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March 25, 2022

Data-Protection Déjà Vu All Over Again

For the second time in less than a year, Justice St. Louis of the Federal Court has set aside the issuance of a Notice of Compliance ("NOC") to an innovator drug company and remitted the matter to the Minister of Health ("Minister") for what will be a third determination in *Catalyst Pharmaceuticals, Inc v Médunik Canada* ("*Catalyst 2022*").

In *Catalyst 2022*, as in the earlier decision ("*Catalyst 2021*"), the central question was whether the Minister's decision to issue an NOC was based on a reasonable interpretation of the data protection provisions of the *Food and Drug Regulations* ("*Regulations*"). In *Catalyst 2021*, the question could not be answered due to a lack of reasons; in *Catalyst 2022*, the Court's answer was "no". Although the facts of the case are complex, one thing is clear: the drug submissions of innovators and generics alike may be subject to the strictures of the data protection regime.

Background

In November 2019, Catalyst Pharmaceuticals, Inc. ("Catalyst") filed a new drug submission ("NDS") with Health Canada, seeking approval for its amifampridine phosphate product, marketed as FIRDAPSE. In December 2019, Médunik Canada ("Médunik") filed an NDS seeking approval for a closely related product, containing amifampridine free base and marketed as RUZURGI. Both innovator companies sought approval to market their products for the treatment of an ultra-rare disease (Lambert-Eaton myasthenic syndrome, or LEMS).

No drug containing amifampridine had been approved in Canada and no treatment for LEMS was commercially available. As such, both submissions were granted priority review status, and both companies were advised that their proposed products appeared to be "innovative" drugs and eligible for data protection.

Under the data protection provisions in section C.08.004.1 of the *Regulations*, an "innovative" drug" is one that contains a medicinal ingredient not previously approved in a drug by the Minister. Where an innovative drug has been designated and listed on Health Canada's Register of Innovative Drugs ("Register"), the innovator who received the NOC for that drug

will, under specified circumstances, obtain the benefit of a data-protection period. In particular, subsection C.08.004.1(3) of the *Regulations* states that if a manufacturer seeks an NOC for a new drug "on the basis of a direct or indirect comparison between the new drug and an innovative drug", then:

- the manufacturer may not file a submission (whether an NDS, and ANDS or a supplement thereto) in respect of the new drug for a period of 6 years after the first NOC was issued to the innovator in respect of the innovative drug (as set out in paragraph C.08.004.1(3)(a) of the *Regulations*); and
- the Minister "shall not approve that submission … and shall not issue an NOC in respect of the new drug" for a period of 8 years after the first NOC was issued to the innovator in respect of the innovative drug (as set out in paragraph C.08.004.1(3)(b)).

Catalyst's NDS contained clinical data regarding efficacy, as well as the results of non-clinical studies evaluating carcinogenicity and toxicity ("CT studies") of FIRDAPSE. The CT studies, which had been submitted previously to the US FDA for the purpose of obtaining approval in that country, were publicly available in the 2018 FDA-approved prescribing information.

Catalyst received its NOC on July 31, 2020. Its product was recognized as an innovative drug, listed on the Register, and granted data protection under the *Regulations*.

As of the date of Catalyst's NOC, Health Canada's review of Médunik's NDS was ongoing. While Médunik's NDS included efficacy data, Médunik had not yet conducted its own CT studies. It included, in its Product Monograph, references to the publicly available CT studies of FIRDAPSE.

Health Canada determined that Médunik's NDS was not subject to the approval prohibition in paragraph C.08.004.1(3)(b) of the *Regulations* because the FIRDAPSE references were included in Médunik's NDS before FIRDAPSE itself had been approved and designated as an innovative drug. There being no innovative drug to which RUZURGI could have been compared at the filing date of Médunik's NDS, Médunik could not have sought approval on the basis of a comparison. Health Canada also determined that the references had not been included for the purpose of seeking approval by way of a comparison with FIRDAPSE in any event.

Médunik received its NOC on August 10, 2020. Given the prior approval of FIRDAPSE, Médunik was advised that its product

was not an innovative drug and not eligible for data protection.

Analysis

Catalyst and Kye argued that if, at approval of an NDS, there is an innovative drug on the Register, and that NDS relies on data relating to the innovative drug, then paragraph C.08.004.1(3)(b) of the *Regulations* applies to prohibit the Minister from issuing an NOC for the new drug. Additionally, they argued that the data relied upon need not be limited to the confidential safety and efficacy data filed by the manufacturer of the innovative drug. Rather, reliance on any data generated for regulatory approval, including publicly available data, should trigger the application of the data protection provisions. The Court agreed.

- **Timing:** According to Justice St. Louis, the Minister's interpretation of the meaning and operation of subsection C.08.004.1(3) was perverse. There was no basis in the language of that subsection to limit the assessment of whether a comparison to an innovative drug was being made to the time Médunik's NDS was filed. Instead, the subsection permits the "comparison" assessment to be made at any time up to the NDS's approval, whether or not an innovative drug was on the Register at the time of filing.
- **Innovator-to-innovator "reliance":** The Court rejected the Minister's view that data protection is not intended to protect an innovator from the competing drugs of other innovators. On the contrary, comparisons made by innovators are equally subject to those provisions.

The Court also found there was some evidence that Médunik had relied on the FIRDAPSE studies in seeking approval of its NDS, and held that the Minister erred in failing to take account of it. The Court pointed in this regard to statements by Médunik to Health Canada that the safe and effective use of its drug was supported by extensive clinical experience and "available nonclinical data" (i.e., the FIRDAPSE CT studies).

Commentary

The facts of this case are unusual: two innovators independently filed NDSs for closely related drugs, and one referred in its submission to publicly available studies about the other's product. Nevertheless, the Court's interpretation as to the timing and the scope of data protection signals that innovators should be cautious when referring?—or being asked by Health Canada to refer?—to the safety or efficacy of related drugs in their NDSs or supplementary filings. Including such references runs a risk, albeit low, that issuance of an NOC could be

blocked until expiry of the eight-year data protection period.

The key takeaways from this decision are that (i) an NDS may be deemed to have been made on the basis of a comparison at any time up to its approval, regardless of whether an innovative drug was on the Register at time the NDS was filed; and (ii) the threshold for “reliance” on data relating to the innovative drug (and hence what amounts to a “comparison”) is ostensibly low.

In the latter regard, for example, a generic manufacturer seeks approval of its submission on the basis of a comparison to the innovative drug’s entire safety and efficacy data file, whereas Médunik’s reference to published CT studies only in its Product Monograph seems to be reliance of a lesser order.

Conclusion

Practically, this decision raises some uncertainty for innovators in similar situations because the existence of another manufacturer’s pending submission for the same or a related drug cannot—due to the confidentiality of submissions—be known unless and until it is approved. Innovators who refer to safety or efficacy information of a related product may be surprised to find the data protection prohibitions being applied to their submissions, should an earlier-filed or intervening submission for the same or a closely related drug be approved first and designated an innovative drug.

Until greater clarity is provided by the Minister and or the courts, pharmaceutical companies not intending to seek approval for their drug submissions on the basis of a comparison should avoid, to the extent possible, referencing the safety and/or efficacy data of any related drug.