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T-10-22

T-130-22

2022 FC 1209

AbbVie Corporation and **AbbVie Biotechnology Ltd** (*Applicants*)

v.

The Minister of Health and **JAMP Pharma Corporation** (*Respondents*)

INDEXED AS: ABBVIE CORPORATION V. CANADA (HEALTH)

Federal Court, Fothergill J.—By videoconference, May 16–17; Ottawa, August 17, 2022.

Patents — Applications for judicial review of two related decisions by respondent Minister of Health (Minister) made pursuant to Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) under Patent Act — Applications concerning: Minister's determination that respondent JAMP Pharma Corporation (JAMP) not a "second person" for purposes of PM(NOC) Regulations, s. 5(1) in respect of its new drug submission (NDS); Minister's decision to issue notice of compliance (NOC) to JAMP permitting it to market three drugs in Canada under brand name SIMLANDI — SIMLANDI "biosimilar" of applicants' HUMIRA — To prevent abuse, subsequent entry manufacturer or "second person" must meet conditions prescribed by s. 5(1) — Second person must file "Form V" in manner approved by Health Canada's Office of Patented Medicines and Liaison (OPML) — HUMIRA assigned single drug identification number (DIN) — Health Canada's Office of Submissions and Intellectual Property (OSIP) initially considered JAMP's NDS incomplete for not including Form V declaration in respect of patents on Patent Register for three HUMIRA drugs — JAMP submitted Form Vs on "without prejudice" basis to avoid delay — Took position that it was not required to comply with s. 5(1) — OPML of opinion that drugs referred to in s. 5(1) must be DIN-specific, restricted to reference biologic drugs (RBDs) identified by Biologic and Radiopharmaceutical Drugs Directorate (BRDD) — OPML confirmed JAMP not second person for purposes of PM(NOC)Regulation, s. 5(1), corresponding obligations therein not arising unless NDS directly or indirectly compared drug to another drug — Found that "another drug" must be interpreted to be CRP (Canadian Reference Product) or RBD, specific with respect to strength, dosage form, route of administration (i.e. DIN-specific) — Determined that "another drug" for purposes of s. 5(1) consisting exclusively of RBDs identified by BRDD — OPML concluded that JAMP not second person pursuant to s. 5(1) — Minister issued NOCs to JAMP for its SIMLANDI pre-filled syringe, auto-injector pen, pre-filled syringe presentations — Applicants noted that text of s. 5(1) not defining "another drug", or limiting it to DIN-specific presentation — Stated that text of s. 5(1) broader, intended to capture all manner of comparison to drug approved for marketing in Canada — Noting that Minister's guidance document requiring active substances or medicinal ingredients of biosimilar, RBD to be similar, not identical — Whether reasonable for Minister to determine that JAMP not "second person" for purposes of PM(NOC) Regulations, s. 5(1) — Whether reasonable for

Minister to issue NOCs to JAMP for its SIMLANDI presentations — Minister's interpretation of s. 5(1) as applying only to DIN-specific version of drug marketed in Canada reasonable — No basis upon which Minister could have expanded RBDs to encompass presentations of HUMIRA beyond those identified by BRDD — BRDD clear that it was responding to inquiry "as to what is the reference biologic drug" for JAMP presentations — Drug that is not marketed not eligible for protections under PM(NOC) Regulations, given explicit marketing requirement under s. 5(1) — Marketing condition ensuring that advantages of PM(NOC) Regulations not conferred on patent holders whose products not available to consumers — General policy behind marketing condition is that patent holder who obtains NOC, but does not use it, should not be entitled to rely on that NOC to obtain collateral advantages because of PM(NOC) Regulations — This supporting narrow interpretation of s. 5(1) — Minister's decision falling within range of acceptable outcomes defensible in respect of facts, law — Minister not precluded from recognizing functional equivalence between RBDs, CRPs — Minister's guidance document stating that dosage form, strength, routes of administration of biosimilar "should be the same" as RBD — Even if term "should" discretionary rather than mandatory, Minister could not be faulted for following recommendation contained in his own guidance document — Enforcement mechanism of PM(NOC) Regulations only available to innovator that markets its innovative drug in Canada — PM(NOC) Regulations, ss. 4, 5 reciprocal in nature — Applicants did not demonstrate that Minister's decision to treat RBDs, CRPs as performing "equivalent role" unreasonable — Here, BRDD able to identify biologic drugs authorized in Canada having same dosage forms, strengths, routes of administration, active ingredient as JAMP presentations — No need for flexibility on part of Minister in selecting RBDs — Applicants' alternative interpretation fell short of demonstrating that Minister's application of guidance document outside range of acceptable, defensible outcomes — Minister having great expertise in PM(NOC) Regulations' application, interpretation — Minister's decision to issue NOC to JAMP reasonable — Applications dismissed.

These were applications for judicial review of two related decisions of the respondent Minister of Health (Minister) made pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (*PM(NOC) Regulations*) under the *Patent Act*.

