



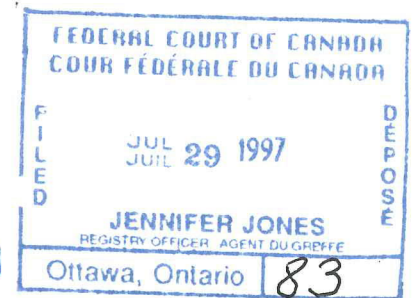
T-1713-95

Ottawa, Ontario, the 24th day of July 1997

Present: The Honourable Mr. Justice Wetston

BETWEEN:

PFIZER CANADA INC. and  
PFIZER CORPORATIONS



Applicants,

- and -

NU-PHARM INC. and  
THE MINISTER OF NATIONAL HEALTH AND WELFARE

Respondents.

**ORDER**

The motion is granted in part. The Originating Notice of Motion is amended to include in paragraph 6:

- 1) The process disclosed in this proceeding ("the Subsequently Disclosed Process") for use in producing fluconazole was not identified to or filed with the Respondent Minister of National Health and Welfare ("the Minister") in a New Drug Submission or Abbreviated New Drug Submission ("NDS") of Nu-Pharm, at the date of its Notice of Allegation, at a date 46 days after its service, or at all. As such, that process does not form part of the New Drug Submission of Nu-Pharm and cannot form the basis of its allegations or a Notice of Allegation. As a result, the allegations in the Notice of Allegation cannot be true and are not justified, and the Notice of Allegation failed to comply with the *Regulations* and is a nullity.
- 2) At the date of service of the Notice of Allegation, the Applicants were not informed of any process filed with the Minister or that any NDS relating to fluconazole or containing the Subsequently Disclosed Process had been filed at that date. At the date of service of the Notice of Allegation, Nu-Pharm had not filed with the Minister any NDS for fluconazole or any NDS containing the Subsequently Disclosed Process and had not complied, and could not comply, with the provisions of section 5(1) of the *Regulations*. As a result, the allegations are a nullity and are not justified.

Judge



T-1713-95

**BETWEEN:**

**PFIZER CANADA INC. and  
PFIZER CORPORATION**

**Applicants,**

**- and -**

**NU-PHARM INC. and  
THE MINISTER OF NATIONAL HEALTH AND WELFARE**

**Respondents.**

**REASONS FOR ORDER**

**WETSTON J.**

This is a motion on behalf of the applicants to amend the originating notice of motion. The applicants seek to add as grounds that: 1) the respondent has failed to provide evidence that the process alleged in the notice of allegation is the same as the process in the New Drug Submission; 2) the respondent has failed to provide a detailed statement of the legal and factual basis and has not complied with the regulations; 3) the process described in the notice of allegation was not filed with the Minister of National Health and Welfare at the date of the notice of allegation or at any point thereafter; and, 4) the respondent had not filed an NDS with the Minister prior to serving the notice of allegation and had not, therefore, complied with section 5(1) of the Regulations.

By virtue of rule 303 this Court has the authority to amend any document, including 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 a notice of motion under rule 303 is whether the amendments are, among other things, necessary for the purpose of determining the real question or questions in controversy between the parties.

In regards to the proposed first amendment, I am satisfied the regulations do not require the respondent, in the manner suggested by the applicants, to

provide evidence that the process in the NDS and the notice of allegation are the same. Indeed, the Court of Appeal has stated in *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302, at 319:

Furthermore, since the regulations clearly allow the Minister, absent a timely application under s. 6, to issue a notice of compliance on the basis of the allegations in the notice of allegation, it would seem that on the hearing of such an application, at least where the notice has alleged non-infringement, the court should start from the proposition that the allegations of fact in the notice of allegation are true except to the extent that the contrary has been shown by the applicant. In determining whether or not the allegations are "justified" (s. 6(2)), the court must then decide whether, on the basis of such facts as have been assumed or proven, the allegations would give rise in law to the conclusion that the patent would not be infringed by the respondent.

I am not satisfied, therefore, that this raises a real question in controversy between the parties.

The applicant also cannot succeed on the second proposed amendment. The respondent did file a "detailed statement of the legal and factual basis" for the allegation. Whether this statement is sufficient will be considered by the hearing judge in determining if the facts presented support the allegation of non-infringement.

The third proposed amendment is essentially an allegation that the respondents do not have a novel process for which they have applied for a Notice of Compliance. The question at this stage is not whether there is evidence to support this allegation but, rather, whether this is a real issue in controversy between the parties. I am satisfied that an amendment in this regard is warranted.

The fourth proposed amendment relates to an allegation that the New Drug Submission had not been filed at the time the notice of allegation was filed and renders, therefore, the notice of allegation invalid. There have been divergent decisions of this court regarding the interpretation of the Regulations regarding the timing of filing New Drug Submissions: *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. Compliance with the regulations may have a bearing on the outcome of the case and this is, therefore, a real issue in controversy between the parties. This amendment shall be permitted.

Accordingly, the motion shall be granted in part.

Howard I. Wetston

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Judge

Ottawa, Ontario  
July 24, 1997