Federal Court  Cour fédérale

Date: 20110415

Docket: T-152-10

Citation: 2011 FC 465

Ottawa, Ontario, April 15, 2011

PRESENT: The Honourable Mr. Justice de Montigny

BETWEEN:

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Applicant

and

THE MINISTER OF HEALTH AND GLAXOSMITHKLINE INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] The Canadian Generic Pharmaceutical Association (the "CGPA") appeals an Order of Prothonotary Lafrenière, dated December 1, 2010 (the "Order"). Prothonotary Lafrenière struck the CGPA's application for judicial review, which challenged a decision by the Minister of Health (the "Minister") to maintain the listing of fluticasone furoate on Health Canada's Register of Innovative Drugs (the "Register"). The Prothonotary decided to strike the application on the grounds that the CGPA does not have the standing to challenge the listing of a particular drug product on the Register pursuant to the data protection provisions in section C.08.004.1 of the *Food and Drug Regulations*, C.R.C., c. 870 (the "*Regulations*").

[2] For the reasons that follow, I am of the view that this appeal must be dismissed. It is plain and obvious that the CGPA is not directly affected by the Minister's decision, and cannot meet the test for "public interest" standing. As a result, the association has no chance of success and the application was properly struck on a preliminary motion.

I. Facts

[3] The Respondent GlaxoSmithKline obtained a Notice of Compliance ("NOC") for its drug AVAMYS, which contains the medicinal ingredient *fluticasone furoate*, in August 2007. In October 2009, AVAMYS was added to the Register, with the result that no generic manufacturer may file a new drug submission for another version of AVAMYS until August 2013, and no NOC may be issued for any such submission until February 2016.

[4] The Register is intended to be a list of what are referred to as "innovative drugs". This data protection regime was published on October 18, 2006 in the *Canada Gazette Part II*, Vol. 140, No. 21, SOR/DORS/2006-241 and registered on October 5, 2006. The data protection provision, now C.08.004.1 of the *Regulations*, imposes a monopoly that operates in addition to, and independent of, the patent-related monopolies set out in the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133.

[5] C.08.004.1 of the *Regulations* creates a scheme whereby the manufacturer of an "innovative drug" is awarded a minimum of eight years of market exclusivity for the innovative drug product. A further six months of market exclusivity can be obtained if certain studies relevant to pediatric populations are conducted. The most relevant portions of C.08.004.1 are set out below:

***Food and Drug Regulations*, C.R.C, c. 870**

C.08.004.1 (1) The following definitions apply in this section.

"innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante)

"pediatric populations" means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (population pédiatrique)

[…]

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,

(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and

(b) the Minister shall not approve that submission or supplement and shall not

***Règlement sur les aliments et drogues*, C.R.C., ch. 870**

C.08.004.1 (1) Les définitions qui suivent s'appliquent au présent article.

« drogue innovante » S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (innovative drug)

« population pédiatrique » S'entend de chacun des groupes suivants : les bébés prématurés nés avant la 37e semaine de gestation, les bébés menés à terme et âgés de 0 à 27 jours, tous les enfants âgés de 28 jours à deux ans, ceux âgés de deux ans et un jour à 11 ans et ceux âgés de 11 ans et un jour à 18 ans. (pediatric populations)

[…]

(3) Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :

a) le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;

b) le ministre ne peut approuver une telle présentation ou un tel supplément et ne

issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	peut délivrer d'avis de conformité pour cette nouvelle drogue avant l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.
[…]	[…]
(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).	(9) Le ministre tient un registre des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4).

[6] An "innovative drug" is defined in C.08.004.1 as a drug that contains a medicinal ingredient that has not previously been approved in a drug. The definition of "innovative drugs" excluded drugs that are merely "a variation of a previously approved medicinal ingredient". Section C.08.004.1 provides some examples of what may form a variation of a previously approved medicinal ingredient, such as "a salt, ester, enantiomer, solvate or polymorph" of the previously approved medicinal ingredient. The exclusion of these variations from the protection of C.08.004.1 was introduced to avoid the granting of multiple eight-year terms of market exclusivity where an innovator manufacturer is granted approval for a minor change to an existing medicinal ingredient.

[7] By letter dated December 14, 2009, the CGPA wrote to the Minister requesting that fluticasone furoate be removed from the Register. The ground for its request was a technical and scientific one. The Association alleged that because fluticasone furoate is an ester variation of a previously approved medicinal ingredient (fluticasone propionate), AVAMYS falls outside the definition of "innovative drug" under the *Regulations*, and is not eligible for listing on the Register.

[8] By letter dated January 6, 2010, the Minister rejected the CGPA's request and set out the Minister's reasons for refusing to remove fluticasone furoate from the Register. The Office of Patented Medicines and Liaison ("OPML"), which acts on behalf of the Minister, advised the Association 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", according to the Office. AVAMYS is therefore not excluded from the class of "innovative drugs", and is eligible for listing on the Register.

[9] The CGPA commenced this proceeding by Notice of Application dated February 3, 2010. The CGPA submits that the Minister erred in fact and law by failing to remove AVAMYS from the Register because it is indeed a variation of a previously approved medicinal ingredient (i.e., fluticasone propionate).

