Federal Court  Cour fédérale

Date: 20090508

Docket: T-382-08

Citation: 2009 FC 474

Ottawa, Ontario, May 8, 2009

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA
and MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application by Eli Lilly Canada Inc. (Eli Lilly) challenging a decision by the Minister of Health (Minister) refusing a request to add Eli Lilly's Canadian Patent No. 2,265,712 (the '712 Patent) to the patent register as of the date of the submission of its associated patent lists. The Minister took the position that the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (NOC Regulations) mandate that a patent can only be added to the patent register as of the date that it is deemed to be eligible for listing and not before.

I. Background

[2] On November 27, 2006 Eli Lilly submitted to the Minister patent lists seeking to add its '712 Patent for olanzapine dihydrate to the patent register with respect to several supplementary new drug submissions (SNDS). Those requests were refused by the Minister on January 17, 2007 on the basis that the '712 Patent was, for a variety of stated reasons, ineligible for listing on the patent register. This refusal was followed by an exchange of correspondence between Eli Lilly and the Minister and the provision of additional information in support of Eli Lilly's position. On November 19, 2007 the Minister agreed to list the '712 Patent against three SNDS.

[3] On November 26, 2007 Eli Lilly asked the Minister to consider adding the '712 Patent to the patent register as of the date of its original patent list filing on November 27, 2006. The justification for this request was stated as follows:

> Assuming that the objective of filing a patent list (Form IV) is to provide notice as to the existence of a patent that is potentially relevant to a medicine, the date of filing of the Form IV suffices for that purpose. Consequently, any submissions filed that make reference to Lilly ZYPREXA ZYDIS products should address the '712 Patent if they were filed after the date of filing of Lilly's Form IVs Patent List. In the event that a submission was filed under the *Old Regulations* prior to the amendments of October 2006, those submissions are subject to the *Old Regulations* which do not provide for a patent freeze. In that event, those submissions must also address the '712 Patent as listed.
>
> We trust that you will take every step to ensure that this patent is properly addressed depending upon the filing dates of any Abbreviated New Drug Submissions that make reference to these products, given the proper filing of the '712 Patent List in November 2006. In particular, we note that there are submissions filed by Pharmascience that should address the '712 Patent. We ask for confirmation from the Minister that no NOC will issue in respect of the Pharmascience submissions (or any others filed in respect of

> orally disintegrating olanzapine) until the '712 has been properly addressed by virtue of a NOA.

[4] By letter dated January 4, 2008 the Minister refused Eli Lilly's request for an early listing on the basis that the '712 Patent was properly listed when the Minister determined its eligibility for listing on November 19, 2007. In the result, it was that date that dictated whether a second person was required to address the '712 Patent under s. 5 of the NOC Regulations.

[5] Eli Lilly then sought a reconsideration from the Minister's decision but the initial decision was maintained for the following reasons:

> During the January 16, 2008 meeting, you emphasized your earlier position that the objective of filing a Form IV is to provide notice to a second person as to the existence of a patent that is potentially relevant to a medicine. In your view, the date of filing of the Form IV is the relevant date for this purpose. You, therefore, maintained the position that generic drug submissions filed after the date of filing should trigger section 5 of the *Patented Medicines (Notice of Compliance) Regulations* [S.O.R./93-133 as amended] ("*PM(NOC) Regulations*").
>
> As such, you suggested either (a) listing the patent on an interim basis immediately on the filing date of the Form IV in order to notify potential second persons, and then deleting it from the Patent Register if necessary after a final decision of eligibility has been made; or (b) where the patent can not be listed immediately because the notice of compliance has not issued, back-dating the listing of the patent as of the filing date of the Form IV once the notice of compliance has issued. In response to the OPML's January 4, 2008 reconsideration, you explained your view that the language in subsection 5(1) of the *PM(NOC) Regulations* supports your position by referring to a patent list that has been "submitted" to the Minister.
>
> While there may be certain ambiguities in the language of section 5, the OPML is of the view that, when read in their entire

context, the *PM(NOC) Regulations* do not support the listing of patents on the Patent Register on the date of filing of the relevant Form IV.

Rather, subsection 5(4) of the *PM(NOC) Regulations* refers to those patents that have been 'added to the register", and is consistent with the language is subsections 5(1) and 5(2) which refer to patents that have been both submitted and listed "on the register". This language appears to indicate that the appropriate date for notice to a second person is the date of the decision of eligibility under section 4 and not the date of filing of the relevant Form IV.

In further response to your suggestions for listing, we would note that section 4 provides for certain eligibility requirements to be met in advance of listing a patent on the Patent Register, rather than listing all patents prior to determining their eligibility. In addition, we do not view back-dating the listing of a patent to be a practical option. The notice function upon which you base this suggestion would be lost, as a generic drug manufacturer would not know which patents need to be addressed when it files a submission. Furthermore, back-dating the listing would not accord with subsection 5(4) of the *PM(NOC) Regulations*.

Therefore, as noted in the January 4, 2008 reconsideration letter, in the event that a patent is found to be eligible for listing in respect of a drug, it will be added to the Patent Register only upon issuance of the relevant notice of compliance for that drug. When a notice of compliance has already issued, patents added to the Patent Register under subsection 4(6) will be added as of the date of the final decision of eligibility.

In light of the above, the OPML maintains the position that the '712 patent was listed properly on the Patent Register as of the date of the final decision of eligibility on November 19, 2007. November 19, 2007 is, therefore, the date used to determine whether a second person is required to address the '712 patent under section 5 of the *PM(NOC) Regulations*.

[6] It is this decision by the Minister which is challenged by Eli Lilly on this application.

