Date: 20070803

Docket: T-585-06

Citation: 2007 FC 817

OTTAWA, ONTARIO, AUGUST 3, 2007

PRESENT: The Honourable Mr. Justice Harrington

BETWEEN:

ABBOTT LABORATORIES LIMITED
TAP PHARMACEUTICALS INC.

Applicants

and

THE MINISTER OF HEALTH, APOTEX INC.
and TAKEDA PHARMACEUTICAL COMPANY LIMITED

Respondents

REASONS FOR ORDER AND ORDER

[1] Evidence in applications, which are supposed to be more streamlined and simpler than trials, is normally by way of affidavit and cross-examination thereon. The applicant files its affidavits, followed by the other parties.

[2] Additional affidavits are not permitted, unless the Court grants leave under Federal Courts Rule 312. The Applicants (collectively "Abbott") moved for leave to file affidavits from five

experts in reply to the affidavits filed by the Respondent Apotex. Prothonotary Tabib granted Abbott leave to file part of one affidavit, but refused the other four. This is an appeal from her order, limited to one affidavit, that of Dr. Peter Unge.

[3] The Applicants, Abbott as agent and TAP as Takeda's Canadian licensee, market a drug known as Prevacid®. It is used to treat gastrointestinal ailments such as ulcers caused by the bacterium H. pylori. Its active pharmaceutical ingredient is lansoprazole. Takeda is the owner of Canadian patent 2,009,741 ('741) which claims various antibacterial uses thereof.

[4] Apotex has sought permission from the Minister of Health to market its generic version of lansoprazole. Abbott responded by applying for an order from this Court prohibiting the Minister from granting approval in the form of a Notice of Compliance ("NOC") until patent '741 expires. The battleground is the *Patented Medicines (Notice of Compliance) Regulations*.

[5] These regulations have been intensely litigated and have been considered by the Supreme Court in such cases as *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, 39 C.P.R. (4th) 449 and *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, 80 C.P.R. (3d) 368. More recently, Mr. Justice Hughes recapitulated their history in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, [2007] F.C.J. No. 420 (QL).

[6] Suffice it to say the Regulations came into play when Apotex served a Notice of Allegation ("NOA") in which it alleged that its generic version of lansoprazole would not infringe upon the patent, which in any event is invalid. The next step was for Abbott to apply for the said prohibition order and to file various affidavits which it hopes will ultimately support its position that Apotex's allegations are not justified.

[7] The Regulations require Takeda, as the holder of the patent, to be added as a party. Takeda, which asserts its patent is valid, also filed affidavits, followed by Apotex's affidavits. As is customary, the Minister takes no position.

[8] The evidence from Dr. Peter Unge which Abbott proposes to file relates to Apotex's allegation that patent '741 is invalid on the grounds of obviousness and lack of invention. In that connection, Apotex not only cited but reproduced in full an abstract from Dr. Unge and others entitled "Does Omeprazole 40mg. o.m. Improve Antimicrobial Therapy Directed Towards Gastric *Campylobacter pylori* in Patients with Antral Gastritis?" which had been published in November 1988. (For the purposes of the motion, Abbott suggests that no distinction need be drawn between lansoprazole and omeprazole, and between H. pylori and C. pylori.)

[9] Apotex had filed an affidavit from Dr. David Graham in which he offers an opinion as to what the "Unge Abstract" teaches. It is Abbott's position that Dr. Graham went far beyond the allegations in the NOA. Accordingly, it moved to file an affidavit from Dr. Unge himself.

THE DECISION UNDER APPEAL

[10] The motion before Prothonotary Tabib covered 15 different issues. It is important to keep in mind that the appeal is limited to her refusal to let Dr. Unge file an affidavit. Abbott submits that only two paragraphs of her order are essential to this appeal.

[11] After noting that Abbott had filed affidavits from 12 expert witnesses-in-chief, and now wanted to file five additional expert affidavits, she said:

> While the determinations I have made with respect to whether leave should be granted to file the various affidavits or parts thereof are essentially based on whether the material is necessary, would assist the Court in determining the issues before it or was available at an earlier date, the fact that the Applicants may well already have exceeded the limits provided in Section 7 of the *Canada Evidence Act* as to the number of experts they may call on any one issue, without having sought prior leave, and the significant delay on the part of the Applicants in bringing the present motion have been generally weighed in considering whether granting leave would serve the interests of justice or might cause prejudice to the other party. (See: *Eli Lilly Canada Inc. v. Novopharm Ltd. et al.*, 2007 FC 596 at par. 5 to 7; *Pharmascience Inc. v. Canada (Minister of Health),* 2007 FCA 140 at par. 41 and *Altana Pharma et al. v. Novopharm Ltd. et al.*, 2007 FC 637.)

[12] In regards to the Unge Abstract, she said:

> The importance of the Unge Abstract was well understood from the NOA and several experts, including Abbott's, but also Takeda's, comprehensively discussed whether the Unge Abstract teaches or suggests the use of lansoprazole as an antibacterial agent. There is nothing that could not have been anticipated in paragraph 139 of Dr. Graham's affidavit. With respect to the "no need for further testing," I can't find that the NOA's allegation of obviousness does not include this as part of the test. To the extent the personal evidence of Dr. Unge is relevant to understanding the Unge Abstract, its necessity or usefulness was foreseeable. Leave to file reply is refused.

ISSUES IN APPEAL

[13] Federal Courts Rule 51 provides that prothonotaries' orders may be appealed to a judge of this Court. What is the standard on appeal given that an order might arise from a finding of fact, a conclusion in law, or be discretionary in nature?

[14] Likewise, Rule 312 itself gives no guidance as to the circumstances in which leave to file additional affidavits should be granted. Did the Prothonotary exercise her discretion on judicial principles?