[10] In its application, the CGPA seeks: (1) an order of mandamus directing the Minister to remove fluticasone furoate from the Register; or (2) alternatively, a declaration that fluticasone furoate ought not to have been added to the Register and that its listing has no legal effect.

[11] There is no dispute in this proceeding that the CGPA is an industry association that represents most generic drug manufacturers in Canada with respect to regulatory and legal issues affecting its members. For example, when the draft provisions that led to the current version of C.08.004.1 were published, the CGPA provided feedback to the government on the wording and desirability of the regime. Indeed, the CGPA has challenged (unsuccessfully) the validity of

C.08.004.1 before this Court: see *Canadian Generic Pharmaceutical Association v Canada (Minister of Health)*, 2009 FC 725; aff'd 2010 FCA 334.

[12] The Respondent GSK brought a motion seeking to dismiss this application for judicial review alleging that it is bereft of any possibility of success for two reasons. First, GSK asserted that the application does not pertain to a "decision" within the meaning of section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7. Second, GSK asserted that the CGPA lacks standing to seek judicial review, either as a "person interested" or in support of the "public interest".

[13] The Minister generally agreed that the second of these two grounds is valid, and that it constituted a sufficient basis for this Court to grant the Respondent's motion to strike the CGPA's application.

[14] Mr. James Keon, president of the 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 the 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 the 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 in 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.

[15] On cross-examination, Mr. Keon admitted that the 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, the CGPA has never filed a drug submission for fluticasone furoate (AVAMYS). Mr. Keon refused to say whether the association intends to do so in the future. He also refused to say whether the CGPA represents the public interest by furthering the interests of, for example, the provincial formularies, patients, or drug purchasers. He would only say that the CGPA represents the interests of its member companies.

II. <u>The decision under appeal</u>

[16] The Prothonotary first sets out the facts above. He then notes that he need not decide one of the points disputed by the parties; that is, whether the Minister's refusal to remove the drug from the Register at the CGPA's request constitutes a reviewable decision, either in its own right or as a reconsideration of the initial decision to place the drug on the list.

[17] Rather, he declares that the key issue to be decided is *whether the CGPA has standing to seek judicial review of the decision* (that is, of the decision to add fluticasone furoate to the Register, or the refusal to remove it) – either as a person interested or on behalf of public interest.

[18] He observes that the Court rarely uses its jurisdiction to strike an application for judicial review before hearing that application on the merits, except for in cases like this one where the applicant clearly has no standing to bring the application: *Apotex Inc. v Canada (Governor in Council)*, 2007 FC 232, at para 33.

[19] He then considers and rejects the CGPA's argument that it has standing because it is "directly affected" by the listing of the drug on the Register. He notes that while collective organizations such as the Applicant are indeed *occasionally* permitted to bring applications on behalf of their members, this is not a case where such a proceeding is appropriate, and distinguishes this case from others where such a proceeding was allowed.

[20] The Prothonotary explained that in order to have standing within the meaning of s. 18.1 of the *Federal Courts Act*, a party must be "directly affected" by the impugned decision. To be directly affected, the decision must adversely affect a party's legal rights, impose a legal obligation on it, or cause it direct prejudice (*Rothmans of Pall Mall Canada Ltd v Canada (Minister of National Revenue)*, [1976] 2 FC 500 (FCA), at para 13; *CanWest MediaWorks Inc v Canada (Minister of Health) et al*, 2007 FC 752 at para 13, aff'd 2008 FCA 207; *Independent Contractors and Business Association v Canada (Minister of Labour)*, [1998] FCJ No 352; 39 CLR (2d) 121, at paras 30-31 (FCA)).

[21] The Prothonotary finds that the CGPA fails to meet this test – as a trade association advocating on behalf of member companies, it does not manufacture drugs, submit drug submissions, obtain NOCs, or sell drugs. Nor has the CGPA or any of its members filed a drug submission for fluticasone furoate or even expressed an intention to manufacture it. As such, the decision under review does not adversely affect the CGPA's legal rights, nor does it impose an obligation or prejudice upon it. Therefore, it is not directly affected.

[22] Furthermore, under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*PM(NOC) Regulations*"), a generic manufacturer (and, by analogy, an association of generic

manufacturers like the CGPA) does not have standing to challenge the Minister's decision to list a patent on the Register unless it has filed an ANDS referencing the impugned drug: *Apotex Inc v Canada (Minister of National Health and Welfare)* (1998), 82 CPR (3d) 65, at para 5 (FCTD).

[23] Next, the Prothonotary considered the CGPA's argument that it had public interest standing. He rejected this argument by applying the three-part test set out in *Canadian Council of Churches v Canada (Minister of Employment and Immigration)*, [1992] 1 SCR 236, at 253:

- First, is there a serious issue raised as to the invalidity of legislation in question?
- Second, has it been established that the plaintiff is directly affected by the legislation or, if not, does the plaintiff have a genuine interest in its validity?
- Third, is there another reasonable and effective way to bring the issue before the Court?

[24] The Prothonotary accepted that the application met the first criterion of raising a serious issue.