The first application (Court File No. T-10-22) concerned the Minister's determination that respondent JAMP Pharma Corporation (JAMP) is not a "second person" for the purposes of subsection 5(1) of the PM(NOC) Regulations in respect of its new drug submission (NDS). The second application (Court File No. T-130-22) concerned the Minister's decision to issue a notice of compliance (NOC) to JAMP permitting it to market three drugs in Canada under the brand name SIMLANDI. SIMLANDI is a "biosimilar" of the applicants' HUMIRA, a biologic, injectable drug that first received approval in Canada in 2004 as a 50 mg/mL concentration of adalimumab. HUMIRA is used to treat numerous medical conditions including rheumatoid arthritis, adult and pediatric Crohn's disease, and psoriasis. Pursuant to subsection 55.2(1) of the *Patent Act*, subsequent entry drug manufacturers are eligible for an "early work" exception that allows manufacturers such as JAMP to make, construct, use or sell a patented drug solely for the purpose of developing and seeking approval of a competitor drug, without risking patent infringement. To prevent abuse, a subsequent entry manufacturer or "second person" must meet the conditions prescribed by subsection 5(1). Subsection 5(2.1) of the PM(NOC) Regulations requires a second person to include statements or allegations with respect to each of the listed patents. To comply with these requirements, a second person must file a "Form V" in the manner approved by Health Canada's Office of Patented Medicines and Liaison (OPML) that must include information about the second person's NDS, the drug it is being compared to, and the required statements and allegations found in subsection 5(2.1) of the PM(NOC) Regulations. Even though HUMIRA was available in a vial, a syringe and an auto-injecting pen, it was assigned a single drug identification number (DIN). Health Canada's Office of Submissions and Intellectual Property (OSIP) initially considered JAMP's NDS to be incomplete because it did not include a Form V declaration in respect of the patents on the Patent Register for three HUMIRA drugs. When JAMP provided three sets of Form Vs for SIMLANDI, the OSIP considered the NDS administratively complete, and assigned it a filing date of January 7, 2021. JAMP clarified that it had submitted the Form Vs on a "without prejudice" basis to avoid delay. JAMP took the position that it was not required to comply with subsection 5(1). The OPML opined that the drugs referred to in subsection 5(1) must be DIN-specific, and were restricted to the reference biologic drugs (RBDs) identified by the Biologic and Radiopharmaceutical Drugs Directorate

(BRDD). The OPML confirmed its preliminary determination that JAMP was not a second person for the purposes of subsection 5(1) of the PM(NOC) Regulations, and the corresponding obligations did not arise unless the NDS "directly or indirectly compares the drug with, or … reference" to "another drug".The OPML found that "another drug" must be interpreted to be "the CRP [Canadian Reference Product] or RBD (as the case may be), and is specific with respect to strength, dosage form, and route of administration (i.e. it is DIN-specific)." The OPML determined that "another drug" for the purposes of subsection 5(1) consists exclusively of the RBDs identified by the BRDD. At the time JAMP filed its NDS, the RBDs were not marketed in Canada. The OPML therefore concluded that JAMP was not a second person pursuant to subsection 5(1). In 2022, the Minister issued NOCs to JAMP for its SIMLANDI 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 presentations. The applicants took issue with the Minister's interpretation of the term "another drug". The applicants noted that the text of subsection 5(1) does not define "another drug", or limit it to a DIN-specific presentation. The applicants stated that the text of subsection 5(1) is broader, and is intended to capture all manner of comparison to a drug that is approved for marketing in Canada by way of NOC, whether "direct", "indirect"; or even by way of "reference" where the first person's NOC is one in respect of which a patent list has been filed. The applicants noted that the Minister's guidance document requires the active substances or medicinal ingredients of the biosimilar and RBD to be similar, not identical.

The main issues were whether it was reasonable for the Minister to determine that JAMP was not a "second person" for the purposes of s. 5(1) of the PM(NOC) Regulations, and whether it was reasonable for the Minister to issue NOCs to JAMP for its SIMLANDI presentations.

Held, the applications should be dismissed.

The Minister's interpretation of subsection 5(1) as applying only to a DIN-specific version of a drug that is marketed in Canada was reasonable, particularly considering the statutory objective of providing a patent enforcement mechanism only in relation to products that are in fact available to Canadians. The BRDD identified only three RBDs for the JAMP presentations. There was no basis upon which the Minister could have expanded the RBDs to encompass presentations of HUMIRA beyond those identified by the BRDD. The identification of RBDs is a role performed on behalf of the Minister exclusively by the BRDD. The BRDD was clear in its correspondence that it was responding to an inquiry "as to what is the reference biologic drug" for the JAMP Presentations. The BRDD confirmed that "the dosage form(s), strength(s), and route(s) of administration of SIMLANDI should be the same as that of the reference biologic drug". The Minister concluded that a drug that is not marketed is not eligible for the protections under the PM(NOC) Regulations, given the explicit marketing requirement under subsection 5(1). The marketing condition is included to ensure that the advantages of the PM(NOC) Regulations are not conferred on patent holders whose products are, for whatever reason, not generally available to consumers. The general policy behind the marketing condition is that a patent holder who obtains a NOC, but does not use it, should not be entitled to rely on that NOC to obtain collateral advantages because of the PM(NOC) Regulations. This tends to support a narrow interpretation of subsection 5(1). The applicants' various arguments in opposition to the Minister's interpretation of subsection 5(1) of the PM(NOC) Regulations were comprehensively addressed in the Minister's decision. The Minister's reasons allowed the Court to understand why the decision was made, and to conclude that it fell within the range of acceptable outcomes defensible in respect of the facts and law. The RBD for a biosimilar does not share the legislated requirements applicable to CRPs for generic small-molecules. Unlike the RBD for a biosimilar, the CRP for a generic drug is required by the *Food and Drug Regulations* to "contain identical amounts of the identical medicinal ingredients, in a comparable dosage form". However, this does not preclude the Minister from recognizing a functional equivalence between RBDs and CRPs. According to the Minister's guidance document, dosage form, strength and routes of administration of a biosimilar "should be the same" as the RBD. Even if "should" is understood to be discretionary rather than mandatory, the Minister could not be faulted for following the recommendation contained in his own guidance document. The enforcement mechanism of the PM(NOC) Regulations is only available to an innovator that markets its innovative drug in Canada. Patent listing under subsection 4(1) of the PM(NOC) Regulations is DIN-specific. This matters, because sections 4 and 5 are reciprocal in nature: section 4 establishes the patent list a second