DISCUSSION

[15] The Prothonotary's order was discretionary in nature. It has been clearly established that such orders should stand unless the questions raised in the motion are vital to the final issue in the case, or the order was clearly wrong in the sense that the discretion was based upon a wrong principle or a misapprehension of the facts (*Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, [2003] 1 S.C.R. 450; *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459 and *R. v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425, [1993] F.C.J. No. 103). Her order was not, nor could it have been, vital to the final issue (*Fieldturf Inc. v. Winnipeg Enterprises Corp.*, 2007 FCA 95, [2007] F.C.J. No. 334 (QL)). It follows that her order stands unless clearly wrong.

[16] Turning now to Rule 312, this Court has held that in exercising discretion to allow the filing of additional evidence, a four-part conjunctive test must be considered: a) whether the further

evidence serves the interests of justice; b) whether the further evidence will assist the Court; c) whether granting the motion will cause substantial or serious prejudice to the other side and d) whether the evidence was not available or could not have been anticipated as being relevant at an earlier date (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 984, [2006] F.C.J. No. 1243, Teitelbaum J. and *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 506, [2007] F.C.J. No. 681, Mosley J.).

[17] Abbott argues that the Prothonotary's decision derives, at least in part, from a wrong principle. Neither party in the written submissions filed before the hearing had raised section 7 of the *Canada Evidence Act*. That section reads:

> Where, in any trial or other proceeding, criminal or civil, it is intended by the prosecution or the defence, or by any party, to examine as witnesses professional or other experts entitled according to the law or practice to give opinion evidence, not more than five of such witnesses may be called on either side without the leave of the court or judge or person presiding.
>
> Lorsque, dans un procès ou autre procédure pénale ou civile, le poursuivant ou la défense, ou toute autre partie, se propose d'interroger comme témoins des experts professionnels ou autres autorisés par la loi ou la pratique à rendre des témoignages d'opinion, il ne peut être appelé plus de cinq de ces témoins de chaque côté sans la permission du tribunal, du juge ou de la personne qui préside.

[18] There might have been room for argument if Prothonotary Tabib had made no mention of the *Canada Evidence Act* before issuing her order. However, Abbott admits that she raised the point during the hearing. She was entitled to do so (*Wire Rope Industries of Canada (1966) Ltd. v. B.C. Marine Shipbuilders Ltd. And Straits Towing Ltd.*, [1981] 1 S.C.R. 363). Although Abbott now says

it was not prepared to argue the point on the spot, as it had to sort out how many experts were called on different points, the fact of the matter is that it did not ask for a postponement, and so cannot be heard now to say it was taken by surprise and that the rules of natural justice were not observed.

[19] Furthermore, it is clear from a reading of her order that section 7 of the *Canada Evidence Act* did not play a role in her disallowance of Dr. Unge's affidavit, although it may have on another. Dr. Graham had also dealt with another issue which was lansoprazole's potency and efficacy *in vivo*. Prothonotary Tabib allowed a proportion of a proposed affidavit from a Dr. Armstrong. However, she added: "Leave to file Dr. Fass' affidavit will not be granted, as, to the extent it is not merely duplicative of Dr. Armstrong, it does go beyond a necessary reply and improperly adds evidence that could have been introduced in chief."

[20] An applicant such as Abbott is caught in a conundrum. If Dr. Graham's affidavit goes beyond the NOA, it could move to have the relevant portions struck. However, since these applications are intended to be summary in nature, that is a point more properly argued when the application is heard on the merits (*David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588, [1994] F.C.J. No. 1629 (C.A.)). If Dr. Graham's affidavit did not go beyond the NOA, then his points should have been anticipated and Dr. Unge's affidavit filed in chief.

[21] I find the short term solution set out in the decision of Mr. Justice Mosley in *Pfizer*, above, to be particularly helpful. He noted that the adequacy of a NOA depends on whether the detailed statement was sufficient to make the patentee fully aware of the grounds on which, in this case, the

patent was said to be invalid. In that case, Mr. Justice Mosley was of the view that interpretation of the NOA and the affidavit was a matter of law. He held the Prothonotary in that case erred in finding that an issue addressed in the affidavit had been raised and contained in the NOA. He considered the matter *de novo* and allowed the affidavit. His view of the NOA is not binding on the judge who decides on the merits. Rather, the holding is that the reply affidavit may assist the Court.

[22] The Unge Abstract is very short. It described treatment of three groups of patients. One was treated with omeprazole plus amoxicillin, one with omeprazole alone and one with amoxicillin alone. The results differed. He concluded: “Further and extended study appears to be justified”.

[23] It is Dr. Graham’s evidence, among other things, that omeprazole may have a direct or indirect antimicrobial effect on H. pylori and that combination therapy with omeprazole or lansoprazole would be more efficacious than use of either single agent.

[24] I agree with Prothonotary Tabib that the Unge Abstract was well understood and that several experts, including Takeda’s, discussed its teachings. The issues raised should have been anticipated as they did not go beyond the NOA. She did not misdirect herself.

[25] For these reasons, I would dismiss the appeal. In the alternative, should it be that her order was clearly wrong in the sense that discretion was based upon a wrong principle of law or misapprehension of the facts, I would exercise my discretion *de novo* the same way she did. To a large extent, Dr. Unge’s affidavit is based on what his intended purpose was in carrying out the

study and what he considers it stands for. However, the Abstract speaks for itself. It is not what Dr. Unge intended but what he said which contributes to the state of the art. The Abstract objectively says whatever it says. At the hearing on the merits, Abbott is entitled to make representations as to what the Abstract means. It does not need Dr. Unge's help by way of an affidavit in reply.

ORDER

The motion in appeal from the order of Prothonotary Tabib is dismissed with costs.

"Sean Harrington"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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