Federal Court  Cour fédérale

Date: 20201029

Dockets: T-870-20
T-1048-20

Citation: 2020 FC 1013

Ottawa, Ontario, October 29, 2020

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

FRESENIUS KABI CANADA LTD.

Applicant

and

THE MINISTER OF HEALTH

Respondent

JUDGMENT AND REASONS

I. Introduction

[1] This is a consolidated application for judicial review of two decisions of the Minister of Health [Respondent], issued through the Office of Patented Medicines and Liaison [OPML], under the Office of Submissions and Intellectual Property [OSIP] within Health Canada. In the decisions, dated July 30, 2020 and September 1, 2020 [the "Decisions"], the Respondent failed to issue an Notice of Compliance [NOC] to Fresenius Kabi Canada Ltd. [Applicant] in respect of its

New Drug Submission [NDS] No. 230637 for the drug product IDACIO™, adalimumab 40 mg in 0.8mL (50mg/mL).

II. Background

[2] IDACIO is a biosimilar of AbbVie Biotechnology Ltd.'s [AbbVie] drug, marketed under the brand name HUMIRA®. AbbVie is the owner of the Canadian Patents listed in the Patent Registrar in respect of HUMIRA: 2,385,745, 2,494,756, 2,504,868, 2,847,142, 2,898,009 and 2,801,917. As required, the Applicant sought to address each of the listed patents, when seeking the issuance of an NOC, pursuant to subsections 7(1)-(2) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*NOC Regulations*]. An NOC is a prerequisite for the Applicant to engage in the advertising and selling of IDACIO, under other regulatory frameworks in Canada.

[3] AbbVie and the Applicant had entered into a confidential licensing agreement [the "Agreement"], which governed their relationship and authorized the Applicant to perform certain acts under the listed patents. In reference to the Agreement, the Applicant sought to rely on AbbVie's consent under subsection 7(2) of the *NOC Regulations*. This provision exempts the Applicant from meeting certain conditions set out in subsection 7(1), which are required before the Respondent can issue an NOC. It is the interpretation of what constitutes effective consent under subsection 7(2) of the *NOC Regulations* that forms the basis of this application.

[4] AbbVie expressed forms of consent to the Respondent on several occasions, including in letters dated September 30, 2019, October 15, 2019 and December 4, 2019, addressed to OSIP.

The substance of the consent was similar. As succinctly stated by the Applicant, "[t]he patent owner (AbbVie) has provided consent to (a) issuance of an NOC in accordance with its confidential agreement with Fresenius, (b) the making and constructing of IDACIO, and (c) the using and selling of IDACIO on or after February 15, 2021". The letters specified that consent was being provided pursuant to subsection 7(2) of the *NOC Regulations*. For example, the December 4, 2019 letter specified:

> Pursuant to s. 7(2) of the *Patented Medicines (Notice of Compliance Regulations)*, and solely for the purpose of these *Regulations*, AbbVie Biotechnology Ltd. […] herby consents to the making, constructing, and, on and after February 15, 2021, to the using and selling in Canada by Fresenius Kabi Canada Ltd, of IDACIO…

[5] In addition, there were several communications between the parties and AbbVie, seeking to clarify the nature of the consent provided:

A. On October 28, 2019, OSIP informed the Applicant that the effective date for consent under subsection 7(2) of the *NOC Regulations* would be February 16, 2021;
B. A determination was rendered by OSIP on December 6, 2019, that the requirements of subsection 7(2) of the *NOC Regulations* had not been met. AbbVie's consent is effective after February 15, 2021;
C. Following a request in March of 2020, OSIP agreed to consider further submissions from the Applicant. However, on April 6, 2020, OSIP stated that the OPML "does not rely on the contents/text of settlement agreements between first and second persons" for the purposes of administering the *NOC Regulations*;
D. Between April 27, 2020 and June 15, 2020, the Applicant submitted excerpts from the Agreement with AbbVie, explanations of the Agreement and submissions in regards to

the specific challenges facing biosimilars, including as it relates to advertising, pre-clearance and lot testing;

E. On July 27, 2020, OSIP asked AbbVie to clarify its intent expressed in the December 4, 2019 letter. AbbVie provided a response, dated August 7, 2020. The response referred to sections of the Agreement, but left the determination to OSIP, as to whether consent was effective under subsection 7(2) of the *NOC Regulations*;

F. On July 30, 2020, Health Canada advised that the examination (i.e. the safety and efficacy review) of Submission No. 230637 was completed and that it was seeking confirmation from AbbVie as to the effective date of consent. The NOC would not issue until effective consent is obtained. This July Decision forms the basis for the first application for judicial review (T-870-20); and

G. The September Decision was issued on September 1, 2020, and forms the basis of the second application for judicial review (T-1048-20). These Decisions are described in further detail below.

I. Decisions Under Review

[6] Two decisions are under review in this current application. The July Decision explained that the effective date of consent was being sought from AbbVie, prior to the issuance of an NOC. This was based on the Respondent's previously expressed position (for example, in its December 6, 2019 determination) that compared to the activities granted by the NOC, which allows "selling" and "advertising", consent to only "making" and "constructing" would not meet the requirements of subsection 7(2) of the *NOC Regulations*.

[7] The September Decision confirmed that the Respondent remains of the view that the NOC cannot issue until the effective date of consent of February 15, 2021, when AbbVie has provided consent to all four activities in subsection 7(2) of the *NOC Regulations* - making, constructing, using or selling. The consent from AbbVie must be unequivocal, in addition to authorizing all four activities. The Respondent found that use of the word "or" to connect the four activities in subsection 7(2) of the *NOC Regulations* cannot be interpreted in a manner that would lead to an absurd result or that would undermine the effective patent enforcement mechanism of the *NOC Regulations*. Further, a settlement or license could not evidence consent, which must be unequivocal and provided by the owner of the patent. The Respondent would otherwise be in a position of having to interpret agreements, with representations of only one of the parties. The Respondent's determination could not be circumvented by consideration of the alleged hurdles faced in bringing a biosimilar to market.

II. Issues

[8] The issues are:

A. Was the Respondent's refusal to issue an NOC until February 15, 2021, on the basis of its interpretation of effective consent under subsection 7(2) of the *NOC Regulations*, unreasonable?

B. If the Respondent's Decisions are unreasonable, should this Court grant an order of *mandamus*?

III. Standard of Review

[9] The standard of review is that of reasonableness (*Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 83-87 [*Vavilov*]).

IV. Relevant Provisions

[10] Subsection 7(1)-(2) of the *NOC Regulations*:

> **7(1)** The Minister shall not issue a notice of compliance to a second person before the latest of
>
> > **(a)** the day after the expiry of all of the patents and certificates of supplementary protection in respect of which the second person is required to make a statement or allegation under subsection 5(1) or (2) and that are not the subject of an allegation;
> >
> > **(b)** the day on which the second person complies with paragraph 5(3)(e);
> >
> > **(c)** the 46th day after the day on which a notice of allegation under paragraph 5(3)(a) is served;
> >
> > **(d)** the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1);
> >
> > **(e)** the day after the expiry of all of the patents and certificates of supplementary protection in respect of which a declaration of infringement has been made in an action brought under subsection 6(1); and
> >
> > **(f)** the day after the expiry of all of the certificates of supplementary protection, other than any that were held not to be infringed in an action referred to in paragraph (e), that
> >
> > > **(i)** set out a patent referred to in paragraph (a) or (e),
> > >
> > > **(ii)** are not the subject of a statement or allegation made under subsection 5(1) or (2), and

> **(iii)** are included on the register in respect of the same submission or supplement as the patent.
>
> **(2)** Subsection (1) does not apply in respect of a patent or a certificate of supplementary protection if the Minister has been provided with evidence from the owner of the patent of their consent to the making, constructing, using or selling of the drug in Canada by the second person.