person must circumnavigate. The applicants did not demonstrate that the Minister's decision to treat RBDs and CRPs as performing an "equivalent role" was unreasonable. Biosimilars are "subject to existing laws and regulations outlined in the [PM(NOC) Regulations] and [section] C.08.004.1 of the *Food and Drug Regulations*". In this case, the BRDD was able to identify biologic drugs that were authorized in Canada that had the same dosage forms, strengths and routes of administration and active ingredient as the JAMP presentations. There was no need for flexibility on the part of the Minister in selecting the RBDs. The applicants' alternative interpretation fell short of demonstrating that the Minister's application of the guidance document was outside the range of acceptable, defensible outcomes. The PM(NOC) Regulations are closely connected with the Minister's functions, and the Minister has great expertise in their application and interpretation. This was apparent in the lengthy and careful reasoning of the Minister in the decisions challenged in this proceeding. The Minister's decision to issue a NOC to JAMP on the basis that JAMP was not a "second person" for the purposes of subsection 5(1) was reasonable.

STATUTES AND REGULATIONS CITED

Food and Drug Regulations, C.R.C., c. 870, s. C.08.001.1, "pharmaceutical equivalent".

Patent Act, R.S.C., 1985, c. P-4, s. 55.2(1).

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 4, 5, 6(1), 7(1).

TREATIES AND OTHER INSTRUMENTS CITED

Protocol replacing the North American Free Trade Agreement with the Agreement between Canada, the United States of America, and the United Mexican States, July 1, 2020, [2020] Can. T.S. No. 5, Art. 20.50, as amended by the *Protocol of Amendment to the Agreement between Canada, the United States of America, and the United Mexican States*, [2020] Can. T.S. No. 6, Art. 3F.

CASES CITED

APPLIED:

Canada (Minister of Citizenship and Immigration) v. Vavilov, 2019 SCC 65, [2019] 4 S.C.R. 653; *Teva Canada Limited v. Pfizer Canada Inc.*, 2016 FCA 248, [2017] 3 F.C.R. 80.

CONSIDERED:

Rogers Communications Inc. v. Society of Composers, Authors and Music Publishers of Canada, 2012 SCC 35, [2012] 2 S.C.R. 283; *Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30; *Natco Pharma (Canada) Inc. v. Canada (Health)*, 2020 FC 788, [2021] 1 F.C.R. D-2; *Elanco v. Canada (Attorney General)*, 2019 FC 5.

REFERRED TO:

Fresenius Kabi Canada Ltd. v. Canada (Health), 2020 FC 1013, [2021] 1 F.C.R. D-12; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533; *Astrazeneca Canada Inc. v. Canada (Minister of Health)*, 2005 FCA 189, [2006] 1 F.C.R. 297, revd 2006 SCC 49, [2006] 2 S.C.R. 560.

AUTHORS CITED

Health Canada. Guidance Document. *Information and Submission Requirements for Biosimilar Biologic Drugs*, Ottawa: Minister of Health, 2010.

APPLICATIONS for judicial review of two related decisions by the respondent Minister of Health

made pursuant to the *Patented Medicines (Notice of Compliance) Regulations* under the *Patent Act*. Applications dismissed.

APPEARANCES

Steven G. Mason, *David Tait*, *James S.S. Holtom* and *Adam H. Kanji* for applicants.

J. Sanderson Graham, *Elizabeth Koudys* and *Kirk Shannon* for respondent Minister of Health.

Andrew Brodkin, *Jordan Scopa* and *Jaclyn Tilak* for respondent JAMP Pharma Corporation.

SOLICITORS OF RECORD

McCarthy Tétrault LLP, Toronto, for applicants.

Deputy Attorney General of Canada for respondent Minister of Health.

Goodmans LLP, Toronto, for respondent JAMP Pharma Corporation.

The following are the reasons for judgment and judgment rendered in English by

FOTHERGILL J.:

I. Overview

[1] AbbVie Corporation and AbbVie Biotechnology Ltd. (collectively AbbVie) seek judicial review of two related decisions of the Minister of Health (Minister) made pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (PM(NOC) Regulations) under the *Patent Act*, R.S.C., 1985, c. P-4.

[2] The first application (Court File No. T-10-22) concerns the Minister's determination that JAMP Pharma Corporation (JAMP) is not a "second person" for the purposes of subsection 5(1) of the PM(NOC) Regulations in respect of its new drug submission (NDS) 244990. The second application (Court File No. T-130-22) concerns the Minister's decision to issue a notice of compliance (NOC) to JAMP permitting it to market three drugs in Canada under the brand name SIMLANDI.

[3] JAMP's SIMLANDI is a "biosimilar" of AbbVie's HUMIRA (adalimumab). In its NDS, JAMP relied on three HUMIRA drugs with the same 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.

[4] The PM(NOC) Regulations are closely connected with the Minister's functions, and the Minister has great expertise in their application and interpretation. The Minister's interpretation of subsection 5(1) of the PM(NOC) Regulations as applying only to a version of a drug that has a specific drug identification number (DIN) and that is marketed in Canada was reasonable, particularly considering the statutory objective of providing a patent enforcement mechanism only in relation to products that are in fact available to Canadians.

[5] The applications for judicial review are therefore dismissed.

II. Background

A. *PM(NOC) Regulations*

[6] The PM(NOC) Regulations seek to align the drug approval process of a subsequent entry or generic drug under the *Food and Drug Regulations*, C.R.C., c. 870, with certain patent rights pertaining to the first or innovative drug. Specifically, the PM(NOC) Regulations seek to balance the patent rights associated with innovative drugs against the timely market entry of lower-priced competitor drugs (*Fresenius Kabi Canada Ltd. v. Canada (Health)*, 2020 FC 1013, [2021] 1 F.C.R. D-12, at paragraph 13).

