMA. NAFTA and TRIPS accorded data protection to a "new chemical entity" without specifying the meaning of "new". The majority in *Takeda Canada Inc. v. Canada (Health)*, 2013 FCA 13 ("*Takeda FCA*") found that the lack of definition allowed Canada to adopt its own definition through the use of "innovative drug" to exclude certain classes of compounds, including enantiomers.

33. CUSMA removed all uncertainty over what is meant by "new" by defining "new pharmaceutical products". The only requirement to be "new" under CUSMA is that the chemical entity has not been previously approved in Canada. Under this clear definition, the justification for interpreting "innovative drug" to automatically exclude the enumerated variations from data protection no longer exists. The factual basis for *Takeda FCA* changed under CUSMA and therefore that decision is no longer binding.

34. Additionally, when assessing whether the Minister erred by holding that the relevant time to determine data protection eligibility was at the time SPRAVATO was issued an NOC, the Federal Court erred in law by:

(a) failing to consider that the Decision lacked justification for the Minister's interpretation of timing requirements under the *Regulations* and fashioning its own reasons to address the deficiency;

(b) interpreting the *Regulations* to allow the Minister's timing argument to succeed, in a way that does not accord with the *Regulations*' language and purpose; and

(c) neglecting to consider the Minister's reasoning in light of the full record.

35. According to *Vavilov*, the reviewing court must consider whether the decision bears the hallmarks of reasonableness — justification, transparency and intelligibility — and whether it is justified in relation to the relevant factual and legal constraints that bear on the decision.

36. The Minister reasoned that when a generic manufacturer files a drug submission comparing its drug to an "innovative drug", the OSIP is required to determine whether that innovative drug has *already been granted* data protection. However, there is no preliminary step for evaluating whether a drug is captured within the definition of "innovative drug" required under subsection C.08.004.1(1) or set out in any other part of the *Regulations* and the Minister provided no justification for this interpretation. The Federal Court did not acknowledge the lack of justification, which is an error of law.

37. The Federal Court also added its own justification for the timing requirement, which was not included in the Decision, to bridge the fundamental gap in the Minister's reasoning. This type of analysis is not permissible under a reasonableness review and is an error of law.

38. Lastly, the Federal Court found that the Minister's interpretation of Janssen's request for data protection to commence on July 1, 2020 was reasonable, seemingly based only on one phrase picked out of Janssen's submissions. There was, however, myriad of evidence in Janssen's submissions pointing toward a different request for relief, none of which the Federal Court acknowledged.

39. Under *Vavilov,* the reviewing court must consider the decision in light of the record before the decision maker and consider whether the decision is based on a rational chain of analysis. The Federal Court erred in law in not considering the entire record before the Minister in evaluating whether the Decision was reasonable. If the Federal Court had considered the full text of Janssen's submissions to the Minister, it would have been apparent that the Minister's interpretation of Janssen's request for relief was entirely unreasonable.

**The Decision and Judgment Should be Set Aside**

40. Had the Federal Court followed *Vavilov* and conducted a proper reasonableness analysis, the only conclusion that could be reached is that the Minister's interpretation of "innovative drug" extends beyond the statutory scheme under CUSMA, and the Minister's reading in of a timing requirement to the *Regulations* lacked any reasonable support and was tainted by an irrational assumption.

41. The Decision was therefore impossible to justify and unreasonable and both it and the Judgment should be set aside by this Honourable Court.

February 2, 2023

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