Federal Court  Cour fédérale

Date: 20101201

Docket: T-152-10

Citation: 2010 FC 1211

Vancouver, British Columbia, December 1, 2010

PRESENT: **Roger R. Lafrenière, Esquire**
Prothonotary

BETWEEN:

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Applicant

and

THE MINISTER OF HEALTH AND GLAXOSMITHKLINE INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] The Respondent, GlaxoSmithKline (GSK), seeks an order dismissing the application for judicial review commenced by the Applicant, Canadian Generic Pharmaceutical Association (CGPA).

[2] GSK submits that the application is bereft of any possibility of success for two reasons. First, the application does not pertain to a "decision" within the meaning of section 18.1 of the

Federal Courts Act. Second, CGPA lacks standing to seek judicial review – either as a "person interested" or in support of the "public interest".

[3] For the reasons that follow, I conclude that CGPA is not a person directly affected by the decision within the meaning of section 18.1 of the *Federal Courts Act*, nor a person entitled to make the application in the public interest. Since the finding of lack of standing is determinative, it is not necessary to consider whether the decision at issue in the application is amenable to judicial review.

Facts

[4] By way of background, GSK obtained a Notice of Compliance (NOC) for Avamys® (fluticasone furoate) on August 14, 2007. On October 26, 2009, Avamys® was added to the Register of Innovative Drugs (Register) maintained by the Minister of Health (Minister) pursuant to section C.08.004.1 of the *Food and Drug Regulations*, C.R.C. 1978, c. 870 (*Regulations*). As a result of being listed on the Register, no generic manufacturer can file an abbreviated new drug submission (ANDS) for fluticasone furoate until August 14, 2013 and no NOC can issue until February 14, 2016.

[5] CGPA is an industry association representing most generic drug manufacturers in Canada with respect to regulatory and legal issues affecting its members. By letter dated December 14, 2009, CGPA wrote to the Office of Patented Medicines and Liaison (OPML), on behalf of the Minister, requesting that her decision be set aside and that Avamys® be removed from the Register. CGPA alleged that Avamys® (i.e., fluticasone furoate) is an ester variation of a

previously approved medicinal ingredient (i.e., fluticasone propionate) and falls outside the definition of "innovative drug" under the *Regulations*.

[6] CGPA's request was refused by the Minister on January 6, 2010. The Minister advised CGPA that *fluticasone furoate* and *fluticasone propionate* are both esters of *fluticasone*. Since *fluticasone* is not a medicinal ingredient "previously approved in a drug by the Minister", *fluticasone furoate* is not a "variation of a previously approved medicinal ingredient".

[7] CGPA subsequently brought the present application to review the Minister's decision to maintain Avamys® on the Register of Innovative Drugs by Notice of Application dated February 3, 2010. CGPA claims that the Minister erred in failing to grant its request to remove Avamys® from the Register on the basis that it is a variation of a previously approved medicinal ingredient (i.e., fluticasone propionate). In its prayer for relief, CGPA seeks: (i) an order of mandamus directing the Minister to remove fluticasone furoate from the Register; or (ii) alternatively, a declaration that fluticasone furoate ought not to have been added to the Register and its listing has no legal effect.

[8] Mr. James Keon, president of CGPA, filed an affidavit in response to GSK's motion to strike. Mr. Keon states that developing a generic version of a brand name product and obtaining approval from Health Canada is a very costly and time-intensive process for generic drug manufacturers. According to Mr. Keon, if CGPA is not permitted to bring this proceeding challenging an improper listing on the Register of Innovative Drugs, then it is unlikely that any of CGPA member companies would individually challenge the listing of fluticasone furoate. This is

because each company would be required to make a substantial investment in developing a fluticasone furoate product and conducting expensive and necessary studies to support an abbreviated new drug submission. The delay, burden, uncertainty and cost of litigation challenging the listing of fluticasone furoate on the Register of Innovative Drugs by an individual company would be significant.

[9] On cross-examination, Mr. Keon admitted that CGPA is not a drug manufacturer, that it does not file new drug submissions and that it has never received a notice of compliance nor sold a drug product in Canada. In particular, CGPA has never filed a drug submission for fluticasone furoate (AVAMYS®). Mr. Keon refused to answer whether the association intends to do so in the future. He also refused to say whether CGPA represents the public interest, such as the provincial formularies, patients or drug purchasers. He would only say that CGPA represents the interests of its Member Companies.

