Federal Court of Appeal  Cour d'appel fédérale

Date: 20121207

Docket: A-452-11

Citation: 2012 FCA 322

CORAM: **SHARLOW J.A.**
DAWSON J.A.
TRUDEL J.A.

BETWEEN:

APOTEX INC.

Appellant

and

MINISTER OF HEALTH and
ATTORNEY GENERAL OF CANADA

Respondents

Heard at Toronto, Ontario, on October 24, 2012.

Judgment delivered at Ottawa, Ontario, on December 7, 2012.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: SHARLOW J.A.
TRUDEL J.A.

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] On August 26, 2010, Apotex Inc. commenced an application for judicial review of the Minister of Health's treatment of its submission for a Notice of Compliance (NOC) for Omeprazole Magnesium tablets (Tablets).

[2] A judge of the Federal Court dismissed the application on the ground that, in substance, Apotex' application was brought in respect of three discrete decisions made by the Minister during

the drug review process. Those decisions were: what Apotex characterizes to be a revocation by the Minister on December 5, 2008 of an "approvability status" for the Tablets, the Minister's issuance on February 9, 2009 of a "Notice of Non-Compliance withdrawal letter" for the Tablets, and the Minister's decision on July 27, 2009 to deny Apotex' request for reconsideration of the February 9, 2009 decision. Notwithstanding, the application for judicial review was commenced 13 months after the last of the three decisions. Therefore, the Judge found that the application was brought outside the time period specified in subsection 18.1(2) of the *Federal Courts Act*, R.S.C. 1985, c. F-7.

[3] The Judge went on to find there was no merit to Apotex' motion, brought in the alternative, to extend the time in which the application could be commenced.

[4] Finally, the Judge dismissed Apotex' argument that it had a vested right to a NOC because the Minister had previously concluded her examination of Apotex' submission and decided that a NOC would issue when the requirements of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 were met (PMNOC Regulations). Those requirements would be met on the expiration of a patent owned by AstraZeneca Canada Inc. Until the expiration of this patent, Apotex' submission was on what is referred to as "patent hold".

[5] This is an appeal of the decision of the Federal Court. On this appeal, Apotex argues that the Federal Court Judge erred in law in concluding that:

(a) Apotex' application for judicial review was subject to the 30-day filing requirement contained in subsection 18.1(2) of the *Federal Courts Act*;

(b) Apotex did not meet the test for an extension of time; and

(c) Apotex did not have a vested right to a NOC.

[6] For the reasons that follow, I have concluded that the Federal Court Judge did not err as asserted. Therefore, I would dismiss the appeal with costs.

Consideration of the Issues

(a) Was Apotex' application subject to the 30-day filing requirement?

[7] Both in the Federal Court and this Court, Apotex argued that its application was not filed out of time because the actions it complains of formed a continuing course of unfair and seemingly biased conduct, to which the 30-day time limit does not apply. Apotex relied upon the decision of this Court in *Krause v. Canada*, [1999] 2 F.C. 476, [1999] F.C.J. No. 179.

[8] The Judge rejected Apotex' characterization of its application. He observed that in its amended notice of application Apotex sought prerogative relief in connection with three ministerial decisions. In his view, the application involved "a fairness challenge to three discrete administrative decisions" (reasons, paragraph 18), and Apotex' position was a "colourable device intended to permit Apotex to avoid violating both the letter and the spirit of [sub]section 18.1(2) of the *Federal Courts Act* and Rule 302" (reasons, paragraph 21).

[9] The Judge's characterization of Apotex' position was based upon his review of its amended notice of application and was a conclusion of mixed fact and law. As such, in the absence of an extricable error of law (which is not alleged by Apotex), this Court may set aside the Judge's

conclusion only if a palpable and overriding error is demonstrated (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, at paragraphs 10 and 36).

[10] In my view, no such error has been demonstrated. The primary relief sought by Apotex was an order quashing the Minister's decision of December 5, 2008 to revoke her prior approval of Apotex' submission and an order compelling the Minister to issue a NOC to Apotex for its Tablets. No relief was sought compelling the Minister to cease any allegedly unfair or biased conduct.

[11] Apotex' amended notice of application supported the Judge's conclusion that it sought prerogative relief in connection with three separate decisions and so was subject to subsection 18.1(2) of the *Federal Courts Act*.

(b) Did Apotex meet the test for an extension of time?

