Chirality Matters: Dismissal of Janssen's Judicial Review Confirms Enantiomers Are Not "Innovative Drugs" for Obtaining Data Protection

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On January 5, 2023, the Federal Court dismissed Janssen's application for judicial review of the decision of the Minister of Health finding SPRAVATO was not an innovative drug under subsection C.08.004.1(1) of the *Food and Drug Regulations* [the *Regulations*] and therefore not eligible for data protection.

The Minister's First Decision

Janssen developed the drug SPRAVATO for the treatment of Major Depressive Disorder. The medicinal ingredient in SPRAVATO is esketamine hydrochloride which is an enantiomer of ketamine hydrochloride. Drugs containing ketamine hydrochloride have previously been approved by the Minister of Health.

According to the *Regulations,* an "innovative drug means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, *enantiomer*, solvate or polymorph." (emphasis added)

As esketamine hydrochloride is an enantiomer of ketamine hydrochloride, the Minister determined that SPRAVATO did not qualify as an innovative drug and thus not entitled to data protection.

The Minister's Second Decision

As a result of the implementation of the Canada-United States Mexico Agreement [CUSMA], Janssen requested the Minister reconsider SPRAVATO as an innovative drug because the Minister had to interpret the *Regulations* consistently with CUSMA. The Minister refused the request, concluding data protection eligibility is assessed at the time of approval. Moreover, even if SPRAVATO were to be reassessed the conclusion would remain the same. Janssen sought judicial review of this decision.

Issues before the Federal Court

1. Did Janssen improperly include fresh evidence?
2. Was the decision reasonable?
    a. Did the Minister err by holding SPRAVATO is not an "innovative drug"?
    b. Did the Minister err by holding that the relevant time to determine data protection eligibility was at the time SPRAVATO was issued a Notice of Compliance [NOC]?

Janssen's foreign jurisdiction affidavits were denied as fresh evidence

Janssen sought to introduce three foreign jurisdiction affidavits regarding SPRAVATO being granted data protection in the United States, European Union, and Australia. However, the Court determined that the affidavits did not fit an exception to

permit a reviewing court on judicial review to consider new evidence. Thus, the affidavits were deemed to not aid the Court in assessing the reasonableness of the decision and not permitted as evidence.

It was reasonable to conclude that SPRAVATO is not an "innovative drug"

Janssen argued that the implementation of CUSMA changed the language for conferring data protection. Under NAFTA, the language was "utilize new chemical entities", while CUSMA introduced the language of drugs that "do not contain a chemical entity that has been previously approved". Even though the definition of innovative drug was not amended in the *Regulations*, Janssen alleged this changed language in CUSMA changed the meaning of "innovative drug" to include enantiomers.

Janssen further argued the *Regulations* must be interpreted to be wholly consistent with CUSMA. The Court pointed out that a treaty is only binding on Canadian law if the legislature gives the treaty provisions effect through domestic legislation. While treaties are relevant to the context of a statute, ultimately the domestic legislation governs. A treaty cannot be used to support an interpretation that is not consistent with the legislation. Here, the legislation specifically excluded enantiomers from the definition of an innovative drug and thus CUSMA cannot be used for a contrary interpretation.

The Court also confirmed that Canada had some leeway in implementing the provisions of CUSMA. CUSMA was not implemented without qualification. C.08.004.1(2) of the *Regulations* specifically states that this section is to implement Articles 20.48 and 20.49 of CUSMA, and paragraph 39 of TRIPS. The Statement of Implementation indicated that Article 20.48 did not require changes to Canada's regime for the protection of test or other data, and that the protection under CUSMA is similar to that of NAFTA. Moreover, the language of "chemical entity", relied on by Janssen was not defined in the treaty, and thus the interpretation of "chemical entity" to exclude enantiomers of previously approved drugs was appropriate. As such, the Court deemed it was reasonable to conclude SPRAVATO was not an innovative drug.

Data protection is assessed at the time of NOC issuance

Janssen sought a retroactive declaration of SPRAVATO as an innovative drug. However, this would be inconsistent with the language of the *Regulations* for the six-year no-filing period and eight-year no-marketing period, which begins the day the NOC is issued. The NOC for SPRAVATO was issued May 20, 2020, which also serves as the date for data protection eligibility. This language is also consistent with CUSMA, which provides protection from the date of marketing approval.

To reassess SPRAVATO as an "innovative drug" from the implementation of CUSMA (July 1, 2020) would be inconsistent with the legislation. This would generate different dates for the NOC and for the period of data protection (May 20, 2020, and July 1, 2020, respectively). Moreover, it was not disputed that SPRAVATO was not an "innovative drug" when the NOC was issued pre-CUSMA. To reassess SPRAVATO and come to the contrary conclusion would create a regulatory anomaly, as from May 20, 2020 to July 1, 2020, SPRAVATO was clearly not an innovative drug. Thus, the Court held it was reasonable to refuse Janssen's request for reconsideration.

Conclusion

The dismissal of Janssen's application for judicial review serves as a reminder that the language of the legislature is paramount. Treaties, while useful for statutory interpretation must come second to legislative intent. As in this case, it is the implementation of international obligations that ultimately matters. The deliberate choice of the legislature to exclude enantiomers from data protection cannot be overridden by treaties and their implementation in foreign jurisdictions. While excluding enantiomers creates an uphill battle for Janssen and other innovators, the battlefield is not judicial review but the legislation itself.