[7] The PM(NOC) Regulations require the Minister to maintain a Patent Register on which innovative drugs such as HUMIRA are listed, together with any associated patents. Once a patent is placed on the Patent Register, a subsequent-entry manufacturer must either await the expiry of the patent or address the listed patent in accordance with the prescribed process.

[8] Pursuant to subsection 55.2(1) of the *Patent Act*, subsequent entry drug manufacturers are eligible for an "early work" exception that allows manufacturers such as JAMP to make, construct, use or sell a patented drug solely for the purpose of developing and seeking approval of a competitor drug, without risking patent infringement.

[9] To prevent abuse, a subsequent entry manufacturer or "second person" must meet the conditions prescribed by subsection 5(1) of the PM(NOC) Regulations. Under this provision, the reference drug for the proposed generic or biosimilar must be one that is "marketed" in Canada:

> **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).

[10] Subsection 5(2.1) of the PM(NOC) Regulations requires a second person to include statements or allegations with respect to each of the listed patents. The statements may include confirmation of consent from the owner of the patent, or confirmation that the second person understands the NOC will not be issued until the patent expires.

[11] Alternatively, the second person may make one or more of the following allegations:

> **(i)** the statement made by the first person under paragraph 4(4)(d) is false,
>
> **(ii)** that patent or certificate of supplementary protection is invalid or void,
>
> **(iii)** that patent or certificate of supplementary protection is ineligible for inclusion on the register,

> **(iv)** that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed,
>
> **(v)** that patent or certificate of supplementary protection has expired, or
>
> **(vi)** in the case of a certificate of supplementary protection, that certificate of supplementary protection cannot take effect.

[12] To comply with these requirements, a second person must file a "Form V" in the manner approved by Health Canada's Office of Patented Medicines and Liaison (OPML). The form must include information about the second person's NDS, the drug it is being compared to, and the required statements and allegations found in subsection 5(2.1) of the PM(NOC) Regulations.

[13] If an allegation is made under subsection 5(2.1), then subsection 5(3) of the PM(NOC) Regulations requires the second person to serve a Notice of Allegation (NOA) on the first person. The first person then has 45 days to bring an action in this Court pursuant to subsection 6(1):

> **6 (1)** The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

[14] Once an action under subsection 6(1) has been commenced, subsection 7(1)(d) of the PM(NOC) Regulations prohibits the Minister from issuing an NOC to the second person until 24 months after the issuance of the statement of claim or until the action is dismissed. The Court may shorten or extend the 24-month period if it finds a party has not acted diligently in carrying out its obligations under the PM(NOC) Regulations or has not reasonably cooperated in expediting the action, so long as the Court has not made a declaration referred to subsection 6(1).

B. *HUMIRA (AbbVie)*

[15] HUMIRA is a biologic, injectable drug that 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.

[16] When HUMIRA was approved in 2004, the sole approved presentations were a 40 mg/0.8 mL vial and a 40 mg/0.8 mL single-use pre-filled syringe. The sole approved use was for rheumatoid arthritis. Even though HUMIRA was available in a vial, a syringe and an auto-injecting pen, it was assigned a single DIN (DIN 02258595).

[17] High-concentration HUMIRA was approved in Canada in 2016 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). When AbbVie sought approval for the high-concentration presentations of HUMIRA, the Minister required each one to have a unique DIN, but did not assign any additional DINs to the three original presentations.

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

C. *SIMLANDI (JAMP)*

[19] In December 2020 or January 2021, JAMP sought regulatory approval in Canada for SIMLANDI in the 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 (collectively JAMP Presentations).

[20] Health Canada's Office of Submissions and Intellectual Property (OSIP) initially considered JAMP's NDS to be incomplete because it did not include a Form V declaration, as required by subsection 5(1) of the PM(NOC) Regulations, in respect of the patents on the Register for three HUMIRA drugs. The OSIP wrote to JAMP on December 30, 2020, to request compliance, noting that the NDS would be placed on hold until the Form Vs were received.

[21] On January 7, 2021, JAMP provided three sets of Form Vs for SIMLANDI, one for each of JAMP's three drugs listing the corresponding HUMIRA drugs as the reference products (DINs 02458349, 02458357 and 02466872). The OSIP considered the NDS administratively complete, and assigned it a filing date of January 7, 2021.

[22] In a letter to OSIP dated January 28, 2021, JAMP clarified that it had submitted the Form Vs on a "without prejudice" basis to avoid delay. JAMP took the position that it was not required to comply with subsection 5(1) of the PM(NOC) Regulations. In further correspondence dated February 19, 2021, JAMP explained that the referenced HUMIRA products had not been marketed in Canada for several years, and requested marketing information from OSIP.

[23] The same day, JAMP served NOAs on AbbVie pursuant to subsection 5(3) of the PM(NOC) Regulations, "without prejudice" to JAMP's position that it was not required to comply with section 5.

D. *The Minister's Decisions*

[24] On March 15, 2021, the OPML advised AbbVie of its preliminary view that the following HUMIRA presentations had never been marketed in Canada: 80 mg/0.8 mL pre-filled syringe (DIN 02466872); and 40 mg/0.4 mL pre-filled syringe (DIN 02458349). The OPML also expressed the preliminary view that the 40 mg/0.4 mL pen (DIN 02458357) had not been marketed in Canada since November 21, 2018. The OPML asked AbbVie to provide information or documents regarding the marketing status of the HUMIRA reference biologic drugs (RBDs) within 10 calendar days.

[25] By letter dated March 18, 2021, AbbVie requested an extension of time in which to respond, and indicated that it intended to take the position that JAMP was "early working the listed patents, as well as directly or indirectly comparing its biosimilar with, or making reference to, a drug that is marketed in Canada under an NOC".

[26] On March 29, 2021, the OPML advised JAMP and AbbVie that it was "beginning anew in order to increase the transparency of the process". The parties were given time

to prepare their submissions, and to respond to a preliminary decision of the OPML. Both parties made submissions.

