Date: 20090323

Docket: T-575-08

Citation: 2009 FC 251

Ottawa, Ontario, March 23, 2009

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

PFIZER CANADA INC., PFIZER LIMITED and PFIZER RESEARCH AND DEVELOPMENT COMPANY, NV/SA

Applicants

and

PHARMASCIENCE INC. and THE MINISTER OF HEALTH

Respondents

AMENDED REASONS FOR ORDER AND ORDER

[1] This is an appeal by Pfizer Canada Inc., Pfizer Limited and Pfizer Research and Development Company, NV/SA (collectively referred to as Pfizer) from a Prothonotary's decision which denied a motion for production of documents that Pfizer says are necessary and relevant to the prosecution of its Notice of Compliance (NOC) application. This proceeding arises from the second of two motions by Pfizer seeking production of essentially the same material. The initial motion was dismissed by Prothonotary Kevin Aalto whose decision was upheld on appeal by Justice Russel Zinn.

I. Background

[2] Pharmascience Inc. served its Notice of Allegation (NOA) on Pfizer on February 22, 2008 in respect of Pfizer's 1,321,393 and 2,170,278 Patents, which concern the drug product Norvasc (amlodipine besylate). Pfizer responded with an application under the NOC Regulations seeking an order prohibiting the Minister of Health (Minister) from issuing a NOC to Pharmascience until the expiry of those patents. Pharmascience responded with a motion of dismissal under ss. 6(5)(a) and (b) of the NOC Regulations on the basis of allegations of non-infringement and ineligible listing.

[3] Pfizer initially sought production of a range of documents that were ostensibly relevant to an argument that the Minister may have erred in his treatment of Pharmascience's new drug submission. Pfizer brought a motion for production of several documents which it asserted were necessary "to make its case regarding the adequacy of Pharmascience's drug submission". It is clear from the record that this motion was more narrowly framed than Pfizer's initial letter of May 5, 2008 to Pharmascience which had demanded these documents also on the basis of their claimed relevance to Pharmascience's allegation of non-infringement. I have no evidence before me to indicate why Pfizer later framed its initial motion as narrowly as it did and without any obvious reference to the substantive issue of non-infringement.

[4] In Pfizer's initial motion to produce, Prothonotary Aalto examined the issue of relevance in the context of allegations concerning the actions of the Minister. He also considered the issue of

their relevance to the substantive issue of non-infringement. This is evident from the following passage from his decision:

> It is the Notice of Allegation that defines the issues to be determined in the proceedings under the Regulations. The Notice of Allegation in this case deals with validity and infringement and not with matters of safety and efficacy [see s.5 of the Regulations; and, see also, *Fournier Pharma Inc. v. Canada (Minister of Health)* 2004 FC 1718 at pars. 6 and 8; and, *Bayer, supra*.]. Pharmascience has provided Pfizer with relevant portions of the Pharmascience NDS for the Pharmascience product in issue. Those documents disclose, among other things, the drug substance, manufacturer name, the specifications for the drug substance, the manufacturing process and stability protocols for that product. Pharmascience has also provided a copy of its product monograph. Those are obviously necessary, relevant and important documents.
>
> In the circumstances of this case I am not persuaded that the additional extensive of array of documents sought by Pfizer are either necessary, relevant or important for Pfizer to be able to assert its position in this proceeding. There is a pending motion by Pharmascience under section 6(5) of the Regulations. The issues raised on that motion relate to whether or not the drug product of Pharmascience is the same as the drug product of Pfizer and estoppel. The documents sought by Pfizer are also not relevant to the issues raised on that motion. In the end result the motion is dismissed. […]

[5] Prothonotary Aalto's decision was appealed and the appeal was heard by Justice Zinn: see *Pfizer Canada Inc. et al. v. Pharmascience Inc. et al.*, 2008 FC 950. Justice Zinn recognized that Prothonotary Aalto's decision was not limited to the relevance of the requested documents to the actions of the Minister but also included the question of their relevance to the substantive issues raised in Pharmascience's NOA. According to Justice Zinn's decision, Pfizer argued before him that Prothonotary Aalto had erred by characterizing the requested documents as being directed to

issues of product safety and efficacy (see para. 16). Justice Zinn dismissed the appeal on the basis that the documents were not relevant to any issue arising in the proceeding (see para. 18).