V. Analysis

[11] It is the Applicant's position that consent to any single patent right under subsection 7(2) of the *NOC Regulations* allows the Respondent to issue an NOC. AbbVie does not object to immediate issuance of an NOC and any patent infringement issues between the Applicant and AbbVie are resolved by way of the Agreement. Further, the Respondent's reading of subsection 7(2) of the *NOC Regulations* is contrary to its plain text and inconsistent with its purpose and the Decisions to withhold an NOC prior to February 15, 2021, is unreasonable where there is no risk of patent infringement.

[12] The Respondent alleges that unequivocal consent from AbbVie in relation to the entire bundle of patent rights under subsection 7(2) of the *NOC Regulations* is required before an NOC can be issued. The "or" in subsection 7(2) of the *NOC Regulations*, linking the four patents rights, cannot be interpreted disjunctively as this would lead to an absurd result or one that defeats the clear intent of the provision. AbbVie did not provide consent to all the activities listed under subsection 7(2) of the *NOC Regulations* until February 15, 2021.

[13] The *NOC Regulations* under the *Patent Act*, RSC, 1985, c P-4 [*Patent Act*], seek to align the drug approval process of a subsequent entry or generic drug, under the *Food and Drug*

Regulations, CRC, c 870 [*Food and Drug Regulations*], with certain patent rights pertaining to the first or innovative drug. Particularly, the *NOC Regulations* seek to balance the patent rights associated with innovative drugs against the timely market entry of lower-priced competitor drugs (*Regulatory Impact Analysis Statement*, (2006) C Gaz II, Vol 140, No 21 at 1510 [RIAS]).

[14] Subsection 55.2(1) of the *Patent Act* provides for an "early-working" exception, where subsequent entry drug manufacturers may use a patented, innovative drug as it relates to seeking approvals in respect of a competing version of that drug. The *NOC Regulations* prevent abuse of the exception by setting out conditions that must be met prior to the issuance of an NOC. These conditions, set out in subsection 7(1) of the *NOC Regulations*, do not apply where evidence of consent has been provided by the patent owner in accordance with subsection 7(2). At issue is the interpretation of "consent to the making, constructing, using or selling", pursuant to subsection 7(2) of the *NOC Regulations*:

> (2) Subsection (1) does not apply in respect of a patent or a certificate of supplementary protection if the Minister has been provided with evidence from the owner of the patent of their consent to the making, constructing, using or selling of the drug in Canada by the second person.

[15] For the reasons that follow, the Decisions are unreasonable on the basis of the following:

A. AbbVie provided unequivocal consent to all four activities in subsection 7(2) of the *NOC Regulations*. The temporal nature of the consent does not render it ineffective;

B. The Respondent erred in its analysis of the text of subsection 7(2) of the *NOC Regulations* and its interpretation of the disjunctive, but inclusive "or"; and

C. The Respondent erred in its interpretation of the purpose of the *NOC Regulations* by failing to recognize the dual purpose of the regime.

[16] In its letters, for example, the December 4, 2019 letter, AbbVie unequivocally provides its consent pursuant to subsection 7(2) of the *NOC Regulations* to all four activities. There is a temporal aspect to its consent, whereby it "hereby consents to the making, constructing, and, on and after February 15, 2021, to the using and selling in Canada by Fresenius Kabi Canada Ltd, of IDACIO…" This consent is clear and unequivocal as to the patent owner's intentions. AbbVie does not object to the immediate issuance of an NOC. These expressions of consent do not require interpretation of the Agreement and do not support the Respondent's finding that the patent owner's consent is uncertain. The temporal nature of the consent to all four activities does not support the finding that consent is only effective as of February 15, 2021.

