Federal Court  Cour fédérale

Date: 20101221

Docket: T-1372-10

Citation: 2010 FC 1310

Ottawa, Ontario, this 21st day of December 2010

Present: The Honourable Mr. Justice Pinard

BETWEEN:

APOTEX INC.

Applicant

and

MINISTER OF HEALTH and
ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR ORDER AND ORDER

[1] The respondents have brought a motion seeking an Order to strike the underlying application for judicial review. The respondents identify the following issues on this motion:

1) Is the application out of time contrary to subsection 18.1(2) of the *Federal Courts Act*?
2) Should the application be struck as it is not limited to a single order contrary to Rule 302 of the *Federal Courts Rules*?
3) If the application is not struck on the above grounds, should the Court strike out further parts of the application, specifically:
    a. Those parts related to allegations regarding "vested rights"?

   b. Those parts regarding "revocation" of the "patent hold" status of Apotex's submission?
4) If the application is to proceed:
   a. Should the proceeding be specially managed?
   b. Should the respondents be given additional time to prepare responses to Apotex's Rule-317 request and the application itself?

1. Factual background

[2] In the underlying application, Apotex Inc. (the applicant) asks this Court to quash certain decisions made by the Minister of Health related to the granting of approval for sale of its *Apo-Omeprazole* tablets. The applicant asks this Court to compel the Minister to issue a Notice of Compliance ("NOC") or alternatively to quash the decisions and proceed in a further review of its drug submission.

[3] In April 2000, the applicant filed a submission for approval for sale of its *Apo-Omeprazole* tablets with the Therapeutic Products Directorate ("TPD"). The TPD has the delegated authority to review new drug submissions. In March 2003 the applicant was advised that its submission was satisfactory and that the issuance of a NOC was on "patent hold". That is, the issuance of the NOC was on hold pending the resolution of certain applications under the *Patented Medicines (Notice of Compliance) Regulations* (the "PMNOC Regulations"). Later, in December 2008, the TPD notified the applicant by letter that it was revoking the approval status of the submission. The TPD's justification for this decision was that the bioequivalence study filed by the applicant with its Abbreviated New Drug Submission ("ANDS") had not been appropriately conducted. The TPD stated that it had newly discovered that the applicant's study had been conducted with a "light meal" and not a "high fat meal" as required.

[4] The applicant objected, but the TPD issued a Notice of Non-Compliance Withdrawal letter. The applicant requested reconsideration of the Notice of Non-Compliance Withdrawal letter but this was denied by the TPD. The applicant then sought for the matter to be referred to an external panel; this request was also denied.

[5] The applicant subsequently learned of certain facts and documents through an *Access to Information Act* request. It alleges that these revelations taint the Minister's decision to revoke approval for its *Apo-Omeprazole* tablets. The applicant alleges that the Minister's delegates acted in a way that demonstrated a reasonable apprehension of bias, and that the TPD had been aware during the initial review of the 2003 submission that a low fat meal had been used in the bioequivalence study. The applicant says that this means there was no basis for the Minister to revoke approvability status in December 2008. The applicant further alleges that when approvability status was revoked, a favourable review of the 2003 submission was not disclosed, even throughout the reconsideration period. The applicant further alleges that the Minister's delegates made the decision to revoke approvability status at least six months before the applicant was advised of this decision. The applicant says this delay was in contravention of an earlier agreement it had with the Minister dated May 24, 2005 to "resolve disputes in a fair and timely manner".

[6] The applicant also claims that it learned through this request that the Acting Director of the Bureau of Pharmaceutical Sciences had secretly instructed staff involved in the reconsideration not to approve it. The applicant further alleges that the TPD had initially determined that it would be appropriate to refer the matter to an external panel, but that this decision was reversed on May 22,

2009 after an external panel had found in the applicant's favour in respect of a nearly identical situation involving its *Apo-Lansoprazole* product.

[7] The applicant claims that the foregoing allegations constitute a continuing course of intransigent, disingenuous and seemingly biased conduct by the Minister's delegates in respect of its reviews of the *Apo-Omeprazole* tablet submission. The applicant claims that this conduct was carried out with a view to revoking the approvability status of the *Apo-Omeprazole* submissions and protecting that revocation from reconsideration. As such, it asserts that the revocation of approvability status, the issuance of the Non-Compliance Withdrawal letter, and the refusal to allow independent reconsideration of the matter constitute a continuing course of conduct that began in early 2008 and continues to the present.

2. Analysis

[8] In *Odynsky v. League for Human Rights of B'Nai Brith Canada et al.*, 2009 FCA 82, the Federal Court of Appeal conclusively held that in order to succeed on a motion to strike in the context of an application for judicial review, the moving party must show that the application is so clearly improper as to be bereft of any possibility of success. As held by the Federal Court of Appeal, justice is typically better served by allowing the application judge to deal with all of the issues raised in a judicial review application, as motions to strike may unduly or unnecessarily delay the expeditious determination of the issues.

A. *Is the application time-barred?*

[9] The respondents say that the applicant's application to review certain decisions was brought out of time, contrary to the 30-day time limit imposed by subsection 18.1(2) of the *Federal Courts Act*, R.S.C. 1985, c. F-7. They also contend that the instant case is just the sort of exceptional case where a motion to strike an application on the basis of timeliness ought to be allowed. On the other hand, the applicant contends that what it seeks to review is not an "order" or "decision" subject to the time limitation in subsection 18.1(2), but rather a "matter" which consists of a continuing course of conduct. The applicant does not agree that there are factors at play in the present case justifying a departure from the usual practice of leaving limitations issues to the application judge (*Hamilton-Wentworth (Regional Municipality) v. Canada (Minister of the Environment)*, [2000] F.C.J. No. 440 (T.D.), 187 F.T.R. 287).

[10] As set out in *Krause v. Canada* (C.A.), [1999] 2 F.C. 476, and followed by Justice Michael Phelan in *Airth v. The Minister of National Revenue*, 2006 FC 1442, where the subject-matter of a judicial review application is a "matter" rather than a "decision or order", the 30-day time limit does not apply: *Airth* at para 5. A matter is distinguished from a decision or order by considering whether what is at issue is a "singular decision" or instead "part of a course of conduct, all of which the Applicant challenges": *Airth* at para 9.

[11] In the present case, at this stage, I am not prepared to accept the respondents' characterization of the underlying application as one that seeks to combine the review of three discrete decisions. It appears that the applicant is requesting relief arising out of a number of decisions and other conduct of the same decision maker, operating under the same statute (the *Food*

and Drug Regulations), arising out of the same factual matrix (the *Apo-Omeprazole* ANDS). Further, as the applicant points out, each action it now challenges was contingent upon the previous decision that had been made. The Notice of Application discloses a complex set of facts and an inter-related series of decisions all concerning Apotex's ANDS for *Apo-Omeprazole*. Further, the applicant has alleged that its decision to now challenge the Minister's conduct with regard to its drug submission is motivated by factual revelations produced through recent Access to Information Requests. The applicant claims that these new facts reveal a continuing course of seemingly biased conduct on the part of the Minister's delegates that both pre-dates and post-dates the individual "decisions".

[12] In my view, given the *Krause*, *Airth* and *Hamilton-Wentworth* decisions above, there is certainly a debatable issue as to whether it can be said that the applicant's attack in this case is simply on the Minister's decision to revoke approval status for the *Apo-Omeprazole* submission, or any other individual decision in the parties' long history with respect to *Apo-Omeprazole*. Consequently, I do not see how it can be said that the application is bereft of any chance of success on the basis that it is out of time. The serious question of whether the proper approach is to view the underlying application for judicial review as directed to a "matter" or a continuing course of conduct to which the 30-day time limit imposed by subsection 18.1(2) of the *Federal Courts Act* should not apply ought to be determined by the application judge.

B. *Should the application be struck as it is not limited to a single order contrary to Rule 302?*

[13] The respondents characterize the underlying application as a case where three or more independently-arising decisions have been "packaged" together. They rely upon Rule 302 to assert

that the applicant's application should be struck as no more than one order may be challenged in a single judicial review application.

[14] In view of my above conclusion that the subject-matter of the underlying application is a debatable issue which must be determined by the application judge, it follows that the question concerning the application of Rule 302 also ought to be left to the application judge.

C. *Does the applicant have "vested rights" to a NOC?*

[15] According to the respondents, the applicant has asserted that because its ANDS was on "patent hold" as of March 2003, it had (a) a "vested right" to the issuance of a NOC subject only to compliance with the PMNOC Regulations, and (b) a "vested right" to the subsequent application of the Minister's procedures on appeals and reconsiderations, as they existed in March 2003. The respondents say that the applicant has cited neither law nor facts in support of its claim to any "vested rights".

[16] In my view, the applicant is correct when it asserts that the respondents are seeking to litigate the substance of the application, which is improper on a motion to strike. The Federal Court of Appeal has held that, in light of the decision in *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588, motions to strike applications for judicial review should only be brought in exceptional circumstances, given the summary nature of the proceedings: *LJP Sales Agency Inc v. Minister of National Revenue*, 2007 FCA 114 at para 8.

[17] In this case, the respondents not only say that there is no basis in law for the applicant's "vested rights" argument, but further that prior jurisprudence from both the Supreme Court of Canada and this Court stands for the proposition that the Minister retains the power to revoke authorization any time prior to the actual issuance of a NOC: *Comeau's Sea Foods Ltd. v. Canada (Minister of Fisheries and Oceans)*, [1997] 1 S.C.R. 12 at paras 39-51, and *Ferring Inc. v. The Minister of Health et al.*, 2007 FC 300. In my opinion, those cases do not stand directly contrary to the applicant's position.

[18] *Comeau's Sea Foods Ltd.* is put forward for the general proposition that where a Minister is given a statutory discretion to issue licenses, the Minister retains the power to revoke authorization any time prior to the actual issuance of the license. However, as I understand it, that case was decided in greatly different factual circumstances and on the basis of a very different statutory scheme than those at issue in the case at bar. Under the *Fisheries Act*, the Minister was given broad discretion to authorize and issue fishing licenses, unfettered by any regulations until after a license was issued (at paras 36, 40, and 49). According to the Supreme Court, this allowed the Minister to revoke an authorization in implementing government policy to address pressing concerns. By comparison, the Minister's discretion to issue a NOC under the *Food and Drug Regulations* is quite narrow. Subject to the application of the PMNOC Regulations, section C.08.004 of the Regulations is quite clear that after completing an examination of the new drug submission the Minister must either issue a NOC or issue a notice of non-compliance. In my opinion, the Regulations appear to preclude the type of broad policy-based discretion found by the Court in *Comeau's Sea Foods Ltd.*

[19] While the *Ferring* case cited by the respondents deals with the PMNOC Regulations, I do not think that it can be taken as a direct authority. As the applicant points out, the *Ferring* case deals with whether or not the Minister is *functus officio* as to the issue of whether a generic is a second person pursuant to the PMNOC Regulations. While the Court in that case determined that the Minister retained discretion, it was the discretion to re-address whether certain companies were second persons under the PMNOC Regulations, not the discretion to issue a NOC. As such, I do not think that *Ferring* can be taken as an authority that is directly contrary to the applicant's position. That said, I would also add that I agree with the respondents' assertion that the decision of the Federal Court of Appeal in *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742, cannot be taken as authority for the existence of such "vested rights" given the unique factual circumstances in that case. Given the dearth of authorities directly on point, and the arguably contradictory jurisprudence, I am of the view that this is an issue that is clearly best left to the application judge to deal with on the basis of a complete record and full argument.

[20] Thus while the *Comeau's Sea Foods Ltd.* and *Ferring* decisions, above, indicate that there may not be a vested right to a NOC as claimed by the applicant, I do not believe that it can be said that there is an authority directly contrary to its position. That is, following *LJP Sales Agency Inc.*, above, neither party has put forward an authority decided on materially indistinguishable facts addressing the exact issue in question in this application. Consequently, I do not think that it can be said that the applicant's argument with regard to its alleged "vested rights" is bereft of any possibility of success.

D. *Respondents' alternate requests: case management and extensions of time*

[21] In the circumstances, I agree with the respondents' alternate requests. Accordingly, I will order that the matter continue as a specially managed proceeding; that counsel shall file with the Registry of the Court, either jointly or separately, before the expiration of ten (10) days from the date of the Order supported by these reasons, a document outlining the steps remaining to be taken in this proceeding, together with a proposed timetable for the completion of the necessary steps; and that any further directions be issued by the case management judge.

3. Conclusion

[22] For the above-mentioned reasons, the respondents' motion to strike the underlying application for judicial review in whole or in part will be dismissed, with costs in the cause.

[23] In response to the respondents' motion to strike the underlying application, the applicant, out of an abundance of caution, has brought a motion seeking (a) leave to amend its Notice of Application, and (b) an order granting an extension of time to commence the underlying application pursuant to subsection 18.1(2) of the *Federal Courts Act*.

[24] At the hearing before me, counsel for the parties agreed that if the motion to strike was dismissed, and that a question of the application of subsection 18.1(2) of the *Federal Courts Act* was left to the application judge, the applicant's motion ought also to be dealt with by the application judge. A distinct Order will be made accordingly.

ORDER

The respondents' motion to strike the underlying application for judicial review in whole or in part is dismissed, with costs in the cause.

This matter will continue as a specially managed proceeding.

Counsel shall file with the Registry of the Court, either jointly or separately, before the expiration of ten (10) days from the date of this Order, a document outlining the steps remaining to be taken in this proceeding, together with a proposed timetable for the completion of the necessary steps.

Any further directions will be issued by the case management judge.

"Yvon Pinard"

Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1372-10
STYLE OF CAUSE:	APOTEX INC. v. MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA
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APPEARANCES:

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