Federal Court  Cour fédérale

Date: 20130114

Docket: T-689-11

Citation: 2013 FC 28

Ottawa, Ontario, January 14, 2013

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

TEVA CANADA LIMITED AND THE MINISTER OF HEALTH

Respondents

and

ELI LILLY AND COMPANY AND TAKEDA PHARMACEUTICAL COMPANY LIMITED

Respondent Patentees

REASONS FOR JUDGMENT AND JUDGMENT

[1] This application was brought by Eli Lilly Canada Inc. (Lilly) under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations), seeking an Order prohibiting the Minister of Health (Minister) from issuing a Notice of Compliance (NOC) to Teva Canada Limited

(Teva) with respect to a generic version of Lilly's injectable pemetrexed disodium compound (Alimta) until the expiry of Canada Letters Patents 1,340,794 (the 794 Patent) and 2,400,155 (the 155 Patent). The application was initiated in response to a Notice of Allegation (NOA) delivered by Teva on March 11, 2011.

[2] Subsequent to the filing of this application, Teva established to the satisfaction of Lilly that its product would not infringe the 155 Patent. On the basis of that acknowledgement no Order of prohibition can be issued and the claim to relief with respect to the 155 Patent is moot.

[3] Between December 2011 and February 2012, Teva was granted three extensions to file its evidence in support of its allegation of invalidity concerning the 794 Patent. Teva failed to file its evidence and on March 5, 2012 it advised Lilly and the Court that it had withdrawn its NOA and Detailed Statement. Lilly, in turn, took the position that it was entitled to rely on the statutory presumption of the validity of the 794 Patent – a position that Teva does not dispute.

[4] The only remaining issue before the Court concerns the appropriate disposition of this application in the face of the above-described history. Lilly contends that it is entitled to an Order prohibiting the Minister from issuing a NOC to Teva until the expiry of the 794 Patent. Teva maintains that the application should be dismissed for mootness.

Analysis

[5] Lilly argues that the Regulations are a complete code of procedure for dealing with applications of this type and that they do not authorize or contemplate the withdrawal of a NOA

except in the limited circumstances provided for in subsection 5(6). According to Lilly, Teva is not entitled to maintain its submission to the Minister for a NOC in the face of the withdrawal of its NOA and it must also cancel that submission. Alternatively, it can amend its submission by advising the Minister that it will await the expiry of the 794 Patent.

[6] It seems to me that Lilly is over-reading subsection 5(6) of the Regulations. That provision requires a second person to revoke its NOA and for the judicial application to be discontinued in the face of either a notice from the Minister that the submission is non-compliant with the *Food and Drug Regulations*, CRC, c 870, or where the second person's submission to the Minister is cancelled. The provision does not imply that the second person cannot unilaterally withdraw its NOA subject, of course, to the right of the Court to dispose of the proceeding before it on appropriate terms including an award of costs. Indeed, the practice of withdrawing NOAs has been acknowledged many times by this Court, albeit with appropriate concerns about relitigation and abuse of process. This point was well expressed by Justice Marshall Rothstein in *Merck Frosst Canada Inc v Canada*, [1997] FCJ no 347 at para 23, (1997) 72 CPR (3d) 468, in the following passage:

> 23 Here, a second allegation is based upon what is said to be a different non-infringing process. While the Court must guard against abuse of its process, and clearly the successive filing and subsequent withdrawal of allegations could in some circumstances be abusive, I am not prepared to say that the mere withdrawing of an allegation is, for all purposes, abusive. Each case must be determined on its own facts and, in this case, it has not been argued and I have no reason to believe that the second notice of allegations is a duplication of the first. Therefore, I am not satisfied this is a case of abuse and that the matter is one of public importance which requires resolution of a moot application.

[7] In *Eli Lilly v Novopharm*, 2007 FC 596, [2007] FCJ no 800, Justice Roger Hughes also recognized that a second person may, in some circumstances, withdraw its NOA and proceed under another. There Justice Hughes relied, in part, on the Federal Court of Appeal decisions in *Pharmascience v Canada*, 2007 FCA 140, [2007] FCJ no 506, and in *AstraZeneca v Apotex*, 2005 FCA 183, [2005] FCJ no 842.

[8] While I accept that the Regulations are a complete code of procedure, I do not agree that, in the face of this Court's jurisprudence, subsection 5(6) can be interpreted as expansively as Lilly contends. If the provision was intended to restrict the practice of withdrawing a NOA or to ensure the concurrency of the ministerial and patent review processes it could easily have said so. Instead, subsection 5(6) expressly states that a second person may file its NOA "on or after" it makes its submission to the Minister. This does not imply any temporal limitation on a second person once its NOC submission is filed. It is left up to the second person to decide when to file its NOA bearing in mind that any delay in doing so could well be financially disadvantageous.