[27] The OPML issued its preliminary decision on September 22, 2021, concluding that JAMP was not a second person under subsection 5(1) of the PM(NOC) Regulations. The OPML was of the opinion that the drugs referred to in subsection 5(1) of the PM(NOC) Regulations must be DIN-specific, and were restricted to the RBDs identified by the Biologic and Radiopharmaceutical Drugs Directorate (BRDD).

[28] The OPML held that any interpretation of subsection 5(1) of the PM(NOC) Regulations should not undermine the interpretation and administration of section 4. This provision permits a first person to list eligible patents on the Register by submitting a patent list in relation to its NDS. Subsection 4(4) requires that a patent list identify, among other things, the patent, drug submission, DIN, medicinal ingredient, brand name, dosage form, strength and route of administration to which the list relates.

[29] The OPML invited the parties' responses to its preliminary findings, as well as submissions on the application of subsection 7(1) of the PM(NOC) Regulations to the issuance of an NOC to JAMP for SIMLANDI. JAMP and AbbVie submitted their responses on October 29, 2021.

[30] AbbVie acknowledged that the 40 mg/0.4 mL and 80 mg/0.8 mL presentations of HUMIRA were not sold in Canada. However, it informed the OPML that the 20 mg/0.2 mL presentation, which contains high-concentration (100 mg/mL) HUMIRA in a pre-filled syringe, was sold in Canada. AbbVie noted that JAMP's NDS compared SIMLANDI to high-concentration (100 mg/mL) HUMIRA, which AbbVie continues to market and sell in Canada.

[31] AbbVie asserted that JAMP relied on the data for the original 50 mg/mL presentations of HUMIRA. JAMP responded that its regulatory submission sought approval by comparison only with AbbVie's 40 mg/0.4 mL and 80 mg/0.8 mL presentations. JAMP emphasized that it had not sought approval by comparison with AbbVie's 40 mg/0.8 mL or 20 mg/0.2mL presentations.

[32] The OPML issued its final decision on December 23, 2021. The decision comprises 36 pages of single-spaced text.

[33] The OPML confirmed its preliminary determination that JAMP was not a second person for the purposes of subsection 5(1) of the PM(NOC) Regulations, and the corresponding obligations did not arise unless the NDS "directly or indirectly compares the drug with, or … reference" to "another drug". The OPML found that "another drug" must be interpreted to be "the CRP or RBD (as the case may be), and is specific with respect to strength, dosage form, and route of administration (i.e. it is DIN-specific)." CRP refers to Canadian Reference Product, the required comparator for new generic drugs.

[34] The OPML continued:

> The "another drug" cannot be broadened to encompass any strength or dosage form of the medicinal ingredient in the CRP or RBD, and the direct or indirect comparison, or reference must be to the DIN-specific "another drug." Finally, as "another drug" is DIN-specific, the marketing requirement for "another drug" is likewise DIN-specific.

[35] The OPML determined that “another drug” for the purposes of subsection 5(1) consists exclusively of the RBDs identified by the BRDD. At the time JAMP filed its NDS, the RBDs were not marketed in Canada. The OPML therefore concluded that JAMP was not a second person pursuant to subsection 5(1) of the PM(NOC) Regulations.

[36] On January 5, 2022, the Minister issued NOCs to JAMP for its SIMLANDI 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 presentations. JAMP launched its products on April 13, 2022.

III. Issues

[37] This application for judicial review raises the following issues:

A. What is the standard of review?

B. Was the Minister’s determination that JAMP was not a “second person” for the purposes of subsection 5(1) of the PM(NOC) Regulations reasonable?

C. Was the Minister’s decision to issue NOCs to JAMP for its SIMLANDI Presentations reasonable?

IV. Analysis

A. *What is the standard of review?*

[38] AbbVie says correctness is the appropriate standard of review for the Minister’s interpretation of “another drug” under subsection 5(1) of the PM(NOC) Regulations, because “the rule of law requires consistency, and […] a final and determinate answer is necessary” (citing *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 (*Vavilov*), at paragraph 53). AbbVie also asserts correctness is the applicable standard of review where both the executive and judicial branches of government have concurrent first-instance jurisdiction over a question of legislative interpretation.

[39] In *Rogers Communications Inc. v. Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35, [2012] 2 S.C.R. 283 (*Rogers*), the Supreme Court of Canada held that it would be inconsistent for the court to review a legal question on judicial review on a deferential standard and decide exactly the same legal question *de novo* if it arose in an infringement action in the court at first instance (at paragraphs 13–14).

[40] On July 15, 2022, after the parties had presented their arguments in this proceeding, the Supreme Court of Canada issued its decision in *Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30. In that ruling, a majority of the Supreme Court (*per* Rowe J.A.) confirmed that concurrent first instance jurisdiction should be recognized as a further category of correctness: when courts and administrative bodies have concurrent first instance jurisdiction over a legal issue in a statute, applying the standard of correctness review to the issue accords with legislative intent and promotes the rule of law (at paragraph 28).

[41] AbbVie says this rationale applies to the scheme of the PM(NOC) Regulations. Because subsection 6(1) confers upon the Court jurisdiction to hear an action, AbbVie says this Court and the Minister have concurrent jurisdiction to determine whether an entity is a "second person" for the purposes of subsection 5(1). I disagree.