[12] Apotex did not challenge the correctness of the Judge's statement, at paragraph 22 of his reasons, concerning the elements of the test to be applied when considering motions to extend time:

(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.

[13] Apotex argues, however, that rather than applying the entirety of the test, the Judge erred in law by only considering the first and last elements of the test. Moreover, Apotex argues that "where the underlying judicial review application has strong merits, or where justice so requires, the court

should give less or even no weight to the other factors of the test. A strong case on the merits may counterbalance a less than satisfactory justification for delay."

[14] The Judge's refusal to extend the time limitation is a discretionary decision, subject to deference. This Court cannot intervene unless the Judge misdirected himself, failed to give sufficient weight to relevant factors, proceeded on a wrong principle of law, or made a decision that is so clearly wrong that it amounts to an injustice (*Sellathurai v. Canada (Minister of Public Safety and Emergency Preparedness)*, 2011 FCA 223, [2011] F.C.J. No. 1003, at paragraph 18).

[15] In my view, the Judge made no reviewable error. I reject Apotex' submission that the Judge erred in principle by failing to consider expressly the merits of the application and the issue of prejudice.

[16] The seminal authority with respect to the test to be applied on motions seeking an extension of time is the decision of this Court in *Grewal v. Minister of Employment and Immigration*, [1985] 2 F.C. 263, 63 N.R. 106. There Chief Justice Thurlow, writing for himself and Justice Mahoney, wrote at page 272 [cited to F.C.] (emphasis added):

> The underlying consideration, however, which, as it seems to me, must be borne in mind in dealing with any application of this kind, is whether, in the circumstances presented, to do justice between the parties calls for the grant of the extension.

[17] Chief Justice Thurlow later continued at pages 277 and 278 (emphasis added):

> Among the matters to be taken into account in resolving the first of these questions is whether the applicant intended within the 10-day period to bring the application and had that intention continuously thereafter. Any abandonment of that intention, any laxity or failure of the applicant to pursue it as diligently as could

> reasonably be expected of him could but militate strongly against his case for an extension. The length of the period for which an extension is required and whether any and what prejudice to an opposing party will result from an extension being granted are also relevant. But, in the end, whether or not the explanation justifies the necessary extension must depend on the facts of the particular case and it would, in my opinion, be wrong to attempt to lay down rules which would fetter a discretionary power which Parliament has not fettered.

[18] These passages do not support the argument that it is an error of principle to fail to expressly consider each of the four factors.

[19] This is reflected in the decision of this Court in *Exeter v. Canada (Attorney General)*, 2011 FCA 253, 423 N.R. 262, where this Court disposed of an appeal from a decision refusing an extension of time on the basis of applying only one element of the four-part test. At paragraph 8 of the reasons, the Court stated:

> In my view, it is not necessary to examine the Federal Court's finding about the appellant's explanation for the delay. This is because the appellant's motion fails on the alternate, equally fatal ground that her application has no prospect of success: […].

[20] Additionally, I reject Apotex' contention that the Judge did not have regard to the merits of the application. At paragraph 28 of the reasons, he wrote:

> […] 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.

(c) Did Apotex have a vested right to a NOC?

[21] Notwithstanding his conclusion that the application was brought out of time, the Judge considered whether Apotex had a right to a NOC because this was an issue "arguably not disposed

of by the failure to bring this application on a timely basis." (reasons, paragraph 31). I agree, and as the issue was fully argued on the appeal it is appropriate to consider Apotex' arguments to the effect that the Minister's discretion was sufficiently exercised or solidified that Apotex had acquired a right to have a NOC issue for its Tablets.

[22] Apotex' argument that it had a vested right to a NOC may be summarized as follows:

i) It is necessary to review the scope and nature of the Minister's authority under the *Food and Drug Regulations*, C.R.C., c. 870 (Regulations) in order to determine the interrelated questions of, first, when her discretion has been exercised in respect of a submission, and, second, whether she is afforded an opportunity to revisit or reconsider a prior decision.

ii) Sections C.08.001-C.08.003 contain provisions which prevent the sale or advertising of a "new drug" unless, among other things, one of the defined types of submissions has been filed with the Minister, and a NOC has issued in respect of that submission.

iii) Subsection C.08.004(1) of the Regulations provides (emphasis added):

