Date: 20071207

Docket: T-1718-07

Citation: 2007 FC 1291

Ottawa, Ontario, December 7, 2007

PRESENT: The Honourable Mr. Justice Phelan

BETWEEN:

ABBOTT LABORATORIES LIMITED and
TAP PHARMACEUTICALS INC.

Applicants

and

THE MINISTER OF HEALTH,
NOVOPHARM LIMITED and
TAKEDA PHARMACEUTICAL COMPANY LIMITED

Respondents

REASONS FOR ORDER AND ORDER

[1] Abbott Laboratories Limited and TAP Pharmaceuticals Inc. (referred to together as "Abbott") moved for an order requiring Novopharm Limited (Novopharm) to serve its evidence prior to service of Abbott's evidence; a reverse order of evidence filing. The proceeding in question is an application under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The patent in issue is Canadian Patent No. 2,009,741 (the '741 Patent).

[2] This is the second NOC in respect of this '741 Patent. In *Abbott Laboratories Ltd. v. Canada (Minister of Health)* (2007), 55 C.P.R. (4th) 48, Justice von Finckenstein dealt with the issue of whether Novopharm's (Novopharm) generic version of the drug lansoprazole would infringe the '741 Patent in the manner it was proposed to be marketed.

[3] Justice von Finckenstein found that infringement would occur because Novopharm's product monograph and label would induce or encourage physicians to prescribe the generic version for use that would infringe the '741 Patent.

[4] Subsequent to that judgment, Novopharm filed a new Notice of Allegation (NOA) in respect of its generic version of the drug. As a result, Abbott seeks to have Novopharm file its evidence first despite the fact that Abbott is the applicant for an order prohibiting the issuance of a Notice of Compliance in favour of Novopharm.

[5] Abbott relies on the unique circumstances of this case – that it is the re-litigation of the infringement issue. Abbott contends therefore that Novopharm must have "better evidence" and an explanation for not initially putting forward its best case ("best foot forward") so as to avoid this second litigation being an abuse of process.

[6] While it is somewhat counter-intuitive to many that a losing party can re-litigate its NOC proceeding by filing a new NOA, because of the unusual nature of NOCs, this is the case in certain circumstances. (See *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 140)

[7] Novopharm argues firstly that this Court has no jurisdiction to make the proposed order because the Rules require an applicant to file evidence first and secondly that, in any event, this is not an appropriate case to make such an order.

[8] For the reasons to follow, I disagree with Novopharm in respect of the first point but agree on the second.

A. *Jurisdiction*

[9] Rule 55 gives this Court sufficient authority "in special circumstances" to make an order dispensing with the usual rules under which an applicant files its evidence first.

[10] Similarly, if this case was under "case management", which it is not but will be, it would be within the discretion of the case management judge/prothonotary to make a similar order in the appropriate circumstances.

[11] Therefore, the real issue in this motion is whether this is an appropriate case or are there special circumstances to make an order reversing the order of filing evidence and the making of submissions.

B. *Special Case/Appropriate Circumstances*

[12] The Applicant relies on what are described as the unique facts of this proceeding – the fact that there had been an earlier NOC decision on the same issue. The Applicant does not say that this latest NOC proceeding is an abuse of process or is covered by the principles of *res judicata* or issue estoppel.

[13] The starting point of the analysis of the appropriateness of the proposed order are the comments by Justice Sexton in *Abbott Laboratories*, *supra*, at paragraph 46, where he recognizes that multiple NOC proceedings as to the infringement issue may be permissible where there are significant differences in formulations between the respective NOCs. This is not the case for validity challenges in NOCs.

[14] NOC proceedings are unusual proceedings. Once commenced, there are limited circumstances for amendment which generally require a court decision before a new amended formulation can be filed. The burden for a generic is that the submission of an amended formulation results in a 24-month stay imposed on a generic manufacturer no matter how meritorious the generic's position may be.

[15] The difference in regards to multiple NOCs between invalidity challenges and infringement challenges is based on the distinctly different characteristics of the challenges. A challenge to

validity is based upon immutable facts; the patent is fixed and it is either valid or it is not. An infringement challenge is based upon the proposed use, which use can be changed.

[16] With respect to infringement, the generic describes the proposed use – it is then incumbent on the innovators to show how that use will infringe the patent.

[17] Given the recognition that infringement claims may be the subject of subsequent NOC proceedings, after a court decision on the same patent, there are no “special circumstances” which justify a departure from the usual order of proceeding. The Applicant is in the best position to know in what manner the new formulation infringes the patent.

[18] To the extent that there are issues as to whether the new formulation is a significant change and issues as to discoverability, due diligence and explanations regarding “best foot forward”, these are matters which are more appropriately dealt with by the judge hearing the NOC proceeding. It is a more efficient and fairer manner of proceeding and there is no argument advanced here to strike the NOC on the grounds of abuse.

[19] Therefore, this motion is dismissed with costs to Novopharm. Since infringement not validity was the critical issue, Takeda Pharmaceutical Company Limited’s involvement was not strictly necessary and no costs on this motion will be awarded to it.

[20] The parties acknowledge that case management would be helpful and therefore a separate order placing this matter under case management will be issued.

ORDER

THIS COURT ORDERS that this motion is dismissed with costs to Novopharm.

"Michael L. Phelan"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1718-07
STYLE OF CAUSE:	ABBOTT LABORATORIES LIMITED and TAP PHARMACEUTICALS INC. and THE MINISTER OF HEALTH, NOVOPHARM LIMITED and TAKEDA PHARMACEUTICAL COMPANY LIMITED
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	December 3, 2007
REASONS FOR ORDER AND ORDER:	Phelan J.
DATED:	December 7, 2007

APPEARANCES:

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