[42] In *Teva Canada Limited v. Pfizer Canada Inc.*, 2016 FCA 248, [2017] 3 F.C.R. 80 (*Teva*), the Federal Court of Appeal found that *Rogers* had no application in a case where the Minister has "exclusive jurisdiction to decide whether a drug submission filed by a second person makes a comparison with a Canadian reference product so as to require the second person to address a patent listed on the Patent Register" (at paragraph 55). As the Federal Court of Appeal explained at paragraphs 56 and 57 (*per* Dawson J.A.):

> Aside from the Court's potential role on an application for judicial review of a ministerial decision made under section 5, the [*PM(NOC) Regulations*] provide a role for the Court as a first instance decision maker only under section 6: where a first person has initiated an application for prohibition it is for the Court to determine whether the allegations contained in a second person's notice of allegation are justified. On an application for prohibition, the Court does not consider whether section 5 ought to have been triggered in the first place. It follows that in a prohibition application there is no possibility of conflicting interpretations between the Minister and the Court with respect to whether section 5 was triggered.
>
> In my view, the question of whether a drug submission triggers section 5 of the [*PM(NOC) Regulations*] is a question of mixed fact and law. It is well settled that reasonableness is the standard of review to be applied to such questions.

[43] *Teva* squarely rejects AbbVie's reading of the PM(NOC) Regulations as conferring concurrent jurisdiction on the executive and judicial branches with respect to whether subsection 5(1) of the PM(NOC) Regulations applies in a particular case. AbbVie has failed to rebut the presumption in *Vavilov* that reasonableness applies to judicial review of the administrative decisions at issue in this case.

[44] The Minister's decisions are therefore subject to review by this Court against the standard of reasonableness. The Court will intervene only if "there are sufficiently serious shortcomings in the decision such that it cannot be said to exhibit the requisite degree of justification, intelligibility and transparency" (*Vavilov*, at paragraph 100).

[45] The Court must consider both the outcome of the administrative decision and its underlying rationale (*Vavilov*, at paragraph 15). The criteria of "justification, intelligibility and transparency" are met if the reasons allow the Court to understand why the decision was made, and determine whether it falls within the range of acceptable outcomes defensible in respect of the facts and law (*Vavilov*, at paragraphs 85–86).

[46] Courts must pay respectful attention to the decision maker's reasons, acknowledging the specialized expertise of administrative decision makers, and must be cautious not to substitute their own views of the proper outcome (*Vavilov*, at paragraphs 75 and 83). When conducting reasonableness review of a decision maker's interpretation of a statute or regulation, the Court does not undertake a *de novo* analysis. Rather, courts are to assume that those who interpret the law, whether courts or administrative decision makers, will do so in a manner consistent with the modern principles of statutory interpretation (*Vavilov,* at paragraphs 116–118).

B. *Was the Minister's determination that JAMP was not a "second person" for the purposes of subsection 5(1) of the PM(NOC) Regulations reasonable?*

[47] AbbVie takes issue with the Minister's finding that the term "another drug" in subsection 5(1) of the PM(NOC) Regulations is confined to the RBDs identified by the BRDD, and that the RBDs must have an identical dosage form, strength, and route of administration. AbbVie notes that the text of subsection 5(1) does not define "another drug", or limit it to a DIN-specific presentation.

[48] AbbVie says there are numerous instances where the PM(NOC) Regulations do refer explicitly to DINs, and argues that the absence of a similarly explicit reference in subsection 5(1) is a strong signal that "another drug" for the purposes of that provision need not be DIN-specific. According to AbbVie, the text of subsection 5(1) is broader, and is intended to capture all manner of comparison to a drug that is approved for marketing in Canada by way of NOC, whether "direct", "indirect"; or even by way of "reference" where the first person's NOC is one in respect of which a patent list has been filed.

[49] The Minister maintains that subsection 5(1) of the PM(NOC) Regulations applies only where a manufacturer 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. The Minister found that JAMP was not a second person under subsection 5(1) for the simple reason that AbbVie was not marketing in Canada the HUMIRA drugs that JAMP relied on for its NDS.

[50] JAMP agrees that the Minister's analysis was reasonable, noting that patent listing under subsection 4(1) of the PM(NOC) Regulations is DIN-specific. The patent list must identify, among other things, the "medicinal ingredient, brand name, dosage form [and] strength … to which the list relates" [at subparagraph 4(4)(b)]. JAMP submits sections 4 and 5 of the PM(NOC) Regulations are reciprocal in nature, as section 4 sets up the patent list that the second person must circumnavigate (citing *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 (*Bristol-Myers*), at paragraph 61 and *Teva*, at paragraphs 82–83).

[51] According to the Minister's decision respecting JAMP's status as a second person (at paragraphs 14–16):

> The suitability of a RBD is key to the authorization of a biosimilar drug. "Reference biologic drug" (i.e. RBD) is not defined in the *Food and Drugs Act* or in the FDR, but it is defined in section 1.4 of the BRDD's Biosimilar Guidance as follows:
>
> > ***Reference biologic drug (Médicament biologique de référence)***
> >
> > A biologic drug authorized on the basis of a complete quality, non-clinical, and clinical data package, to which a biosimilar is compared to demonstrate similarity.
>
> The Biosimilar Guidance describes the requirements for the selection of a "Reference biologic drug" (i.e. RBD) at section 2.1.3 as follows:
>
> > **2.1.3 Reference biologic drug**

> A biosimilar [drug] must be subsequent to a biologic drug that is authorized in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies.
>
> The onus is on the sponsor to demonstrate that the chosen reference biologic drug is suitable to support the submission. The sponsor should consult with the [Biologic and Radiopharmaceutical Drugs Directorate] early in the drug development process to ensure the suitability of the reference biologic drug.
>
> The following should be considered when selecting a reference biologic drug:
>
> ● **The dosage form(s), strength(s), and route(s) of administration of the biosimilar [drug] should be the same as that of the reference biologic drug.**
>
> […]
>
> ● **The active substances (medicinal ingredients) of the biosimilar [drug] and the reference biologic drug must be shown to be similar.**
>
> [Emphasis added]

Therefore, the Biosimilar Guidance specifies that the dosage form(s), strength(s), and route(s) of administration of the biosimilar drug should be the same as that of the RBD, and that the active substances (medicinal ingredients) of the biosimilar drug and the RBD must be shown to be similar.

