Date: 20070215

Docket: A-83-06

Citation: 2007 FCA 73

CORAM: **LÉTOURNEAU J.A.**
SEXTON J.A.
EVANS J.A.

BETWEEN:

ABBOTT LABORATORIES and
ABBOTT LABORATORIES LIMITED

Appellants
(Applicants)

and

THE MINISTER OF HEALTH and
PHARMASCIENCE INC.

Respondents

Heard at Toronto, Ontario, on February 15, 2007.

Judgment delivered from the Bench at Toronto, Ontario, on February 15, 2007.

REASONS FOR JUDGMENT OF THE COURT BY: EVANS J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on February 15, 2007)

EVANS J.A.

[1] This is an appeal by Abbott Laboratories and Abbott Laboratories Ltd. ("Abbott") from a decision of a Judge of the Federal Court dismissing Abbott's application for an order of prohibition under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("Regulations"). The order restrained the Minister of Health from issuing a Notice of Compliance ("NOC") to

Pharmascience Inc. in respect of its drug containing crystalline form II of the molecule clarithromycin.

[2] Clarithromycin is polymorphic, that is, it can be arranged in different crystal forms which have different properties. Abbott holds Canadian Patent No. 2,277,274 ("'274 patent") for the invention of form 0 clarithromycin. This patent is listed on the register against Abbott's drug, BIAXIN®, an antibiotic used to treat infections, which contains form II clarithromycin. It is the product with which Pharmascience compared its drug, which also contains form II clarithromycin, when it made its Abbreviated New Drug Submission to the Minister for a NOC.

[3] The Applications Judge held that Pharmascience's Notice of Allegations ("NOA") was justified when it stated that its clarithromycin product would not infringe Abbott's '274 patent, because, in its finished state, Pharmascience's product contains only form II clarithromycin. The fact that form 0, claimed by the patent, was produced at an intermediate stage in the manufacturing process of the Pharmascience product did not bring it within paragraph 5(1)(*b*) of the *Regulations*. The Judge's decision, dated February 2, 2006, is reported as *Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 120, [2006] 4 F.C.R. 41.

[4] On May 18, 2006, this Court released its decision in *Abbott Laboratories v. Canada (Minister of Health)*, 2006 FCA 782, 350 N.R. 242 ("*Ratiopharm*"), which also involved the '274 patent, an Abbott comparator drug called Biaxin Bid and a "copycat" drug containing form II clarithromycin, produced by generic drug manufacturer, Ratiopharm, Writing for the Court,

Sharlow J.A. held that the making of form 0 clarithromycin in the intermediate stage of the process was within the scope of subparagraph 5(1)(*b*)(iv) of the Regulations, even though only form II was present in Ratiopharm's finished product.

[5] Counsel for Pharmascience in the present case argued that *Ratiopharm* was distinguishable, because many of the claims in the '274 patent, especially claim 1, claimed "a crystalline antibiotic … form 0 solvate." Properly construed, she said, the patent was limited to claims for form II clarithromycin when prepared for use as an antibiotic, and was not a "stand alone" claim for form II clarithromycin in itself, regardless of use. Accordingly, counsel submitted, Pharmascience's product did not infringe the '274 patent, because its form 0 was only an intermediate and was not used, or intended for use, as an antibiotic.

[6] We do not agree. This issue was considered by the Applications Judge who, assisted by expert witnesses, concluded that a person skilled in the art would understand "antibiotic" in the claims in the '274 patent as claims for a substance with antibacterial activity, independent of its intended use. Counsel for Pharmascience conceded that form 0 could be ingested, and would be effective as an antibiotic. We are not persuaded that the Judge improperly abdicated to experts his responsibility to construe the patent, or that, on the basis of the evidence before him, he made a palpable and overriding error in his conclusion.

[7] Nor are we persuaded that the Judge erred in finding that the '274 patent was a claim "for the medicine itself" for the purpose of subsection 5(1)(*b*)(iv) of the Regulations, as defined by subsection 2(1),

prior to the recent amendments to the Regulations by SOR/2006-242. There was ample evidence before the Applications Judge to support his finding that clarithromycin, and its forms, is "the medicine itself".

[8] Finally, we decided not to consider an argument which counsel for Pharmascience made for the first time at the hearing of the appeal. She argued that the Supreme Court of Canada's decision in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, released on November 3, 2006, implicitly reversed *Ratiopharm.*

[9] This issue had not been raised in the NOA or before the Applications Judge (*AstraZeneca* was decided after these events). Nor was it mentioned in Pharmascience's memorandum of fact and law, which could have been supplemented. Indeed, although *AstraZeneca* was decided three months before this appeal was heard, counsel gave no notice whatsoever to counsel for Abbott of her intention to advance this argument at the hearing. In these circumstances, it would be unfair to Abbott, and to the Court, if we had to decide this issue on its merits. We would only note that, after the release of *AstraZeneca*, the Supreme Court refused leave to appeal the *Ratiopharm* decision (Court File No. 31578, February 8, 2007).

[10] For these reasons, the appeal will be allowed, with costs here and below, the decision of the Federal Court will be set aside, and an order of prohibition will be granted restraining the Minister, until the expiry of the '274 patent, from issuing a Notice of Compliance to Pharmascience for clarithromycin 250 mg tablets.

"John M. Evans"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-83-06

(APPEAL FROM AN ORDER OF THE HONOURABLE MR. JUSTICE HARRINGTON, FEDERAL COURT, DATED FEBRUARY 2, 2006, T-433-04 & T-835-04)

STYLE OF CAUSE: ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED v. THE MINISTER OF HEALTH and PHARMASCIENCE INC.

PLACE OF HEARING: Toronto, ON

DATE OF HEARING: February 15, 2007

REASONS FOR ORDER BY: Evans, J.A.

DATED: February 15, 2007

APPEARANCES:

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Carol Hitchman Paula Bremner	For the Respondent, Pharmascience Inc.

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