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T-442-96

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BETWEEN:

**PFIZER CANADA INC. and
UCB PHARMA, INC.,**

Applicants,

and

**APOTEX INC. and
THE MINISTER OF NATIONAL HEALTH AND WELFARE**

Respondents

REASONS FOR ORDER

WETSTON J.:

This motion involves an appeal from a decision of the Associate Senior Prothonotary, dated May 28, 1997, disallowing the applicants' motion to amend an originating notice of motion. By motion dated April 24, 1997, the applicants sought to amend the originating notice of motion by adding an allegation questioning the validity of the Notice of Allegation which had been served before a New Drug Submission for a Notice of Compliance had been filed with the Minister. The April 24th motion was brought just over one year after the commencement of these proceedings. The applicants submit that the motion was brought at that time when certain information came to light indicating that generic companies often served Notices of Allegation before filing submissions for Notices of Compliance.

In his decision, the Associate Senior Prothonotary ("ASP") noted that the failure of a generic company to file a New Drug Submission ("NDS") for a Notice of Compliance prior to serving a notice of allegation could be fatal to the notice of compliance application; however, that issue was not a matter to be finally determined on an interlocutory motion. The ASP further commented on the evidence of Dr. Sherman before a House of Commons committee that many generic companies served the Notice of Allegation before filing a NDS. He found that there was no evidence that this had occurred in the case at bar. As a result, the applicants' motion was denied.

BD

The standard of appeal for a court reviewing the decision of a prothonotary emanates from the discretionary nature of the prothonotary's decision. Such a decision should not be disturbed unless it can be shown that the decision was clearly wrong, that is, that the exercise of the discretion was based on a wrong principle or a misapprehension of the facts, or that the decision raised questions vital to the final issue in the case: *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 (F.C.A.). If either is demonstrated a presiding judge may exercise his or her discretion *de novo.*

The applicants submit that the ASP made a number of errors. It is submitted that he applied a principle relating to striking a pleading, he required evidence to prove the issue raised in the proposed amendment and that, in any event, there was sufficient evidence before him to support the proposed amendment. The applicants also submit that the proposed amendment raised a question vital to the final issue in this case.

In my opinion, the proposed amendment does raise a question vital to the final issue in the case and, therefore, it would be appropriate to exercise my discretion *de novo*. There is no question that the court has the power to allow the amendment of an originating notice of motion: *SNC-Lavalin inc. v. Canada (Minister of Public Works)* (1994), 79 F.T.R. 113 at page 122. The test for amending an originating notice motion under rule 303 is, among other things, whether the amendments are necessary for the purpose of determining the real question or questions in controversy between the parties.

The question of whether a NDS is required to be filed before a notice of allegation can be served on the patentee has not been definitely determined by the Court. Moreover, it has been the subject of differing judicial opinion in this Court: *Merck Frosst Canada Inc. v Canada (Minister of National Health and Welfare)*, unreported, T-1312-96, February 28, 1997; *Merck Frosst v Minister of National Health and Welfare* (1996), 65 C.P.R. (3d) 483. While these proceedings are administrative in nature, compliance with the regulations may have a bearing on the ultimate outcome of the case.

The ASP noted that no amendment should be allowed where it could be defeated in a motion to strike. Generally I agree, but it has been held that the circumstances in which this court will strike an originating notice of motion will be rare and only where it is clearly so improper as to be bereft of any possibility of success: *Pharmacia Inc. v Minister of National Health & Welfare* (1994), 58 C.P.R. (3d) 209 at page 217.

The respondent argued that amendments should be based upon evidence, not mere speculation, otherwise there is no real question in controversy. In this case, the applicants specifically asked Dr. Sherman a number of questions regarding when the NDS was filed but Dr. Sherman refused to answer. Moreover, Dr. Sherman stated before the Standing Committee on Industry, dated March 5, 1997, that there has been a practice by generic companies to serve the notice of allegation before the NDS has been filed.

In my opinion, the proposed amendment should be permitted. This would allow a question which is controversial as between the parties to be argued at the hearing of this matter on the merits. Moreover, I see no prejudice to the respondent by allowing the amendment at this time.

Accordingly, the appeal shall be allowed and leave to amend shall be granted.

Howard I. Wetston

Judge

Ottawa, Ontario
July 25, 1997

FEDERAL COURT OF CANADA
TRIAL DIVISION

NAMES OF SOLICITORS AND SOLICITORS ON THE RECORD

COURT FILE NO.:	T-442-96
STYLE OF CAUSE:	Pfizer Canada Inc. et al. v. Apotex Inc. et al.
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	July 22, 1997
REASONS FOR ORDER OF:	The Honourable Mr. Justice Wetston
DATED:	July 25, 1997

APPEARANCES:

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