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,	C.08.004. (1) Sous réserve de l'article C.08.004.1, après avoir terminé l'examen d'une présentation de drogue nouvelle, d'une présentation abrégée de drogue nouvelle ou d'un supplément à l'une de ces présentations, le ministre :
(*a*) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or	*a*) si la présentation ou le supplément est conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;
(*b*) if that submission or	*b*) si la présentation ou le

supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.	supplément n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, en informe le fabricant.

iv) When the Minister completes her examination of a submission she is compelled to issue a NOC if the submission is found to comply with the relevant requirements.

v) In the present case, after the Minister completed her examination of Apotex' submission, she notified Apotex that the submission was "satisfactory" for the purpose of the Regulations. Therefore, the Minister would have issued a NOC shortly thereafter, but for the operation of the PMNOC Regulations.

vi) Because the Minister must issue a NOC when the submission is found to comply with the relevant requirements, the completion of examination is not an ongoing event. Apotex relies upon the decision of the Supreme Court of Canada in *Mount Sinai Hospital Center v. Quebec (Minister of Health and Social Services)*, 2001 SCC 41, [2001] 2 S.C.R. 281, at paragraph 114, to argue that the Minister is not provided with a period of time in which to change her mind, because she is compelled to act when her examination is completed.

vii) The Regulations do not make any provision for the receipt or review of any new information after a submission is approved, but before a NOC issues. If a NOC is issued and then new information is received to the effect that a drug should no longer be considered safe or effective, section C.08.006 permits the Minister to suspend a NOC. This is the course that should be followed in cases such as the

present where safety and efficacy concerns are said to arise after the Minister completes her examination, but before the NOC is issued.

viii) To conclude its analysis on the Regulations, Apotex argues that the regime does not contemplate the suspension of a NOC before it is issued based on new information, because the same regime requires the NOC to be issued upon completion of the examination without the review of any such new information.

ix) Apotex submits that this analysis is wholly consistent with the decision of this Court in *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742, [1993] F.C.J. No. 1098 (C.A.); aff'd [1994] 3 S.C.R. 1100, [1994] S.C.J. No. 113 (*Apotex v. Canada*).

x) Finally, section 8 of the PMNOC Regulations defines the period of time that is presumptively used to determine the damages a second person suffers when an application for prohibition made under section 6 of the PMNOC Regulations is discontinued or dismissed. The period commences on the date the drug was approved and placed on patent hold. This date is used because it reflects the point in time when the second person would have received a NOC, but for the operation of the PMNOC Regulations. Apotex argues that this date would not have been used as the referential starting point for the damage calculation if the Minister's determination could be revisited, and remain subject to her ongoing discretion to revoke that status.

[23] In my view, Apotex' analysis is flawed for the following reasons.

[24] First, while I agree that it is necessary to review the scope and nature of the Minister's authority under the Regulations, the Regulations must be interpreted in accordance with the preferred approach to statutory interpretation.

[25] This approach has been expressed in the following terms by the Supreme Court of Canada:

> Although much has been written about the interpretation of legislation (see, e.g., Ruth Sullivan, *Statutory Interpretation* (1997); Ruth Sullivan, *Driedger on the Construction of Statutes* (3rd ed. 1994) (hereinafter *"Construction of Statutes"*); Pierre-André Côté, *The Interpretation of Legislation in Canada* (2nd ed. 1991)), Elmer Driedger in *Construction of Statutes* (2nd ed. 1983) best encapsulates the approach upon which I prefer to rely. He recognizes that statutory interpretation cannot be founded on the wording of the legislation alone. At p. 87 he states:
>
> > Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.
>
> Recent cases which have cited the above passage with approval include: *R. v. Hydro-Québec*, [1997] 3 S.C.R. 213; *Royal Bank of Canada v. Sparrow Electric Corp.*, [1997] 1 S.C.R. 411; *Verdun v. Toronto-Dominion Bank*, [1996] 3 S.C.R. 550; *Friesen v. Canada*, [1995] 3 S.C.R. 103.
>
> See: *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27 at paragraph 21. See also: *R. v. Ulybel Enterprises Ltd.*, 2001 SCC 56, [2001] 2 S.C.R. 867 at paragraph 29.