Analysis

[10] GSK submits that the Minister's refusal to remove Avamys® from the Register at CGPA's request is not a "decision" that can be reviewed by this Court. GSK maintains that the refusal was really no more than a reconsideration of an earlier decision, and not a separate decision. For the purpose of these reasons, it is irrelevant which decision is at issue in the application. As noted in the preamble, the key issue to be decided on this motion is whether CGPA has standing to seek judicial review of the initial decision to add fluticasone furoate to the Register, or the refusal by the Minister of CGPA's request to remove the drug from the Register - either as a person interested or on behalf of the public interest.

[11] This Court has jurisdiction to strike an application for judicial review if it is "bereft of all possibility of success": *Lundbeck Canada Inc. v. The Minister of Health et al*., 2008 FC 1379 at para. 34, aff'd 2009 FCA 134; *Apotex Inc. v. Canada (Governor in Council),* 2007 FCA 374 at para. 16. However, an application for judicial review should only be dismissed on an interlocutory motion in the clearest cases. In most cases, the Court's resources should not be expended on motions to strike, which can more efficiently be addressed at the hearing of the application itself: *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc*, [1995] 1 F.C. 588 at para. 10.

[12] An exception to the general rule is made, however, where the applicant clearly has no standing to bring the application: *Apotex Inc. v. Canada (Governor in Council)*, 2007 FC 232 at para. 33. The Court may determine the issue of standing as a preliminary matter on a motion to strike an application for judicial review where there is sufficient material before the Court in terms of facts, law and arguments for an understanding as to the nature of the applicant's interests. This criteria is met in the present case. The Court has the benefit of evidence from CGPA on the issue of standing, and comprehensive submissions from the parties.

Whether CGPA is "Directly Affected"

[13] CGPA submits that it has standing because it is "directly affected" by the listing of fluticasone furoate on the Register. It contends that the refusal to recognize the standing of collective organizations, on the basis that only the members of the organization are "aggrieved", is increasingly being viewed as too formalistic: *Alberta Liquor Store Assn. v. Alberta (Gaming & Liquor Commission)*, 2006 ABQB 904 (*Alberta Liquor*) at para. 20.

[14] This Court has, in a number of cases, allowed an organization to bring an application on behalf of its members. In fact, in *Canadian Generic Pharmaceutical Assn. v. Canada (Governor in Council)*, 2007 FC 154 at para. 17, aff'd 2007 FCA 375 *(CGPA v. Canada)*, Mr. Justice Sean Harrington held, on a preliminary motion, that CGPA had standing to challenge the *vires* of the data protection provisions of the *Regulations* as a person "directly affected" because CGPA was "not an officious inter-meddler". The Federal Court of Appeal affirmed Justice Harrington's findings on public interest standing, but declined to comment on his finding that "it was not plain and obvious that the Respondent was not 'directly affected' within the meaning of section 18.1".

[15] However, the circumstances of the present motion to strike are distinguishable from those before Justice Harrington. Unlike the present motion, no particular drug product was at issue in *CGPA v. Canada*. This is, in my view, a critical distinction. CGPA cannot, simply as a result of its status as an association, acquire a greater standing or be in a better position than its individual members to challenge a listing decision.

[16] In *Alberta Liquor*, at para. 9, Mr. Justice Slatter listed a number of factors that must be weighed in determining whether a party is "aggrieved". An important factor was the relationship between the applicant and the challenged decision, or how directly the challenged administrative act will affect the legally-recognized interests of the applicant. The same factor applies for applications brought in this Court. In order to be "directly affected", within the meaning of section 18.1 of the *Federal Courts Act*, the decision must adversely affect a party's legal rights, impose a legal obligation, or cause direct prejudice: *Rothmans of Pall Mall Canada Ltd. v. Canada (Minister of National Revenue)*, [1976] 2 F.C. 500 (F.C.A.), *CanWest MediaWorks Inc. v. The Minister of*

Health et al., 2007 FC 752 at para. 13, aff'd 2008 FCA 207; *Independent Contractors and Business Assn. v. Canada (Minister of Labour),* [1998] F.C.J. No. 352 at paras. 30-31 (F.C.A.).