[6] Pfizer then brought a second motion for production of substantially the same documents requested in its first motion. This second production motion was based on evidence and argument that the documents were relevant to the substantive issue of non-infringement and that an order ought to issue accordingly. Prothonotary Martha Milczynski heard Pfizer's second motion and dismissed it. Her reasons for doing so are contained in the following passage from her Order:

> Pharmascience resists, as it did in the first motion, to provide any information regarding the process for making the raw material, a description of the manufacturing process, process development or composition of the dosage form and its components. Pharmascience argues that the Applicants sought and were denied this information in the first production motion, and even if there were new documents sought, Pharmascience argues that such requests could have and ought to have been pursued in the first motion. I must agree. The present motion is in effect, the Applicants' "second bite at the cherry" and must be denied.
>
> Particularly in the case of applications under the PMNOC Regulations, motions for production, even if they seek different things (which I am not satisfied is the case here), cannot be brought on a serial or piecemeal basis. Applications under the PMNOC Regulations are summary proceedings and must be heard and determined within the two year period set out. There is no time for multiple production motions and the added complexity and inevitable delay such practice would entail. As set out by the Supreme Court of Canada in *Danyluk v. Ainsworth Technologies Inc.*, 2001 SCC 44, paras. 18-20:
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> > The law rightly seeks a finality to litigation. To advance that objective, it requires litgants [sic] to put their best foot forward to establish the truth of their allegations when first called upon to do so. A litigant, to use the vernacular, is only entitled to one bite at the cherry.

A person should only be vexed once in the same cause.

It is from this decision that the Applicants appeal.

II. Issues

[7] Did the Prothonotary err in her decision to refuse Pfizer's motion for production of documents?

III. Analysis

[8] It is not entirely clear to me that Pfizer fully articulated its relevancy argument in its initial production motion before Prothonotary Aalto. Nevertheless, Pfizer cannot now assert that it overlooked the issue of substantive relevancy on that motion because it initially requested production from Pharmascience on that broader basis in its letter of May 5, 2008. It has also produced no evidence to explain why it so narrowly framed its initial motion when it was apparently of the view that the same documents were relevant to the non-infringement issue.

[9] I can identify no error in Prothonotary Milczynski's decision in the application of her discretion to refuse relief on the basis of issue estoppel or on the alternative ground of abuse of process by re-litigation. In matters such as this an applicant is expected to put its best and strongest case forward at first instance and it should not be permitted to split its argument if it loses on the first attempt. While I accept that these rules may not always be rigidly enforced in the context of interlocutory motions, there should be some explanation offered where the initial motion was not

exhaustive. In these circumstances I would not be disposed to exercise my discretion any differently for exactly the same reasons given by Prothonotary Milczynski.

[10] I also agree with Pharmascience that Pfizer's second motion for production amounts to a collateral attack on the Order of Justice Zinn. Justice Zinn ruled that the requested documents were not relevant to any of the issues arising in the underlying application. Whether or not that finding exceeded the scope of the motion before him, it nevertheless represented a finding that should be addressed on appeal and not effectively challenged with a second motion claiming the same relief.

[11] I would add that I do not find the evidence of Dr. Stephen Byrn to provide a compelling case for the relevancy of these documents. The evidence of Dr. Alexander Klibanov seems to be sufficient to establish that Pfizer's claim amounts to no more than unlikely speculation or, in the vernacular, "a fishing expedition": also see the decision of Prothonotary Aalto in *Pfizer v. Apotex* (T-876-08 and T-886-08) dated February 10, 2009.

[12] In the result, this motion is dismissed.

ORDER

THIS COURT ORDERS that this motion is dismissed.

" R. L. Barnes "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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