[17] The Supreme Court adopted Driedger's "modern principle" of statutory interpretation in *Rizzo & Rizzo Shoes Ltd (Re)*, [1998] 1 SCR 27 at paragraph 21 [*Rizzo*]:

> Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.
>
> (Rizzo, above citing Driedger in *Construction of Statues* (2nd ed, 1983))

[18] As such, statutory interpretation involves consideration of three essential elements, the text, the context and the purpose (*Canada Trustco Mortgage Co v Canada*, 2005 SCC 54). As discussed by the Supreme Court in *Vavilov*, above, at paragraph 118:

> [118] This Court has adopted the "modern principle" as the proper approach to statutory interpretation, because legislative intent can be understood only by reading the language chosen by the legislature in light of the purpose of the provision and the entire relevant context: Sullivan, at pp. 7-8. Those who draft and enact statutes expect that questions about their meaning will be resolved by an analysis that has regard to the text, context and purpose,

> regardless of whether the entity tasked with interpreting the law is a court or an administrative decision maker. An approach to reasonableness review that respects legislative intent must therefore assume that those who interpret the law — whether courts or administrative decision makers — will do so in a manner consistent with this principle of interpretation.

[19] This is not a checklist for conducting reasonableness review, but rather these are elements that can cause a reviewing court to loose confidence in the outcome reached by a decision maker (*Vavilov* at para 106). Further, the decision maker cannot “reverse-engineer” a desired outcome, by adopting an interpretation it knows to be inferior, but plausible, on the basis of the availability or expediency of the interpretation (*Vavilov* at para 121).

[20] OSIP provides at pages 7 and 8 of the September Decision:

> While subsection 7(2) of the *PM(NOC) Regulations* does use "or", an "or" cannot be interpreted disjunctively in a manner that would lead to an absurd result or where the clear intent of the provision in which it is found would be defeated…
>
> …
>
> The “or” in subsection 7(2) of the *PM(NOC) Regulations* was in the corresponding predecessor subsections since the inception of the PM(NOC) Regulations in 1993 (see SOR/93-133, Canada Gazette Part II, Vol. 127, No. 6, pages 1383-1389). However, the provision was never intended to permit Health Canada to issue an NOC without consent for all of the listed activities.

[21] Accordingly, the Respondent circumvents a textual reading of the provision by stating that “or” should be read conjunctively, rather than disjunctively, to avoid an absurd result. A textual reading is rather focused on the ordinary meaning of the words of a provision as the starting point, with the assumption that the author is using the words in their ordinary sense.

[22] Typically, the word "or" is presumed to be disjunctive, but inclusive, such that, as in this case, a patent owner could consent to each or a combination of the activities listed – making, constructing, using or selling – to meet the requirements of subsection 7(2) of the *NOC Regulations*:

> "Or" is always disjunctive in the sense that it always indicates that the things listed before and after the "or" are alternatives. However, "or" is ambiguous in that it may be inclusive or exclusive. … In the case of the inclusive "or," the alternatives may be cumulated: (a) or (b) or both; (a) or (b) or (c), or any two, or all three.
>
> Like the joint and several "and," the inclusive "or" expresses the idea of "and/or."
>
> …
>
> In referring to the inclusive "or," courts sometimes say that the "or" is conjunctive or, worse still, that "or" means "and." "Or" is always disjunctive and, unless the drafter has made a mistake, "or" should never be understood to mean "and."
>
> (Ruth Sullivan, *Statutory Interpretation*, 2nd ed (Toronto: Irwin Law Inc., 2007 at 81-82)).

[23] Two cases relied on by the Respondent in the September Decision actually support this presumption.

[24] In *IWA Local*, the New Brunswick Court of Appeal [NBCA] rejected the view that the Labour Relations Board was prevented from holding a hearing "and" taking a vote, based on statutory language to the effect that the Labour Relations Board "…may make or cause to be made such examination of records or other inquiries as it deems necessary, including the holding of such hearings or the taking of such votes as it deems expedient" [*Emphasis added*]. The NBCA found that the Labour Relations Board could, in its discretion, hold both a hearing and a

vote. While the NBCA makes references to "absurdity", this is in the context of failing to read the "or" as inclusive (*Re International Woodworkers of America, Local 2-306, and Miramichi Forest Products Ltd*, (1971), 21 DLR (3d) 239 (NBCA) at 242 [*IWA Local*]).

