Federal Court  Cour fédérale

Date: 20151106

Docket: T-501-14

Citation: 2015 FC 1206

Ottawa, Ontario, November 6, 2015

PRESENT: The Honourable Madam Justice Gagné

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Applicant

and

THE MINISTER OF HEALTH
ATTORNEY GENERAL OF CANADA
SANOFI-AVENTIS CANADA INC.

Respondents

PUBLIC JUDGMENT AND REASONS
(Identical to Confidential Judgment and Reasons issued October 26, 2015)

[1] This is an application for judicial review of a decision dated January 28, 2014, whereby the Minister of Health [Minister or Health Canada] found the applicant's supplemental new drug submission [SNDS] filed under section C.08.003 of the *Food and Drug Regulations*, CRC 1978, c 870 [FDA Regulations] required Form V, addressing the respondent Sanofi-Aventis Canada Inc's [Sanofi] 2,196,922 patent ['922 Patent] in respect of ELOXATIN. In the Minister's view, the applicant was a "second person" within the meaning of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [PM(NOC) Regulations] and thus had to comply with

subsection 5(2) of those regulations. As a result, the Minister found the SNDS to be administratively incomplete and concluded it would be shredded unless Form V was submitted within ten days.

[2] The applicant argues that Health Canada erred by: (i) wrongly interpreting subsection 5(2) of the PM(NOC) Regulations as including under the scope of that provision a SNDS that is linked to a submission not subject to subsection 5(1); (ii) unreasonably placing a hold on the substantive examination of the NDS until the PM(NOC) Regulations were complied with; and (iii) unreasonably imposing a time frame shorter than that imposed for seeking judicial review.

[3] The present matter is closely related to the matter dealt with by the Court in file number T-1963-13 and was heard at the same time.

[4] For the reasons discussed below, I am of the view that this application for judicial review is moot and therefore should not be decided by the Court.

I. Background

[5] For a comprehensive factual background to this matter, see the reasons of the Court in the sister file *Hospira Healthcare Corporation v The Minister of Health, Attorney General of Canada, Sanofi-Aventis Canada Inc*, 2015 FC 1205, released concurrently with these reasons. The sister file concerns the data protection ELOXATIN enjoys as an innovative drug under the FDA Regulations, which is set to expire on December 15, 2015.

[6] ELOXATIN also enjoys patent protection. It is identified as the '922 Patent, and was listed on the Patent Register on June 19, 2007, two days after Sanofi received its original Notice of Compliance [NOC] for 5 mg/mL oxaliplatin solution for injection. Sanofi's NOC covers both the dried powder dosage and the solution for injection.

[7] At the time the applicant filed its NDS for OXALIPLATIN FOR INJECTION in an intravenous lyophilized powder solution in the strengths of 50 mg and 100 mg, no patent on the Patent Register contained any drug with the active ingredient oxaliplatin. Nor was a NOC issued in respect of any new drugs containing oxaliplatin.

[8] However, the circumstances changed by the time Health Canada examined the applicant's NDS for OXALIPLATIN FOR INJECTION. For various reasons discussed in the sister file, the final examination of the NDS was only complete by October 30, 2013. In the meantime, the '922 Patent had been listed on the Patent Register on June 19, 2007, two days after Sanofi received its NOC for ELOXATIN.

[9] By October 31, 2013, the Minister informed the applicant that the NOC for OXALIPLATIN FOR INJECTION was recommended but that it could not issue pursuant to section C.08.004.1 of the FDA Regulations, until after the expiry of data protection for ELOXATIN. The Minister determined that the NDS was based on comparisons to ELOXATIN. This decision is the impugned decision in the sister file – the notice of application for which was filed on November 28, 2013.

[10] Nevertheless, on December 20, 2013, the applicant chose to introduce a change to the dosage form of OXALIPLATIN FOR INJECTION through a SNDS as provided under section C.08.003 of the FDA Regulations and pursuant to the *Post-Notice of Compliance (NOC) Changes: Quality Guidance* document (Ottawa: Health Canada, 2012). Those provisions apply to those intending to make changes to new drugs after a NOC has been issued, but also, as in the case of the applicant, to those submissions for which a NOC has been recommended, but issuance has been placed on hold. The applicant's SNDS was for the applicant's new finished pharmaceutical dosage form which is presented as a ready-to-use solution for injection (OXALIPLATIN SOLUTION).

