Canadian Patents: Federal Court confirms that the PM(NOC) Regulations provide a patent enforcement mechanism only in relation to products that are in fact available to Canadians

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In a recent Federal Court decision, Justice Fothergill dismissed AbbVie's applications for judicial review of the following decisions of the Minister of Health (the "Minister"):

that JAMP was not a "second person" for the purposes of s 5(1) of the *PM(NOC) Regulations*; and

to issue NOCs to JAMP for its SIMLANDI Presentations.

Background

AbbVie's drug HUMIRA first received approval in Canada in 2004 as a 50 mg/mL concentration of adalimumab. HUMIRA is widely used to treat numerous medical conditions including rheumatoid arthritis, adult and pediatric Crohn's disease, and psoriasis.

In 2016, high-concentration (100 mg/mL) HUMIRA was approved in Canada in a 40 mg/0.4 mL pre-filled syringe (DIN 02458349), and as a 40 mg/0.4 mL pre-filled auto-injector pen (DIN 02458357).

In fact, AbbVie has marketing authorization in Canada for a variety of concentrations, but is actively selling only: the original (lower) 50 mg/mL concentration in 40 mg/0.8 mL strengths in both auto-injector pen and pre-filled syringe presentations, and the newer (higher) 100 mg/mL concentration in a 20 mg/0.2 mL pre-filled syringe.

In December 2020 or January 2021, JAMP sought regulatory approval in Canada for its SIMLANDI drug, a "biosimilar" of AbbVie's HUMIRA, in some of the strengths not actively sold by AbbVie (i.e., a 40 mg/0.4 mL pre-filled syringe, a 40 mg/0.4 mL auto-injector pen, and an 80 mg/0.8 mL pre-filled syringe). In its NDS, JAMP relied on three HUMIRA drug products having the same exact dosage

forms, strengths, and routes of administration as the drugs to be marketed as SIMLANDI. None of these formulations of HUMIRA was marketed in Canada by AbbVie at the time JAMP submitted its NDS. Hereinafter, these drugs (DINs 02458349, 02458357, and 02466872) are referred to as the "referenced HUMIRA products".

In its correspondence with Health Canada's Office of Submissions and Intellectual Property ("OSIP"), and after being told that their NDS was incomplete, JAMP submitted Form Vs on a "without prejudice" basis, yet took the position that it was not required to comply with s 5(1) of the *PM(NOC) Regulations,* as they were not a "second person" as defined therein because the referenced HUMIRA products had not been marketed in Canada for several years and therefore they were not drugs "marketed in Canada" as required by s 5(1).

5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, ***another drug marketed in Canada*** *under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the submission the required statements or allegations set out in subsection (2.1).* [Emphasis ours]

Health Canada's Office of Patented Medicines and Liaison ("OPML") later advised AbbVie of its preliminary view that the referenced HUMIRA products were indeed not currently being marketed in Canada. Therefore, the referenced HUMIRA products did not trigger s 5(1) of the *PM(NOC) Regulations*.

However, AbbVie argued that JAMP nevertheless made reference to a drug product they marketed in Canada, thus falling within s 5(1) of the *PM(NOC) Regulations*. Namely, AbbVie argued that JAMP SIMLANDI indirectly made reference to their HUMIRA 20 mg/0.2 mL pre-filled syringe because both products had the same drug concentration (i.e., 100 mg/mL).

Hence, the issue was to determine whether a second person seeking approval for a drug with a specific dosage strength could be considered to indirectly refer to a "drug marketed in Canada" with another dosage strength but having the same concentration.

The Minister's Decision

After reviewing submissions from both parties, the OPML issued its final decision on December 23, 2021, in which it confirmed its preliminary determination that JAMP was not a second person for the purposes of s 5(1) of the *PM(NOC) Regulations*, and the corresponding obligations did not arise unless the second person's NDS "directly or indirectly compares the drug with, or reference" to "another drug marketed in Canada".

The OPML found that "another drug marketed in Canada" must be interpreted to be specific with respect to strength, dosage form, and route of administration (i.e., it is DIN-specific)." The Minister found that the "indirect" comparison of s 5(1) did not expand the scope of the drugs for which a second person must address the patents listed on the Patent Register beyond the DIN-specific "another drug". Hence, the HUMIRA 20 mg/0.2 mL pre-filled syringe marketed by AbbVie was not a proper reference product for JAMP's 40 mg/0.4 mL pre-filled syringe, 40 mg/0.4 mL auto-injector pen, and 80 mg/0.8 mL pre-filled syringe.

Accordingly, on January 5, 2022, the Minister issued NOCs to JAMP and JAMP launched its products on April 13, 2022.

Subsequently, AbbVie sought judicial review of these two related decisions of the Minister, the result of which is the presently-discussed Federal Court decision.

Ultimately, the Federal Court agreed with the Minister. Specifically, the Federal Court concluded that *inter alia* the following findings by the Minister were reasonable:

that the term “another drug” in s 5(1) of the *PM(NOC) Regulations* is confined to the drug products identified by Health Canada, and that these products must have an identical dosage form, strength, and route of administration to the drug product of the second person.
that s 5(1) of the *PM(NOC) Regulations* applies only where a second person files a submission for an NOC that (1) directly or indirectly compares its drug, or makes reference to “another drug”, (2) that other drug is marketed in Canada under an NOC issued to a first person, and (3) that other drug is a drug in respect of which the first person has submitted a patent list;
that a drug that is not marketed is not eligible for the protections under the *PM(NOC) Regulations*; and
that JAMP was not a second person under s 5(1) for the simple reason that AbbVie was not marketing in Canada the HUMIRA drugs that JAMP relied on for its NDS.

Conclusion

The Minister's decisions, as well as the Federal Court's finding that they were reasonable (pending any appeal), emphasizes one of the statutory objectives of the *PM(NOC) Regulations*, namely to provide a patent enforcement mechanism only in relation to products that are in fact available to Canadians. This also clarifies certain practical effects of this statutory objective, namely that the enforcement mechanism of the *PM(NOC) Regulations* is only available to an innovator that markets its innovative drug in Canada, and that s 5(1) of the *PM(NOC) Regulations* applies only to reference drug products that are identical down to a DIN-specific level with the drug to be approved.

However, this does not mean that innovators are entirely without recourse when it comes to drugs they are not marketing in Canada. Under such circumstances, while innovators may not be able to utilize the *PMNOC Regulations* to prevent a NOC from being issued to a competitor, it can nonetheless commence normal patent infringement proceedings in Federal Court.

A copy of this decision, *AbbVie Corporation v. Canada (Health)*, 2022 FC 1209, is available here.

Our intellectual property team would be happy to help you with any questions you may have regarding the *PM(NOC) Regulations*.