[26] The Supreme Court restated this principle in the following terms in *Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54, [2005] 2 S.C.R. 601 at paragraph 10 (emphasis added):

> It has been long established as a matter of statutory interpretation that "the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament": see *65302 British Columbia Ltd. v. Canada*, [1999] 3 S.C.R. 804, at para. 50. The interpretation of a statutory provision must be made according to a textual, contextual and purposive analysis to find a meaning that is harmonious with the Act as a whole. When the words of a provision are precise and unequivocal, the ordinary meaning of the words play a dominant role in the interpretive process. On the other hand, where the words can support more than one

> reasonable meaning, the ordinary meaning of the words plays a lesser role. The relative effects of ordinary meaning, context and purpose on the interpretive process may vary, but in all cases the court must seek to read the provisions of an Act as a harmonious whole.

[27] This formulation of the proper approach to statutory interpretation was restated in *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 at paragraph 21, and *Canada (Information Commissioner) v. Canada (Minister of National Defence)*, 2011 SCC 25 at paragraph 27.

[28] The proper limit to the use of context was explained in the following way by the majority of the Supreme Court in *Montréal (City) v. 2952-1366 Québec Inc.*, 2005 SCC 62, [2005] 3 S.C.R. 141 at paragraph 15:

> In the interpretation process, the more general the wording adopted by the lawmakers, the more important the context becomes. The contextual approach to interpretation has its limits. Courts perform their interpretative role only when the two components of communication converge toward the same point: the text must lend itself to interpretation, and the lawmakers' intention must be clear from the context.

[29] Apotex' analysis fails to consider the purpose of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (Act) and the Regulations. That purpose has been described by the Supreme Court of Canada to be "to encourage bringing safe and effective medicines to market to advance the nation's health" (*AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paragraph 12). The primary responsibility of the Minister under the Act and the Regulations is to the health and welfare of Canadians.

[30] When the Minister exercises her discretion under section C.08.004 of the Regulations to issue a NOC, she must be satisfied that the drug is safe and effective. Nothing in the wording of the Regulations compels the contrary conclusion and it would, in my view, be an absurd result to construe the Regulations in such a way that the Minister could be compelled to issue a NOC even if she was not satisfied that the drug in question is safe and effective.

[31] Second, in my view, the decision of the Supreme Court of Canada in *Mount Sinai Hospital Center* does not support Apotex' submission that the completion of the Minister's examination is not an ongoing event.

[32] At issue in *Mount Sinai Hospital Center* was the exercise of discretion by the Quebec Minister of Health and Social Services not to issue a permit to the Center under provincial legislation pertaining to the operation of hospitals. For the majority of the Supreme Court, the decision turned on a finding of fact that the Minister had in fact exercised his discretion in favour of the Center, and that the Minister did not validly reverse that exercise of discretion. On the latter point the majority observed that the regulatory scheme at issue did not provide the Minister "[…] with a period of time in which to change his or her mind. Moreover, even if such a power were to be imputed to the Minister on the basis of general discretionary process, the refusal in this case was not a valid exercise of the Minister's discretion" (reasons of the majority at paragraph 114).

[33] There was no finding by the majority that only where legislation or regulations provide a temporal gap can a minister change his or her mind. Moreover, both the majority and the minority (concurring in the result) endorsed the general proposition that "being entitled to the permit is

different than actually holding it" (reasons of the Supreme Court of Canada at paragraphs 1 and 97). As Justice Binnie, writing for himself and the Chief Justice added at paragraph 1, "[i]n government, nothing is done until it is done."

[34] Third, as noted above, Apotex argues that the Regulations make provision for the circumstance where "evidence or new information" comes to the attention of the Minister after a NOC has issued. The absence of equivalent provision to consider new evidence or information received after the completion of the examination, but prior to the issuance of a NOC, is said to reinforce the conclusion that the Minister has no continuing discretion. The position of Apotex is based on the premise that there are only two possible stages for a drug submission under the Regulations: (1) it may be under examination, or (2) the examination has been completed. However, nothing in the Regulations supports the position that there are only two possible stages. In the normal course of events there may well be a time delay between the point where the Minister informs an applicant that the safety and efficacy requirements are met, and the point when the NOC may issue. If, during that period, information comes to the Minister that casts doubt on her initial conclusions, she would be remiss in issuing the NOC.

[35] While the Regulations do not expressly contemplate the effect of a patent hold under the PMNOC Regulations, the broader purpose of the Regulations, and the discretion given to the Minister to give it effect, contemplate that the Minister has the discretion to revisit an application which is on patent hold when she deems it necessary to reconsider the safety and efficacy of the drug.