[11] Attached to the SNDS was a draft product monograph containing references to the respondent Sanofi's ELOXATIN Canadian Product Monograph.

[12] By letter dated January 2, 2014, Health Canada notified the applicant that it was required to submit a Form V addressing Sanofi's '922 Patent; the SNDS triggered the application of subsection 5(2) of the PM(NOC) Regulations.

[13] On January 10, 2014, the applicant requested a reconsideration and withdrawal of the January 2, 2014 letter, taking the view that it is not a "second person" within the meaning of the PM(NOC) Regulations, as subsection 5(2) is only engaged where the SNDS is filed in respect of a submission that is or was subject to subsection 5(1).

[14] By letter dated January 28, 2014, Health Canada maintained its position.

[15] On February 7, 2014, the applicant filed the requested Form V under protest and reasserted that it was not a second person under subsection 5(2) of the PM(NOC) Regulations.

[16] On February 27, 2014, the applicant filed its notice of application (amended on November 12, 2014), the subject of this judicial review.

[17] After the submission was considered administratively complete, the SNDS was placed on Intellectual Property Hold until the remaining requirements of the PM(NOC) Regulations were met in respect of the '922 Patent, in addition to the expiry of data protection. However, that decision rendered by the Minister on September 26, 2014, was not challenged by the applicant.

II. The Impugned Decision

[18] After summarizing the applicant's position, the Minister maintained that the applicant was a "second person" within the meaning of the PM(NOC) Regulations, which is defined in section 2 as "the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections". As such, the applicant was required to comply with subsection 5(2):

> (2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been 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, in the supplement, with respect to each patent on the register in respect of the other drug,

> (*a*) state that the second person accepts that the notice of compliance will not issue until the patent expires; or
>
> (*b*) allege that
>
> (i) the statement made by the first person under paragraph 4(4)(*d*) is false,
>
> (ii) the patent has expired,
>
> (iii) the patent is not valid, or
>
> (iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the supplement is filed.

[19] The Minister concluded that the "Form V Hold" would be maintained on the SNDS until Form V was submitted. The applicant was given ten calendar days from the date of the decision to comply.

III. Analysis

[20] At issue on this application for judicial review is whether the PM(NOC) Regulations apply to the applicant's SNDS when those regulations were irrelevant or not considered in the assessment of its prior submission.

[21] I am of the view that this issue is moot for the following reasons.

[22] First, Sanofi's '922 Patent expired on August 7, 2015. Therefore, the PM(NOC) Regulations no longer prevent the Minister from issuing a NOC for OXALIPLATIN SOLUTION.

[23] Second, although the prohibition arising from the PM(NOC) Regulations is no longer in force, the Minister is still prevented from issuing the applicant's NOC pursuant to the FDA Regulations. The data protection granted to Sanofi's ELOXATIN (for both dosage forms) will expire on December 15, 2015 and even if I had found in the sister file that the data protection did not apply to the applicant's ELOXATIN FOR INJECTION, which I have not, it does apply to its ELOXATIN SOLUTION for two reasons: i) the applicant's SNDS was filed after Sanofi had received its NOC for ELOXATIN and after its '922 Patent was registered on the Patent Register, and ii) the applicant has not filed an application for judicial review of the September 26, 2014 Intellectual Property Hold decision.

[24] Therefore, even if I were to agree with the applicant that the PM(NOC) Regulations did not apply to its SNDS, no NOC could issue in favour of the applicant before December 15, 2015. As a result, this application for judicial review has no real object and it is therefore moot.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed;

2. Costs are granted in favour of both respondents.

"Jocelyne Gagné"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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STYLE OF CAUSE:	HOSPIRA HEALTHCARE CORPORATION v THE MINISTER OF HEALTH, ATTORNEY GENERAL OF CANADA, SANOFI-AVENTIS CANADA INC.
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