[52] The Minister noted in paragraph 18 of the decision that "[a] DIN is assigned to each drug approved to be marketed in Canada and uniquely identifies the following characteristics: brand name; manufacturer (that is, vendor and/or sponsor); medicinal ingredient(s); strength of the medicinal ingredient(s); pharmaceutical dosage form (for example, tablet or solution); and the route of administration". The Minister held that, in order to obtain approval in Canada, it was necessary for SIMLANDI to be subsequent to a biologic drug that was authorized in Canada and to which a reference was made. The dosage form(s), strength(s), and route(s) of administration of SIMLANDI should be the same as those of the RBD. Furthermore, the adalimumab contained in SIMLANDI must be shown to be similar to that of the RBD.

[53] In correspondence dated July 21, 2021, the BRDD identified the following RBDs for the JAMP Presentations:

JAMP Presentation	Reference Biologic Drug
SIMLANDI, adalimumab,40 mg in 0.4 mL sterile solution (100 mg/mL), subcutaneous injection, pre-filled syringe	HUMIRA, adalimumab, DIN 02458349, 40 mg in 0.4 mL sterile solution (100 mg/mL), subcutaneous injection, pre-filled syringe
SIMLANDI, adalimumab, 40 mg in 0.4 mL sterile solution (100 mg/mL), subcutaneous injection, autoinjector	HUMIRA, adalimumab, DIN 02458357, 40 mg in 0.4 mL sterile solution (100 mg/mL), subcutaneous injection, pre-filled pen
SIMLANDI, adalimumab, 80 mg in 0.8 mL sterile solution (100 mg/mL),	HUMIRA, adalimumab, DIN 02466872, 80 mg in 0.8 mL sterile solution

subcutaneous injection, pre-filled syringe	(100 mg/mL), subcutaneous injection, pre-filled syringe

[54] AbbVie says the Minister "misread" the correspondence from the BRDD. The BRDD stated that the 40 mg/0.4 mL and 80mg/0.8 mL presentations of HUMIRA that are authorized in Canada "can serve" as reference products for SIMLANDI, not that they must. AbbVie therefore maintains that the BRDD expressed no view on whether the 20 mg/0.2 mL high-concentration presentation or the original 50 mg/mL concentration of HUMIRA could also serve as the RBD.

[55] There is no merit to this argument. The BRDD identified only three RBDs for the JAMP Presentations. There was no basis upon which the Minister could have expanded the RBDs to encompass presentations of HUMIRA beyond those identified by the BRDD. The identification of RBDs is a role performed on behalf of the Minister exclusively by the BRDD.

[56] Furthermore, the BRDD was clear in its correspondence that it was responding to an inquiry "as to what is the reference biologic drug" for the JAMP Presentations. The BRDD confirmed that "the dosage form(s), strength(s), and route(s) of administration of SIMLANDI should be the same as that of the reference biologic drug".

[57] AbbVie conceded that the HUMIRA 40 mg/0.4mL pre-filled syringe (DIN 02458349) and 40 mg/0.4 mL pre-filled pen (DIN 02458357) were "Dormant Products", and the HUMIRA 80 mg/0.8 mL pre-filled syringe (DIN 02466872) was an "Approved Product", but not a "Marketed Product". This was consistent with information contained in Health Canada's records. The Minister reasonably concluded that these HUMIRA presentations were not marketed in Canada at the time JAMP filed its NDS for the SIMLANDI Presentations.

[58] The Minister found product specificity was a key consideration in the application of the listing requirements under section 4 of the PM(NOC) Regulations (at paragraph 45):

> More specifically, under subsection 4(2) of the *PM(NOC) Regulations*, a patent on a patent list will only be eligible to be added to the Patent Register if the patent contains a claim for the medicinal ingredient, a claim for the formulation, a claim for the dosage form, or a claim for the use of the medicinal ingredient, and the medicinal ingredient, formulation, dosage form, or use (as applicable) has been approved through the issuance of a notice of compliance in respect of the submission.

[59] The Minister observed that subsection 4(4) of the PM(NOC) Regulations requires the patent list to contain, among other things, the patent, the drug submission, and, under paragraph 4(4)(b), "the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates" (at paragraph 46). The Minister took this to mean that the patent list must contain a description of the drug at a DIN-specific level.

[60] The Minister found that the reference in subsection 5(1) of the PM(NOC) Regulations to "indirect" comparison 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”. Citing Justice Nicholas McHaffie’s decision in *Natco Pharma (Canada) Inc. v. Canada (Health)*, 2020 FC 788, [2021] 1 F.C.R. D-2, the Minister held at paragraph 54 of the decision that the “indirect” language was to capture a situation where a generic company seeks to compare its product to another generic drug, rather than to the original innovative drug.

[61] The Minister concluded that a drug that is not marketed is not eligible for the protections under the PM(NOC) Regulations, given the explicit marketing requirement under subsection 5(1): “When considering whether the “another drug” is “marketed in Canada,” the “another drug” will not be considered to be marketed where it has not been made available for sale (i.e. it is approved but the innovative drug manufacturer is not making it available for sale in Canada) or where it has been withdrawn from the market and the DIN is dormant or cancelled” (at paragraph 57).

[62] The marketing condition is included to ensure that the advantages of the PM(NOC) Regulations are not conferred on patent holders whose products are, for whatever reason, not generally available to consumers (*Astrazeneca Canada Inc. v. Canada (Minister of Health)*, 2005 FCA 189, [2006] 1 F.C.R. 297, at paragraph 81 (*per* Sharlow J.A., dissenting, but affirmed by the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paragraph 3)). The general policy behind the marketing condition is that a patent holder who obtains an NOC, but does not use it, should not be entitled to rely on that NOC to obtain collateral advantages because of the PM(NOC) Regulations. This tends to support a narrow interpretation of subsection 5(1).