[36] Fourth, it is correct that in *Apotex v. Canada* this Court found that Apotex had acquired a vested right to an NOC (reasons, paragraph 93). The Supreme Court of Canada dismissed an appeal from that decision, substantially for the reasons given by this Court.

[37] The facts that gave rise to the decision were that on February 15, 1990 Apotex filed a submission in respect of its drug Apo-Enalapril. On December 22, 1992, it initiated an application in which it sought an order in the nature of *mandamus* requiring the Minister to issue a NOC in respect of Apo-Enalapril. By February 3, 1993, Apo-Enalapril met all of the safety and efficacy conditions required for a NOC to issue (reasons, Federal Court of Appeal at paragraphs 22 and 29). This was an important contextual factor.

[38] Notwithstanding that by February 4, 1993 the matter was ready for a decision to be made by the Minister, representatives of Health Canada decided to seek legal advice regarding the authority of the Minister to issue the NOC in view of the impending passage of *The Patent Act Amendment Act*, 1992 (Bill C-91).

[39] The question to be considered was whether Apotex had a vested right to the NOC. This turned on whether the Minister's discretion with respect to the NOC had been spent as of February 4, 1993.

[40] Four issues were found to be relevant to the determination of whether Apotex had a vested right to a NOC: (a) the scope of the Minister's discretion; (b) the relevance of legal advice; (c) the

relevance of pending legislative policy; and (d) whether the matter had reached the Minister for his consideration (reasons, Federal Court of Appeal at paragraph 64).

[41] With respect to the scope of the Minister's discretion, the Court wrote that the "discretion is directly contingent upon the characterization of various considerations as 'relevant' or irrelevant to its exercise." The Court rejected the proposition that the Minister's discretion was, as a matter of statutory construction, sufficiently broad to embrace considerations other than those dealing with safety and efficacy (reasons, Federal Court of Appeal at paragraph 65).

[42] The Court went on to conclude that in delaying his decision the Minister had considered irrelevant factors. Therefore, Apotex was found to have a vested right to a NOC.

[43] Given that in *Apotex v. Canada* the safety and efficacy of the drug were at all times acknowledged, and this Court found that the factors relevant to the Minister's discretion were the safety and efficacy of the drug, I do not read the decision as supportive of the proposition that a right to a NOC can vest when the Minister is not satisfied as to the safety and efficacy of a drug. This issue was simply not before the Court.

[44] Before leaving this point, I have considered Apotex' submission that it was "unfair and arbitrary" for the Minister's officials to prefer the negative result of a 2008 review of its submission over the positive result obtained in 2002 when, it alleges, there had been no material change in circumstances. I have also considered its argument that the conduct of the Minister's officials gives rise to a reasonable apprehension of bias.

[45] Apotex' evidence on these points was addressed by the Minister.

[46] On the whole of the evidence I find that Apotex has failed to establish that the Minister's safety and efficacy concerns were not *bona fide*. The evidence is consistent with there being significant uncertainty within the Therapeutic Products Directorate of Health Canada about the appropriate bioequivalence requirements to be applied to proton pump inhibitors. Such scientific uncertainty does not detract from the *bona fides* of the Minister's safety and efficacy concerns.

[47] Returning to the analysis of Apotex' claim to a vested right, it is next necessary to consider Apotex' assertion that if the Minister's decision to approve a submission could be revisited by the Minister, the date the submission was approved would not have been used as the referential starting point for the damage calculation under section 8 of the PMNOC Regulations. However, if the Minister revisits the initial conclusion and then decides not to issue a NOC to the second party there will be no section 8 claim. Again, I do not find this argument to be of assistance in interpreting the Regulations.

[48] Finally, to conclude, Apotex' position is essentially that, based upon the Minister's initial approval, it had a legitimate expectation that the NOC would issue at the end of the patent hold. However, the doctrine of legitimate expectations does not confer substantive rights of the nature sought by Apotex (see, for example, *Moreau-Bérubé v. New Brunswick (Judicial Council)*, 2002 SCC 11, [2002] 1 S.C.R. 249, at paragraph 78. See also, Brown & Evans, *Judicial Review of Administrative Action in Canada*, Vol. 2, page 7-24).

Conclusion

[49] For these reasons, I would dismiss the appeal with costs.

"Eleanor R. Dawson"

J.A.

"I agree.
K. Sharlow J.A."

"I agree.
Johanne Trudel J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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