



T-421-97

OCT 23 1997

BETWEEN:

FAULDING CANADA INC.

Plaintiff

- and -

PHARMACIA S.p.A.

Defendant

REASONS FOR ORDER

JEROME, A.C.J.:

This action seeks the impeachment of Canadian Patent No. 1,291,037. The defendant brings a motion appealing a portion of an Order rendered by the Associate Senior Prothonotary on July 16, 1997 which declined to strike out the statement of claim, either in whole or in relation to paragraphs 6 to 9, 15, 18, 19, 20 and 32 thereof. In the alternative, the defendant seeks certain particulars allegedly in relation to the plaintiff's standing to bring this action as a "person interested" pursuant to section 60 of the *Patent Act*, namely the formulation of the plaintiff's proposed pharmaceutical preparation which is currently subject of a confidential application for regulatory approval, pending before the Minister of Health.

The test for establishing standing as a "person interested" to impeach a patent was laid down by the Supreme Court of Canada in *Bergeron v. De Kermor Electric Heating Co. Ltd.*, [1926] S.C.R. 72 at 75:

Indisputably, the existence of the patents attacked was calculated directly to affect the appellant prejudicially in his business as a manufacturer and trader, and both in the prosecution of his application and in respect of the protection to be afforded him by his patent if his application for patent should be successful. In these circumstances,

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there seems little room for doubt that the appellant possessed a sufficient "interest", within the meaning of rule 16, to qualify (sic) him to maintain the action...

The plaintiff claims standing because the existence of the patent in suit blocks the plaintiff from obtaining the requisite regulatory approval from the Minister of Health enabling it to market a pharmaceutical preparation in the dosage form of a ready to use solution containing the active ingredient doxorubicin hydrochloride, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*. The patent in suit is directed to "... a stable intravenously injectable ready to use solution of an anthracycline glycoside, e.g. doxorubicin..."

I also consider it significant that the defendant (and/or its predecessor Farmitalia Carlo Erba s.r.l.) and its licensee Pharmacia Inc. sought to enforce the patent in suit (CA 1,291,037) against the plaintiff (then known as David Bull Laboratories (Canada) Inc.) during previous judicial review proceedings brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, in respect of the plaintiff's application for a notice of compliance for the drug doxorubicin. Even though no allegation had been made by the plaintiff in respect of the '037 patent, the defendant still sought a prohibition order barring the grant of a notice of compliance to the plaintiff until expiry of the '037 patent. The relief sought was refused by the Court on jurisdictional grounds.

In my view, therefore, the learned Prothonotary reached the proper conclusion here. More importantly, having in mind the principles set out by the Federal Court of Appeal in *Canada v. Aqua-Germ Investments Ltd.* [1993] 2 F.C. 425, the applicant has not persuaded me that Giles A.S.P. has erred.

For these reasons, the motion by way of appeal of the decision of Giles, A.S.P.
is dismissed with costs.

O T T A W A

October 6, 1997

"James A. Jerome"
A.C.J.

FEDERAL COURT OF CANADA
TRIAL DIVISION

NAMES OF SOLICITORS AND SOLICITORS ON THE RECORD

COURT FILE NO.: T-421-97
STYLE OF CAUSE: FAULDING CANADA INC. V. PHARMACIA S.p.A.
PLACE OF HEARING: TORONTO
DATE OF HEARING: AUGUST 11, 1997
REASONS FOR ORDER OF THE ASSOCIATE CHIEF JUSTICE
DATED: OCTOBER 6, 1997

APPEARANCES:

SUSAN D. BEAUBIEN FOR PLAINTIFF
SHONAGH L. McVEAN FOR DEFENDANT

SOLICITORS OF RECORD:

SHAPIRO, COHEN, OTTAWA, FOR PLAINTIFF
SMART & BIGGAR, TORONTO, FOR DEFENDANT

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