[9] The question, then, is not whether Teva had the right to withdraw its NOA in this case. Clearly it did. The issue before the Court is whether the withdrawal of Teva's NOA, without more, renders this application moot or alternatively whether there remains a non-speculative and meaningful point of controversy between the parties: see *Borowski v Canada*, [1989] 1 SCR 342, [1989] SCJ no 14.

[10] Lilly argues that it would be improper and unjust to permit a second person to withdraw its NOA and Detailed Statement solely to overcome its failure to file evidence. That, of course, is the

kind of abuse of process concern that has been identified in a number of previous cases including *Schering Canada Inc. v Nu-Pharm Inc.*, [1994] FJC no 1396 at para 22, 58 CPR (3d) 14. In this case, however, there is no clear evidence as to what motivated Teva's decision and there has been no attempt by Teva to file a second NOA. At this stage it is speculative to infer any improper or ulterior motive on the part of Teva, or to assume that it will in the future attempt to file a second NOA. Suffice it to say that any attempt by Teva to circumvent the unmet disclosure obligations in this proceeding is likely to be met with some judicial scepticism.

[11] Lilly's concern about its potential exposure to section 8 damages by virtue of Teva's so-called "manipulation" of the system is equally untenable. That risk is based on an assumption that Teva will improperly file a second NOA that will withstand an abuse of process challenge and that the Court will be unmindful of its obligations under subsection 8(4) and 8(5) of the Regulations. This is the type of concern that was rejected by the Federal Court of Appeal in *Sanofi-Aventis v Apotex*, 2006 FCA 328, [2006] FCJ no 1493, as being too remote and speculative to justify a hearing. The same reasoning applies in this case.

[12] Lilly's added concern about the possibility of the Minister issuing a NOC to Teva despite the withdrawal of its NOA is unfounded. That is not an outcome permitted by section 7 of the Regulations. The withdrawal of a NOA renders the second person's submission to the Minister for a NOC non-compliant, and section 7 directs that the Minister not issue a NOC in such circumstances. This was not lost on the Minister in this case. In a letter to Teva dated March 5, 2012 the Director of Patented Medicines and Liaison for Health Canada acknowledged the withdrawal of Teva's NOA and stated that "[a] Notice of Compliance (NOC) will not be issued

until the requirements of the [Regulations] are met". This concern is not a basis for "prohibiting the Minister from doing that which [she] is already prohibited from doing according to the Regulations": see *AB Hassle v Canada*, [1997] FCJ no 280 at para 12, (1997) 72 CPR (3d) 318. To the same effect is the Federal Court of Appeal decision in *AB Hassle v Canada*, [1999] FCJ no 1464, (1999) 3 CPR (4^{th}) 73, where the Court stated at paragraph 11 that "[a]bsent evidence in a given case that the Minister is prepared to ignore his legal duties and exceed his jurisdiction, the Court should not embark on the hearing of a prohibition application. The time of the Court is better spent deciding live issues". Although that case involved a situation where the NOC submission had also been withdrawn, nothing of significance to the outcome turned on that point. Similar comments can be found in *Bayer v Novopharm*, [1997] FCJ no 1785 at para 20, 142 FTR 130.

[13] Although I do not doubt that this Court could issue an Order of prohibition in circumstances similar to these, the weight of authority indicates that it is generally undesirable to do so and that it is preferable to deal with abuse of process concerns as and when they arise: see for example Justice Marc Nadon's decision in *AB Hassle v Canada*, [1997] FCJ no 280, (1997) 72 CPR (3d) 318, and the cases cited therein, and the Federal Court of Appeal decision in *AB Hassle v Canada*, [1999] FCJ no 1464, 3 CPR (4^{th}) 73.

[14] In short, there is no live issue between the parties and the present application is therefore moot. There is no reason to depart from the usual disposition of moot cases, which is to dismiss the proceeding on that ground.

[15] The parties have requested an opportunity to address the issue of costs in light of these reasons. Lilly will have 14 days to file a submission on costs and Teva may reply within 7 days thereafter. Neither submission shall exceed 7 pages in length.

JUDGMENT

THIS COURT'S JUDGMENT is that this application is dismissed with the issue of costs to be reserved.

"R.L. Barnes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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