[25] In *R v Shaw*, the Saskatchewan Court of Appeal held that the use of "or" in the *British North America Act*, respecting "the Imposition of Punishment by Fine, Penalty or Imprisonment for enforcing any Law of the Province" is used "distributively" meaning that the province "may use one or more of them [the powers] at the same time" (*R v Shaw*, [1920] 3 WWR 611 (SKCA) at para 34).

[26] In circumventing this textual analysis, the Respondent also fails to recognize that consent, in any event, has been provided to all four listed activities in subsection 7(2) of the *NOC Regulations*.

[27] The September Decision states at pages 8 and 9 that the *NOC Regulations*:

> …"are intended to provide effective patent enforcement" by ensuring the "early-working" exception does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the innovator considers justified having regard to the generic company's allegation, or the court dismisses the innovator's action under subsection 6(1) of the *PM(NOC) Regulations* 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.

[28] The Respondent asserts that it is reasonable to interpret subsection 7(2) of the *NOC Regulations* in a manner which avoids potential abuse and the derogation of rights of patentees.

This is because the *NOC Regulations* are intended to provide a balance to the early working exception under the *Patent Act*, by aligning the issuance of an NOC under the *Food and Drug Regulations* to a subsequent entry product with the patent status of the reference product. This purpose is allegedly undermined in cases where an NOC is issued that permits the second person to sell the drug when they are not authorized to do so.

[29] However, the Decisions in issue fail to account for the entire context and purpose of the *NOC Regulations*, narrowly focusing on the enforcement aspect. The dual purpose of the *NOC Regulations* is to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower-priced generic competitors (RIAS, above). This dual purpose has been affirmed by the Supreme Court in *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 [*Biolyse*], where the legislative history and the government's public statements reflected a desire to achieve "balance" between the rights of patentees and the "essential" public interest in "assuring the availability of competitively priced generic medicines as soon after patent expiry as possible" (*Biolyse*, above at paras 47-48). This dual purpose is consistent with the limited scope of section 55.2(4) of the *Patent Act*, which is "specifically directed to preventing infringement by persons who use "the patented invention" for the "early working" exception… [which] is all the Governor in Council is authorized to regulate" (*Biolyse* at para 53).

[30] An interpretation of subsection 7(2) that withholds an NOC where consent is clearly provided by the patent owner in respect of the listed activities, and where that patent owner explicitly indicates it is providing the consent sought under subsection 7(2) of the *NOC*

Regulations is unreasonable. I agree that the Respondent should not be placed in a position of having to interpret the Agreement in evaluating effective consent – it is reasonable that this consent should come directly from the patent owner. However, where consent is consistently provided by the patent owner, in specific reference to subsection 7(2) of the *NOC Regulations* – including in letters dated September 30, 2019, October 15, 2019 and December 4, 2019 – it is not the case that unequivocal consent has not been obtained in this case. Indeed, consent to all the activities referenced in section 7(2) of the *NOC Regulations* has been effectively provided, albeit in two different time frames.

[31] The choice of the patent owner to consent to all four activities at different points in time does not amount to an absurdity meriting correction of the inclusive disjunctive understanding of the word "or" to read as a conjunctive "and". In *R v Wu*, the former *Criminal Code* provision (s. 734.7(1)) read that the offender could be jailed for non payment of a fine if:

> (i) that the mechanisms provided by sections 734.5 [suspension of licenses, permits, etc.] and 734.6 [civil enforcement] are not appropriate in the circumstances, *or*
>
> (ii) that the offender has, without reasonable excuse, refused to pay the fine or discharge it under section 736 [fine option program]. [*Emphasis added*]

[32] This sentencing reform had been introduced over concerns of over-jailing the poor for unpaid fines. The results of reading the "or" disjunctively would be absurd because an offender could be jailed nonetheless due to poverty (*R v Wu*, 2003 SCC 73 at paras 60-63 [*Wu*]). The Supreme Court explained that, "[c]ourts have not infrequently read "or" as "and" where the legislative context so requires" (*Wu*, above at para 62). In the Supreme Court's reference to *IWA Local* in making this statement, I do not necessarily understand the Supreme Court to mean that