[17] CGPA wholly fails to meet this test. CGPA is a trade association that advocates on behalf of member companies. It does not manufacture generic drugs, nor does it submit drug submissions, obtain NOCs, or sell drugs in Canada. Neither CGPA, nor admittedly any of its members, have filed a drug submission for fluticasone furoate, or even expressed any intention, present or future, to manufacture the drug. As a result, the decision under review (to maintain the listing of fluticasone furoate on the Register) does not adversely affect the legal rights of CGPA itself, or any of its members. Further, on the evidence before me, the decision also does not impose any legal obligation or cause them any direct prejudice.

[18] It should be noted that, under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*PM(NOC) Regulations*"), generic manufacturers do not have standing to challenge the Minister's decision to list a patent on the Patent Register unless they have filed an ANDS referencing a drug to which the impugned patent relates: *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (1998), 82 C.P.R. (3d) 65 at para. 5 (F.C.T.D.). By analogy, a manufacturer of generic drugs does not have standing to challenge the Minister's decision to list a drug on the Register of Innovative Drugs unless it has attempted to file an ANDS referencing the impugned "innovative drug" as the reference product.

[19] It is plain and obvious that the Minister's decision to list Avamys® on the Register does not in anyway impact or prejudice CGPA or any of its members. GSK has clearly established that CGPA has no standing to bring the application for judicial review as a person "directly affected".

Whether CGPA has public interest standing

[20] GSK also submits that CGPA does not have public interest standing as it does not purport to speak on behalf of the public.

[21] The three-part test for public interest standing is set out by the Supreme Court of Canada in *Canadian Council of Churches v. Canada (Minister of Employment and Immigration),* [1992] 1 S.C.R. 236 at 253, as follows:

(i) Is there a serious issue raised as to the validity of a public act exercised by a statutory authority?

(ii) Is the challenger affected directly by the act or have a genuine interest in the validity of the act in issue?

(iii) Is there no other reasonable or effective manner in which to bring the issue to Court?

[22] For the purpose of this motion, I am prepared to accept that the application raises a serious or justiciable issue.

[23] However, as I have concluded above, CGPA is not "affected directly" and has no "genuine interest" in the decision under review. I agree with GSK that CGPA's primary objective is to have the entire data protection regime struck down as being *ultra vires* rather than to challenge the Minister's refusal to remove the listing of fluticasone furoate from the Register.

[24] The basic purpose of public interest standing is to ensure that legislation is not immunized from challenge. Where there is no such immunization "the very rationale for the public interest litigation party disappears": *Canadian Council of Churches v. Canada (Minister of Employment and Immigration)*, [1992] 1 S.C.R. 236 at p. 256. The *Regulations* specifically allow for generic manufacturers to challenge the listing of "innovative drugs" on the Register. This is the most reasonable and effective procedure to challenge a listing in the Courts.

[25] There is no need to hear from a party whose rights are not directly affected based on an alleged public interest. In fact, on the evidence before me, it appears that the interests being advocated by CGPA are exclusively those of its members, and not the public at large.

[26] A challenge to the *vires* of the data protection *Regulations*, unlike a challenge concerning a particular drug, would be of interest to all generic manufacturers, thereby making CGPA an appropriate representative party. However, in contrast, a specific administrative decision, as in the present case, should only be challenged by parties who are actually subject to the legal duties imposed by that particular decision.

[27] Since the present application pertains to a particular drug, rather than the entire legislative scheme, it is plain and obvious that the preferred, reasonable and effective manner to bring this issue to the Court is by a generic drug manufacturer seeking to submit an ANDS for fluticasone furoate.

Conclusion

[28] This is an appropriate case for this Court to exercise its discretion to make a preliminary determination of standing to dismiss the application.

[29] For all of the above reasons, it is plain and obvious that CGPA has no standing and that the application is bereft of all possibility of success. The Notice of Application is accordingly struck out and the proceeding is dismissed, with prejudice.

ORDER

THIS COURT ORDERS that:

1. The motion is granted.

2. The Notice of Application is struck out and the application is dismissed.

3. In the event the parties are unable to agree on costs on the motion, the parties are granted leave to serve and file written submissions, not exceeding 5 pages in length.

"Roger R. Lafrenière"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

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