[63] AbbVie’s various arguments in opposition to the Minister’s interpretation of subsection 5(1) of the PM(NOC) Regulations were comprehensively addressed in the Minister’s decision. Suffice it to say that the Minister’s reasons allow the Court to understand why the decision was made, and to conclude that it falls within the range of acceptable outcomes defensible in respect of the facts and law. This includes the Minister’s consideration of Canada’s obligations under Article 20.50 of the *Canada-United States-Mexico Agreement*][1], the requirements of procedural fairness, and the doctrine of *functus officio*, none of which figured prominently in the parties’ submissions before this Court.

[64] Despite the Minister’s statement that “the approval of both generic drugs and biosimilars are based on approved reference products [RBDs and CRPs] sharing the same strength and dosage form”, Abbvie insists that an RBD is not analogous to a CRP. However, the Minister said only that “the requirements for the selection of a RBD for a biosimilar, i.e. with respect to dosage form(s), strength(s), and route(s) of administration, are intentionally consistent with those for the selection of a CRP under the ANDS provisions …”. (Emphasis added.)

[65] The RBD for a biosimilar does not share the legislated requirements applicable to CRPs for generic small-molecules. Unlike the RBD for a biosimilar, the CRP for a

[1] *Protocol replacing the North American Free Trade Agreement with the Agreement between Canada, the United States of America, and the United Mexican States*, July 1, 2020, [2020] Can. T.S. No. 5, as amended by the *Protocol of Amendment to the Agreement Between the United States of America, the United Mexican States, and Canada*, July 1, 2020, [2020] Can. T.S. No. 6.

generic drug is required by the *Food and Drug Regulations* to “contain identical amounts of the identical medicinal ingredients, in a comparable dosage form” [at section C.08.001.1, “pharmaceutical equivalent”]. However, this does not preclude the Minister from recognizing a functional equivalence between RBDs and CRPs.

[66] AbbVie notes that the Minister’s guidance document, “Information and Submission Requirements for Biosimilar Biologic Drugs”, requires the active substances or medicinal ingredients of the biosimilar and RBD to be similar, not identical. But according to the document [at page 6], dosage form, strength and routes of administration of a biosimilar “should be the same” as the RBD. Even if “should” is understood to be discretionary rather than mandatory, the Minister cannot be faulted for following the recommendation contained in his own guidance document.

[67] AbbVie complains that a narrow interpretation of “another drug” creates a loophole to circumvent the application of the PM(NOC) Regulations. It allows JAMP to abuse the early-working exception and rely on the data package prepared by AbbVie after considerable research, development and expense. According to AbbVie, this frustrates the purpose of the *Patent Act* by disincentivizing new and improved presentations being brought to market.

[68] However, this argument ignores the clear language in subsection 5(1) of the PM(NOC) Regulations. The enforcement mechanism of the PM(NOC) Regulations is only available to an innovator that markets its innovative drug in Canada.

[69] Patent listing under subsection 4(1) of the PM(NOC) Regulations is DIN-specific. This matters, because sections 4 and 5 are reciprocal in nature: section 4 establishes the patent list a second person must circumnavigate (*Bristol-Myers*, at paragraph 61).

[70] AbbVie has not demonstrated that the Minister’s decision to treat RBDs and CRPs as performing an “equivalent role” is unreasonable. The Minister’s guidance document [at page 5] confirms that biosimilars are “subject to existing laws and regulations outlined in the *Patented Medicines (Notice of Compliance) Regulations* and C.08.004.1 of the *Food and Drug Regulations*”.

[71] In this case, the BRDD was able to identify biologic drugs that were authorized in Canada that had the same dosage forms, strengths and routes of administration and active ingredient as the JAMP Presentations. There was no need for flexibility on the part of the Minister in selecting the RBDs.

[72] I therefore conclude that the Minister’s interpretation of subsection 5(1) of the PM(NOC) Regulations as applying only to a DIN-specific version of a drug that is marketed in Canada was reasonable, particularly considering the statutory objective of providing a patent enforcement mechanism only in relation to products that are in fact available to Canadians. AbbVie’s alternative interpretation, assuming without deciding that it is tenable, falls short of demonstrating that the Minister’s application of the guidance document was outside the range of acceptable, defensible outcomes.

[73] In *Elanco v. Canada (Attorney General)*, 2019 FC 5, Justice Roger Lafrenière observed that the PM(NOC) Regulations are closely connected with the Minister’s functions, and the Minister has great expertise in their application and interpretation (at

paragraph 43). This is apparent in the lengthy and careful reasoning of the Minister in the decisions challenged in this proceeding.

[74] In light of this conclusion, it is unnecessary to address JAMP's objection that AbbVie's argument respecting JAMP's allegedly improper reliance on AbbVie's data in relation to the original 50 mg/mL concentration has been raised for the first time on judicial review. I agree with JAMP that AbbVie will have the opportunity to address its claims of improper "early working" in its patent infringement actions.

C. *Was the Minister's decision to issue NOCs to JAMP for its SIMLANDI Presentations reasonable?*

[75] AbbVie challenges the Minister's decision to issue an NOC to JAMP solely on the basis that the Minister unreasonably found JAMP not to be a "second person" for the purposes of subsection 5(1) of the PM(NOC) Regulations. I have concluded that the Minister's decision in this respect was reasonable, and AbbVie's application for judicial review of the Minister's issuance of an NOC to JAMP must therefore be dismissed.

V. Conclusion

[76] The applications for judicial review are dismissed with costs.

JUDGMENT

THIS COURT'S JUDGMENT is that the applications for judicial review are dismissed with costs.