"or" and "and" can be switched at will. Sullivan describes the difference between resolving ambiguity and correcting a mistake of the legislature:

> The distinction between resolving ambiguity and correcting a drafter's mistake is worth making because the latter calls for much stronger evidence of legislative intent. Ambiguity *must* be resolved one way or another and it may be resolved on somewhat speculative grounds; however, a drafter's mistake can be corrected only if the court knows for sure what the legislature intended, but failed, to say.
>
> (Ruth Sullivan, *Sullivan on the Construction of Statutes*, 6th ed (LexisNexis Canada Inc., 2014) at §4.102)

[33] Accordingly, there is no absurd result as argued by the Respondent. As explained in *Rizzo* at paragraph 27:

> …an interpretation can be considered absurd if it leads to ridiculous or frivolous consequences, if it is extremely unreasonable or inequitable, if it is illogical or incoherent, or if it is incompatible with other provisions or with the object of the legislative enactment.

[34] The issuance of an NOC on the basis of consent provided by a patent owner cannot be considered incoherent or incompatible having regard to the dual purposes of the *NOC Regulations* and the express language of subsection 7(2) of the *NOC Regulations*. Subsection 7(2) of the *NOC Regulations* requires the consent of the patent owner as part of its enforcement machinery.

[35] I further note that an NOC is essential for the timely launch of a biosimilar product, which is critical for biosimilars to remain competitive and establish their market position. The Applicant has pointed to several detrimental impacts inherent to biosimilars, particularly as other

options may exist for a biosimilar adalimumab product. A delayed launch caused by the delayed issuance of an NOC, required for review and approval of pharmaceutical advertising materials and testing, could result in discarding imported product and allow other biosimilars to enter the market.

A. *If the Decisions are unreasonable, should this Court grant an order of mandamus?*

[36] An order of *mandamus* is warranted where the following conditions are met:

A. There is a legal duty to act;

B. The duty is owed to the Applicant;

C. There is a clear right to performance of that duty;

D. Where the duty sought to be enforced is discretionary, certain additional principles apply;

E. No adequate remedy is available to the Applicant;

F. The order sought will have some practical value or effect;

G. The Court finds no equitable bar to the relief sought; and

H. On a balance of convenience, an order of *mandamus* should issue.

(*Apotex Inc v Canada (Attorney General)* (1993), [1994] 1 FC 742 (FCA) at 19-21, aff'd [1994] 3 SCR 1100)

[37] In the current case, the efficacy and safety review of IDACIO has been completed. If an NDS is satisfactory, the Respondent is compelled to issue an NOC. The *Food and Drug Regulations* provide that the Respondent shall issue an NOC if the efficacy and safety requirements are met. The existence of a complex factual and regulatory matrix, as argued by the Respondent, is no longer supported at this stage. Health Canada has exercised its discretion in

completing its examination and section C.08.004 requires the Respondent to issue an NOC in such circumstances:

> **C.08.004(1)** Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,
>
> > (a) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or
> >
> > (b) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, issue a notice to the manufacturer to that effect.

[38] The July Decision confirms the completion of Health Canada's examination of IDACIO, with the requirement of consent under subsection 7(2) of the *NOC Regulations* as the remaining consideration. There is also no discretion under the *NOC Regulations* to withhold an NOC once the patent owner has provided the requisite consent. In this respect, there is no useful purpose in remitting this interpretive question for redetermination (*Vavilov* at para 124). This is an appropriate case for granting an order of *mandamus*.

VI. Conclusion

[39] I grant this application and make an order of *mandamus*, requiring issuance of the NOC in respect of this matter. Costs have not been sought on this application.

JUDGMENT IN T-870-20 AND T-1048-20

THIS COURT'S JUDGMENT is that:

1. The application is granted;

2. The request for an Order for *mandamus* is granted and the Minister of Health shall issue the NOC to Fresenius Kabi Canada Ltd.; and

3. No costs are awarded.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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