II. Issue

[7] The issue as framed by Eli Lilly is that its '712 Patent should have been listed on the patent register by the Minister upon the submission of its associated patent lists and not, as the Minister contends, on the date of the Minister's later determination of its eligibility for listing.

III. Analysis

[8] I agree with Eli Lilly that the issue it raises involves a point of statutory interpretation which must be resolved on the standard of correctness: see *AstraZeneca Canada Inc. v. Minister of Health*, 2005 FCA 189, 40 C.P.R. (4th) 353 at paras. 25 and 26.

[9] Eli Lilly argues that the Minister errs in the interpretation of s. 5 of the NOC Regulations by requiring generic manufacturers (or second persons) to address only patents which have, as of the date of the generic's Notice of Allegation (NOA) submission, been added by the Minister to the patent register. Eli Lilly says that the correct interpretation of s. 5 would require a generic manufacturer to address a patent included in a patent list as of the date the list is filed by the innovator (or first person) with the Minister under ss. 4(1) of the NOC Regulations. In this case Eli Lilly contends that its '712 Patent was legally on the patent register as of the date of the filing of its patent lists on November 27, 2006 and not on November 17, 2007 when the Minister determined that the patent was eligible for listing.

[10] Eli Lilly claims that its argument is supported by a purposive interpretation of the NOC Regulations and, in particular, s. 5 which speaks to a generic manufacturer comparing its proposed

product to an innovator's product "in respect of which a patent list has been submitted". According to Eli Lilly, the interpretation adopted by the Minister creates an unbalanced scheme which operates unfairly on the interests of innovators particularly where, as here, there is a lengthy administrative delay between the submission of a patent list and the actual listing of a patent on the register by the Minister. Here that delay allowed at least one generic manufacturer to avoid having to address Eli Lilly's '712 Patent in its intervening NOA.

[11] Eli Lilly's argument is built upon a tenuous and isolated interpretation of the language of s. 5 of the NOC Regulations and a self-serving view of the overall legislative purposes of the NOC scheme.

[12] Subsection 3(2) of the NOC Regulations requires the Minister to maintain the patent register with the attendant authority to refuse to add or to delete any patent. In the exercise of that authority, the Minister is both entitled to consult with officials in the Patent Office and required to assess the eligibility criteria set out in s. 4 for adding a patent to the register. There is nothing in these provisions which even remotely supports Eli Lilly's argument that the Minister is entitled to list a patent on the register upon the filing of a patent list subject to later delisting if the eligibility requirements in s. 4 are not met.

[13] Eli Lilly relies heavily on the words in ss. 5(1) of the NOC Regulations requiring a generic manufacturer to address in its NOA any reference drug "in respect of which a patent list has been

submitted". This, it says, indicates that it is the date of the submission of the patent list by the innovator that dictates the patents that a generic manufacturer must address in its NOA.

[14] Eli Lilly's argument requires that the words "in respect of which a patent list has been submitted" be viewed in isolation from the surrounding language and from the overall legislative context. The operative language in ss. 5(1) are the words "with respect to each patent on the register". This or similar language is repeated throughout the NOC Regulations and, in particular, in ss. 5(4) which stipulates that a second person is not required in its NOA to address any patent that has not yet been "added to the register". There is no reference in this provision to a second person addressing patents that are included in a patent list filed with the Minister. Indeed s. 4 makes a very clear distinction between the innovator submitting its patent list to the Minister and the determination of the eligibility of a patent "to be added to the register". A patent cannot be added to the register before it is deemed eligible by the Minister.

[15] The obvious intent of these provisions is that the listing of a patent on the register is to be done contemporaneously with the Minister's determination of the patent's eligibility for listing. The effect of this is that, under ss. 5(4), a second person need not address any patent added to the register after the date of the second person's submission for a NOC under ss. 5(1) or ss. 5(2).

[16] There is no question that under the Minister's interpretation of s. 5 of the NOC Regulations the burden or risk created by the lapse of time between the filing of a patent list and the Minister's determination of eligibility under s. 4 falls on the innovator. But the legislative choice that is

inherent in these regulatory provisions cannot be regarded as unfair or imbalanced. It is simply a reflection of a policy which empowers the Minister to determine whether and when a patent is eligible for listing on the patent register thereby becoming the required subject of acknowledgement by a second person. The option asserted by Eli Lilly would create its own potential for mischief by making the innovator the initial arbiter of which patents must be addressed by the simple act of including a patent in a patent list filed with the Minister. Such an approach would require a second person to unnecessarily address patents which the Minister later determined were ineligible for listing on the register.

[17] The NOC Regulations are not and were not intended to be the solution for every point of conflict or clash of competing interests between innovators and their generic counterparts. The fact that a generic manufacturer may, in some cases, obtain a procedural advantage from the inherent delay between the filing of a patent list and the Minister's eligibility determination does not deprive the innovator of its substantive patent rights which can always be the subject of judicial enforcement.

IV. Conclusion

[18] There is no merit to Eli Lilly's argument. The Minister's interpretation of the applicable NOC Regulations was correct in law and the resulting decision under review in this proceeding is, accordingly, upheld. The Minister is entitled to costs payable under Column III.

JUDGMENT

THIS COURT ADJUDGES that this application is dismissed with costs payable to the Respondents under Column III.

" R. L. Barnes "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Mr. Jay Zakaib (613) 783-8806 Ms. Phuong Ngo (613) 783-8806	FOR THE APPLICANT
Mr. Rick Woyiwada (613) 941-2353	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Ottawa, ON,	FOR THE APPLICANT
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENTS