Federal Court  Cour fédérale

Date: 20111114

Docket: T-1372-10

Citation: 2011 FC 1308

Ottawa, Ontario, November 14, 2011

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

APOTEX INC.

Applicant

and

MINISTER OF HEALTH AND
ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application by Apotex Inc. (Apotex) challenging three decisions made by the Minister of Health or by the Minister's delegate (Minister) in connection with the rejection of its submission for a Notice of Compliance (NOC) for Omeprazole Magnesium tablets (Apo-Omeprazole).

[2] For the reasons that follow, this application must be dismissed as untimely. It is, accordingly, unnecessary to address the substantive issues raised by Apotex with one exception –

that being its argument that it had vested rights to a NOC for Apo-Omeprazole tablets or, alternatively, to an external review of the Minister's negative decision.

[3] Apotex brought a motion returnable at the commencement of this application seeking to strike out all or portions of the affidavit of Andrew Adams. The grounds for the motion are that Mr. Adams did not have personal knowledge of the matters deposed to and that the affidavit contains inadmissible opinions and hearsay. The Minister answered the motion with the assertion that the affidavit contains factual evidence based on personal knowledge or, alternatively, that the evidence is admissible under an exception to the hearsay rule. When Apotex argued the motion, its objections were limited to paragraphs 13 to 15, 78 to 80, 27 to 77 (selectively), and 81 to 92. Given that this evidence refers to substantive issues that I have not needed to address in these reasons, it is not strictly necessary to deal with Apotex's motion. However, because there is some merit to Apotex's concerns and because the inappropriate use of affidavits in this Court is a matter of ongoing concern, I will address the issues raised on the motion.

[4] Under Rule 81 of the *Federal Courts Rules*, SOR/98-106 [*Rules*], affidavits relied upon in the context of an application are to be confined to facts within the deponent's personal knowledge. This provision has been interpreted to permit hearsay evidence if it falls within a common-law exception, including the principled exception, but otherwise, it prohibits the assertion of facts obtained from others: see *Canadian Tire Corp v PS Part Source Inc*, 2001 FCA 8 at para 6, 200 FTR 94. Needless to say, affidavits should also be free of unqualified opinion, argument, conclusions of law or speculation: see *Van Duyvenbode v Canada (AG)*, 2009 FCA 120 at para 3, [2009] FCJ no 504 (QL).

[5] Mr. Adams' affidavit does not fully conform to these requirements. It is, in some aspects, argumentative, opinionated, speculative and conclusory. It also contains some inadmissible hearsay. Substantial portions of the affidavit are however unobjectionable and it would be possible to sever the offending material from the rest or to simply ignore it.

[6] I am not convinced that paragraphs 13, 14 and 15 contain inadmissible expert opinion. This is the type of general background evidence, albeit of a scientific nature, that would be known to Mr. Adams by virtue of his position and experience within the Ministry. Furthermore, this evidence was not relevant to a material or controversial issue on the application inasmuch as Apotex's legal challenge was based on the fairness of the process and not on a disagreement about the background science.[1] I would add that Dr. Sherman's affidavit, submitted on behalf of Apotex, contains passages bearing on his view of the background science. These are matters that he too would be able to speak to based on his experience in running Apotex for many years and are similarly unobjectionable.

[7] The same cannot be said of paragraphs 78 to 80 which do purport to express Mr. Adams' opinions, conclusions and arguments on material scientific issues. There is also no linkage between this evidence and any personal involvement by Mr. Adams in the decision-making history of this matter. Whatever Mr. Adams thought the record disclosed is irrelevant.

---

[1] Apotex does not agree with the Minister's scientific rationale for the impugned decisions but concedes that a fairly made science-based decision would be entitled to deference on judicial review.

[8] Apotex concedes that paragraphs 27 to 77 are substantially unobjectionable because they set out a neutral chronology of events as verified by the record. There are, however, a few instances where the passages verge into opinion or analysis or seemingly rely on unspecified hearsay (see paragraphs 33, 53, 57, 63, 65, 68, 70, 71, 73 and 77).

[9] Paragraphs 81 to 97 of the Adams affidavit deal with a number of departmental emails that Dr. Sherman has, in his own affidavit, characterized in unflattering terms. Dr. Sherman deposes in paragraph 134 that the emails "speak for themselves" but he goes on to describe their content as "the antithesis of both scientific integrity and respect for the appropriate regulatory decision making process". He also speculates about the Ministry's motives and advances several arguments about why this evidence discloses a bias. It is perhaps not surprising that Mr. Adams responded to this material in like fashion but that does not render the material any less objectionable from an evidentiary standpoint. The appropriate response to the objectionable material of this sort is simply to ignore it and to consider the admissible evidence independently from the views of witnesses who were not privy to its creation.

[10] In summary, the affidavit material filed by both parties in this proceeding fell short of the standards that apply under our *Rules*. Such lapses are particularly troublesome because the interlocutory disputes they engender are wasteful of scarce Court resources. Greater care is to be expected particularly from litigants who are well versed in the requirements for proper pleading.

Is This Application Out of Time?

[11] The Minister takes the position that this application is out of time and must be dismissed for failing to meet the 30-day filing requirement of subsection 18.1(2) of the *Federal Courts Act*, RSC 1985, c F-7 [*Act*]. Apotex argues that it did not file the application out of time because the actions of which it complains represent a course of ongoing unfair conduct by the Minister that are open to being judicially reviewed at any time. In the alternative, Apotex has brought motions to amend its Notice of Application and to extend the time for bringing this application. The Minister does not oppose the motion to amend but disagrees that this is an appropriate situation to extend time under subsection 18.1(2) of the *Act*.

[12] Apotex brought this application on August 26, 2010. In its Notice of Application Apotex seeks prerogative relief in connection with three ministerial decisions by which a NOC was refused for its Apo-Omeprazole tablets.

[13] The first impugned decision is characterized by Apotex as a revocation by the Minister on December 5, 2008 of an "approvability status" for its Apo-Omeprazole tablets. The second impugned decision concerns the Minister's issuance on February 9, 2009 of a "Notice of Non-Compliance withdrawal letter" for Apo-Omeprazole tablets. The third impugned decision concerns the Minister's decision on July 27, 2009 to deny Apotex's request for reconsideration of the decision to issue a Notice of Non-Compliance withdrawal letter for Apo-Omeprazole tablets.

[14] In its Notice of Application, Apotex characterizes the Minister's decisions as unlawful, unreasonable, unfair, discriminatory, illogical, scientifically untenable and biased. Among other

points, it contends that it had a vested interest in a NOC when the Minister advised it by letter of March 7, 2003 that the examination of Apo-Omeprazole had been completed but that a NOC would not issue until the requirements of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 were met – in other words, that Apotex's application for a NOC was on patent hold.

[15] Apotex also asserts that the Minister's refusal to approve Apo-Omeprazole continues a course of unfair conduct dating back to 1988 with respect to many of its generic pharmaceutical products.

[16] Dr. Sherman's affidavit sworn on September 8, 2010 relates a two decade history of "apparently systemic" and "unfair and discriminatory treatment" by the Minister and the Minister's officials. Much of this history has involved numerous applications for judicial review by Apotex including a series of applications concerning Apo-Omeprazole. It is this ongoing history of acrimony and litigation between Apotex and the Minister that Apotex argues underpins this application and permits it to avoid the strict 30-day filing requirement for initiating a judicial review of the three ministerial decisions it challenges. Presumably, it is this same history that Apotex relies upon to avoid the limitation in Rule 302 that, absent leave of the Court, only one decision at a time can be the subject of an application for judicial review.

[17] Apotex's primary Memorandum of Fact and Law also refers to a "pattern of misconduct" and to a systemic refusal by the Office of Science to "give fair, honest and *bona fide* consideration" to its appeal but it is silent on the question of whether this application was brought out of time. In its motion to extend time, Apotex merely asserts that at the time of filing it was of the view that it

was not subject to the 30-day filing requirement in subsection 18.1(2) of the *Act*. In oral argument, it attempted to justify that view on the strength of the Federal Court of Appeal decisions in *Krause v Canada*, [1999] 2 FC 476 , [1999] FCJ no 179 (QL) [*Krause*], and *Manuge v Canada*, 2008 FC 624 , [2008] FCJ no 787 [*Manuge*].

[18] Neither *Krause* nor *Manuge* are applicable to an application like this which involves a fairness challenge to three discrete administrative decisions. Both *Krause* and *Manuge* were concerned with the lawfulness of the government's implementation of policies on an ongoing basis. This is made clear in the following passage from *Krause*:

> 24 I am satisfied that the exercise of the jurisdiction under section 18 does not depend on the existence of a "decision or order." In Alberta Wilderness Assn. v. Canada (Minister of Fisheries & Oceans), Hugessen J. was of the view that a remedy envisaged by that section "does not require that there be a decision or order actually in existence as a prerequisite to its exercise." In the present case, the existence of the general decision to proceed in accordance with the recommendations of the Canadian Institute of Chartered Accountants does not, in my view, render the subsection 18.1(2) time limit applicable so as to bar the appellants from seeking relief by way of [page 493] mandamus, prohibition and declaration. Otherwise, a person in the position of the appellants would be barred from the possibility of ever obtaining relief under section 18 solely because the alleged invalid or unlawful act stemmed from a decision to take the alleged unlawful step. That decision did not of itself result in a breach of any statutory duties. If such a breach occurred it is because of the actions taken by the responsible Minister in contravention of the relevant statutory provisions.
>
> [Footnote omitted]

[19] In *Manuge*, above, I made a similar point in the following passage:

> 17 There is no question that much of what was of concern to the Court in Grenier and in its earlier decisions in *Tremblay v. Canada*, 2004 FCA 267, [2004] 4 F.C.R. 165 and in *Budisukma Puncak*

> *Sendirian Berhad v. Canada*, 2005 FCA 267, 338 N.R. 75, had to do with the desire for finality around administrative decisions and to ensure that appropriate deference was accorded to the decision maker (see, for example, paras. 27 to 30 in *Grenier*). The Court was also rightfully concerned about a process which would allow a party to collaterally attack a decision well beyond the 30-day time limit for bringing an application for judicial review. All of these are concerns that carry much less significance in a case where the challenge is limited to the lawfulness of a government policy and where the application of that policy has on-going implications for the party affected. It is also perhaps noteworthy that in *Grenier*, *Tremblay* and *Berhad*, the Court's discussion of these policy considerations invariably referred to the lawfulness of the underlying decisions and no explicit reference was made to challenges to government policy, legislation, or conduct. In *Tremblay*, the Court also noted "the fine line that exists between a judicial review and a court action" where extraordinary remedies are sought.[2]

[20] Allowing Apotex to avoid the 30-day filing requirement on this application would open the door to a multitude of similar belated applications and thereby effectively extinguish the requirement. It would also sidestep the need for finality for discrete administrative decisions that are, as here, directly attacked as unlawful. The Federal Court of Appeal well-expressed the principle of finality in the following passages from *Canada (AG) v Trust Business Systems*, 2007 FCA 89, [2007] FCJ no 379 (QL):

> 28 In *Canada v. Berhad*, [2005] F.C.J. No. 1302, 2005 FCA 267, Létourneau J.A. wrote that the thirty-day limit for commencing judicial review applications is in the best interest of the public because it brings finality to administrative decisions and security to those who comply with the decision or who enforce compliance with it. At paragraph 60 he stated:
>
> > The importance of that public interest is reflected in the relatively short time limits for the commencement of challenges to administrative decisions -- within 30

[2] Although my decision in *Manuge* was overturned by the Federal Court of Appeal it was restored by the Supreme Court of Canada in *Manuge v Canada*, 2010 SCC 67, [2010] 3 SRC 672 where Justice Rosalie Abella observed that “at their core, Mr. Manuge’s claims are less about assessing the exercise of delegated statutory authority or the decision-making process…and more about s. 15(1) of the Charter”.

> days from the date on which the decision is communicated, or such further time as the Court may allow on a motion for an extension of time. That time limit is not whimsical. It exists in the public interest, in order to bring finality to administrative decisions so as to ensure their effective implementation without delay and to provide security to those who comply with the decision or enforce compliance with it, often at considerable expense. [Emphasis added]
>
> 29 Accordingly, when the Tribunal issued its determination on the motion on April 25, 2005, the applicant was required under subsection 18.1(2) of the *FCA* to file its notice of application for judicial review within thirty days, as Trust's substantive right to its complaint were finally decided. As the applicant did not do so within the allotted time frame, it is now time-barred to challenge this issue. The authorities relied on by the applicant in *Ernst Zündel and Canadian Association for Free Expression Inc.*, [2000] 4 F.C. 255 and *R. v. Seaboyer*; *R. v. Gayme*, [1991] 2 S.C.R. 577 are distinguishable as they deal with interlocutory issues as opposed to those that have the potential to bring finality to the proceedings.
>
> [Emphasis in original]

[21] I agree with counsel for the Respondent that Apotex's position "is no more than a colourable device intended to permit Apotex to avoid violating both the letter and the spirit of section 18.1(2) of the *Federal Courts Act* and Rule 302". In my view, the 30-day filing requirement does apply to this application and can only be overcome by a meritorious motion to extend time.

Apotex's Motion to Extend Time

[22] Apotex acknowledges that its entitlement to relief is dependant upon its demonstration of all of the following:

a. a continuing intention to pursue the application;

b. that the application has some merit;

c. that no prejudice to the respondent arises from the delay; and

d. that a reasonable explanation for the delay exists.

[23] For the purposes of this motion, it is only necessary to deal with issues (a) and (d).

[24] There is no question that Apotex brought this application well out of time. It was filed 19 months after the first impugned decision, 17 months after the second and 12 months after the third. These lengthy delays require a compelling explanation which is entirely lacking in this case. Indeed, the evidence adduced by Apotex on this motion is at least as significant for what it fails to disclose as for what it asserts.

[25] Dr. Sherman's motion affidavit repeatedly claims that "until July 2010" he was unaware of material evidence that was necessary to make a decision to proceed with litigation against the Minister. According to paragraph 16 of Dr. Sherman's affidavit "[i]t was only upon discovery of these additional facts that I was able to appreciate the purported bases, or more accurately, the lack thereof, upon which the decision of the Minister to revoke approvability and patent hold of Apo-Omeprazole tablets had been founded".

[26] The only significance to Dr. Sherman's reference to July 2010 is that it was sometime in that month that he got around to examining the documents disclosed three months earlier by the Minister in response to Apotex's *Access to Information* request. Despite being quite precise about many other dates, Dr. Sherman's affidavit is notably silent about when Apotex received these documents from the Minister and surprisingly imprecise about when he looked at them. Under cross-

examination, he was asked about the significance of the *Access to Information* cover letter dated April 15, 2010 from Health Canada and he gave the following evidence:

> **26** **Q**. Now the access material itself, you received in April 2010, correct?
>
> **A**. Not as far as I know. I don't know when it came in.
>
> **27** **Q**. You don't know when it came in?
>
> **A**. No. We tried to find out, actually, because it is a question that actually Mr. Radomski asked me. What happened was I found, when he asked me about the dating, the requests that I had sent in, and I found this letter of October 2, 2009. But I did not have and could not find the covering letter that came with the materials. The materials, when they came in, had gone to our regulatory department. I went and got them, and the covering letter wasn't there.
>
> We tried to figure out when it might have come in. I know Mr. Radomski made some inquiries of Health Canada, but they never answered.
>
> **28** **Q**. You recall there was a covering letter, though?
>
> **A**. I don't recall; there would have been. I don't know if I ever saw it.
>
> **29** **Q**. I have a copy of a letter here that says:
>
> "Dear Dr. Sherman: This is in response to your request under the Access to Information Act ..."
>
> …and then the request is quoted. And it says:
>
> "Enclosed are copies of records which respond to your request ..."
>
> …and so on. It appears to be a covering letter for the materials, transmitting to you the materials. It is dated April 15, 2010.
>
> **A**. I don't have that. What of it? I don't have it.
>
> **30** **Q**. But you have no reason to believe that this material was sent later than that, do you?

> **A**. I don't know. I don't have any information. All I can tell you is that when it came in it would have gone to the regulatory department. It was in July that I turned my mind to figuring out what we were going to do, in fact, what we could do, about this file, because Health Canada wasn't cooperating, and…
>
> **31** **Q**. If we can go off the record for a second?
>
> **A**. Yes.
>
> **MR. RADOMSKI**: Okay.
>
> --- Discussion off the Record
>
> **THE WITNESS**: As I was saying, I don't know when it came in. It may well have been in May or, you say there was a letter the end of April. What date did you say?
>
> **MR. WOYIWADA**: April 15.
>
> **THE WITNESS**: It may well have come in in late April, but it would have gone to the regulatory department and no one would have had any reason to review it. I turned my mind to what to do, if anything, in July, and went and got what was available; I got the file to review it, and that was sitting in the file.
>
> When I went through it, I found these surprising ... things that seemed very surprising to me, and sent them to Mr. Radomski, as I have explained.

In my view this evidence is unsatisfactory because it fails to provide a reasonable justification for the delay in filing this application between April 2010 and late August 2010. The inference I draw from the evidence is that this four month delay was the result of either a lack of diligence or a lack of interest but neither meets the test to establish a continuing intention to proceed or explain the failure to do so.

[27] While there was undoubtedly some information in the *Access to Information* records provided to Apotex in April 2010 that could help to inform a decision to bring this application, this will almost always be the case with respect to administrative decisions of this type. Affected parties will rarely have access to all of the information in the decision record. More often than not, parties like Apotex make critical litigation decisions on the basis of incomplete disclosure.

[28] Apotex is a sophisticated litigant with a long history of highly adversarial litigation with the Minister. According to Dr. Sherman's motion affidavit, Apotex is the victim of more than 20 years of unfair and unprincipled decision-making at the hands of the Minister and the Minister's officials. Against this background, it is disingenuous for Dr. Sherman to assert in his motion affidavit that he was "astounded" by what the *Access to Information* documents revealed to him. It is simply not open to a well-informed and well-represented litigant like Apotex to claim the luxury of at least a year and then to bring an application for judicial review. Cases that are arguably far more meritorious and significant to the parties than this one are dismissed by this Court for delays much shorter than those arising here.

[29] Even if there was merit to Apotex's argument that it had no evidentiary basis to proceed with this application until it had reviewed the *Access to Information* records, there is nothing to explain why it failed to make that request until September 30, 2009 – some two months after the last of the Minister's impugned decisions.

[30] There is no merit to Apotex's motion to extend time to bring this application and the motion is accordingly dismissed.

Did Apotex Have a Vested Right to a NOC?

[31] There is only one substantive issue raised by Apotex that I must resolve because it is arguably not disposed of by the failure to bring this application on a timely basis.

[32] Apotex argues that it had a vested right to a NOC for its Apo-Omeprazole tablets when the Minister advised it on March 7, 2003 that the examination of Apo-Omeprazole had been completed subject to the application being placed on patent hold. If Apotex had such a vested right it may well have a corresponding entitlement to bring an application for prerogative relief to enforce the right at any time. Because I do not agree that Apotex has such a vested right, I need not decide whether the temporal requirement of subsection 18.1(2) of the *Act* applies to the determination of this issue.

[33] It seems quite obvious to me that until a NOC is issued, a proponent enjoys no vested interest in a favourable outcome at least with respect to issues that properly fall within the Minister's lawful discretion (ie. pertaining to public safety and efficacy). There is no legal significance attaching to an application for a NOC that has been placed on patent hold. The Minister is fully entitled to revisit scientific issues at any point in the process up to the actual issuance of a NOC. It is only at that point that the Minister's examination is completed in accordance with C.08.004 of the *Food and Drug Regulations*, RSC 1985, c F-27. Indeed, given the lengthy delays that can arise, the Minister would be remiss if such applications were approved at the expiry of the patent hold period without further scrutiny: see *Apotex Inc v Canada (MOH)*, 2011 FCA 86 at paras 6-8, [2011] FCJ no 334 (QL). In this view, I am supported by the decision of

Justice Roger Hughes in *Ferring Inc v Canada*, 2007 FC 300, [2007] FCJ no 420 (QL) where he held:

> 78 In the present case, the Minister is acting in a purely administrative capacity, he is processing an ANDS from its submission to the issuance of an NOC. From time to time, information is provided or sought and obtained and steps are taken by the Minister. The Minister is not acting as a tribunal at all (*Novopharm Ltd. v. Canada (Minister of National Health and Welfare)* (1998), 78 C.P.R. (3rd) 54 at paragraph 16 (F.C.) and *Saskatchewan Wheat Pool v. Canada (Canadian Grain Commissioner)* (2004), 260 F.T.R. 310 at para. 24). This role is a continuing one of the type considered by the Supreme Court of Canada in *Comeau's Sea Foods Ltd. v. Canada (Minister of Fisheries and Oceans)* (1997), 142 D.L.R. (4th) 193. The Minister, as explained by the Supreme Court in *Comeau's Sea Foods* at paragraphs 39 to 51 of its Reasons, is entitled to visit and revisit circumstances from time to time as conditions change and new issues arise. It is only when the final step is taken, in that case, the issuing of a fishing licence, can the issue of *functus* arise. Here that final step is the issuance of an NOC.
>
> 79 The process here is analogous to considerations given by the Commissioner of Patents under the *Patent Act*, *supra*, as to whether he will entertain an application for a compulsory licence (*Merck and Co. v. Brantford Chemicals Inc.* (2005), 37 C.P.R. (4th) 481 (F.C.A.)), or as to whether he will involve a person who is not the person applying for a patent at the point when the patent is allowed (*Monsanto & Co. v. Canada (Commissioner of Patents)* (2000), 1 C.P.R. (4th) 500 (F.C.)). In such situations, the actions of the Commissioner, or here the Minister, cannot be and to be of such finality that they cannot be revisited where appropriate.
>
> 80 Even in circumstances where the final step has been taken such as a prohibition against the Minister from issuing an NOC by a Court order, the matter has been revisited where the underlying patent has been held, in other proceedings, to be invalid (*Hoffmann-La Roche Ltd. v. Canada (Minister of Health and Welfare)*, [1999] F.C.J. No. 662 at para. 14).
>
> 81 I find, therefore, that the Minister cannot be said to have been *functus* at any point in the process. The Minister is entitled, at a point where appropriate, to consider whether a generic is, in the circumstances of the case, a "second person" within the meaning of section 5(1) of the *NOC Regulations*.

[34] It follows, as well, from this that Apotex enjoyed no vested interest in the earlier stipulated process of external review. By the time the Minister got around to making the decision to refuse a NOC to Apotex, that process had changed and all that was required was an internal reconsideration. Apotex had the benefit of that review. It was well aware of the issue that concerned the Minister and it had a meaningful opportunity to make its case for reconsideration. That was all that was required in the circumstances.

[35] For the reasons given above, I reject Apotex's claim that it enjoyed a vested interest in a NOC for its Apo-Omeprazole tablets or, alternatively, to an external review of the Minister's decision. In the result, this application for judicial review is dismissed with costs in the agreed amount of $10,000.00 payable by Apotex to the Minister.

JUDGMENT

THIS COURT'S JUDGMENT is that this application for judicial review is dismissed with costs in the agreed amount of $10,000.00 payable by Apotex to the Minister.

"R.L. Barnes"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1372-10
STYLE OF CAUSE:	APOTEX INC v MINISTER OF HEALTH ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	October 17 to 18, 2011
REASONS FOR JUDGMENT:	BARNES J.
DATED:	November 14, 2011

APPEARANCES:

H.B. Radomski Daniel Cohen	FOR THE APPLICANT
J. Sanderson Graham Agnieszka Zagorska	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Barristers and Solicitors Toronto, ON	FOR THE APPLICANT
Myles J. Kirvan Deputy Attorney General of Canada Ottawa, ON	FOR THE RESPONDENTS