[25] However, he found that it failed on the second criterion of whether the Applicant was directly affected by or had a genuinely interest in the decision, for the reasons set out above. He also stated that because the CGPA's true objective was to strike down the C.008.004.1 regime in its entirety (which was their goal in a concurrent and separate litigation), they did not have a genuine interest in removing fluticasone furoate from the Register.

[26] He also found that the application failed on the third criterion, which asks whether there is another reasonable manner available of bringing the issue before the Court. This criterion concerns

the rationale for public interest standing, which is to ensure that government or other action is not immune from challenge simply because no party has conventional standing.

[27] In the view of the Prothonotary, there is another manner of challenging the decision – that is, via a judicial review application brought by a legitimately interested party, such as a generic manufacturer seeking to submit an ANDS for the drug in question, which is permitted by the *Regulations*.

[28] He notes that the CGPA's true objective seems to be striking down the entire legislative regime as *ultra vires* and acknowledges that the association would have standing if it were to make such a challenge, but that it does not make such an argument in the present case and thus does not have standing.

[29] The Prothonotary therefore concluded that it was plain and obvious that the Applicant had no standing and that the application was bereft of all possibility of success; the Notice of Application was thus struck out and the proceeding was dismissed with prejudice.

III. <u>The issues</u>

[30] There are two issues to be determined on this motion:

i. What is the applicable standard of review for a discretionary order of a Prothonotary?

ii. Is it plain and obvious that the CGPA lacks standing to seek judicial review?

IV. Analysis

[31] An order of a prothonotary may be appealed by motion to a judge under rule 51 of the *Federal Courts Rules*, SOR/98-106. It is settled law that discretionary orders of prothonotaries ought not to be disturbed on appeal unless the questions raised in the motion are vital to the final issue of the case, or unless the orders are clearly wrong: *Canada v Aqua-Gem Investments Ltd*, [1993] 2 FC 425; *Merck & Co v Apotex Inc*, 2003 FCA 488, at para 19.

[32] There is no doubt that a prothonotary's decision to strike an application for judicial review must be considered *de novo*, because it is clearly vital to the issues in the proceeding: *Sanofi-Aventis Canada Inc. v Canada (Minister of Health)*, 2008 FC 129, at para 2. I shall therefore consider the matter afresh without being concerned with whether the Prothonotary erred in respect of questions of law or fact.

[33] In *David Bull Laboratories (Canada) Inc v Pharmacia Inc*, [1995] 1 FC 588 (CA), the Federal Court of Appeal determined that applications for judicial review should not be struck out prior to a hearing on the merits unless the application is "so clearly improper as to be bereft of any possibility of success". The FCA added that "such cases must be very exceptional and cannot include cases … where there is simply a debatable issue as to the adequacy of the allegations in the notice of motion".

[34] The reason for such a stringent test is easy to understand: since a full hearing on the merits of a judicial review application proceeds in much the same way that a motion to strike a notice of application would proceed – that is, on the basis of affidavit evidence and argument before a judge – there is no real advantage or economic reason to strike out an application in a preliminary manner.

Applications for judicial review are intended to be summary proceedings, and therefore, it will ordinarily be more efficient for the Court to deal with a preliminary argument at the hearing on the merits instead of doing so in a preliminary motion which would only add to the cost and time required: see *Addison & Leyen Ltd v Canada*, 2006 FCA 107, at para 5, rev'd on other grounds 2007 SCC 33; *Amnesty International v Canadian Forces*, 2007 FC 1147, at paras 22-24.

[35] That being said, there are exceptions to that general rule, and one of them is where the Applicant has no standing to bring the application: see *Apotex Inc v Canada (Governor in Council)*, 2007 FC 232, at para 33; *Canwest Mediaworks Inc v Canada (Minister of Health)*, 2007 FC 752, at para 10, aff'd 2008 FCA 207. The Supreme Court of Canada accepted that an issue of standing may be properly determined as a preliminary matter where the Court has sufficient information before it for a proper understanding of the interest asserted: *Finlay v Canada (Minister of Finance)*, [1986] 2 SCR 607, at para 16. In the case at bar, I am satisfied that the record before me is sufficient to allow me to make a final determination with respect to the issue of standing.

[36] The CGPA argues that it is directly affected by the decision of the Minister and therefore should be granted standing. The CGPA argued, just as it did before the Prothonotary, that the idea that representative associations do not have standing is increasingly being viewed as too formalistic. In support of this proposition, the Association relied on the decision of my colleague Justice Harrington who held, on a preliminary motion, that the CGPA did indeed have standing to challenge the *vires* of the data protection provisions of the *Regulations* as a person "directly affected": *Canadian Generic Pharmaceutial Association v Canada (Governor in Council)*, 2007 FC 154, at para 17, aff'd 2007 FCA 375.

[37] I do not think it can be seriously contended that the CGPA is directly affected by the Minister's decision to list fluticasone furoate on the Register as an innovative drug; the Prothonotary rightly rejected this argument. Pursuant to s. 18.1(1), no person may seek judicial review in this Court unless that person is "directly affected by the matter in respect of which relief is sought". This Court has developed much jurisprudence for the proper application of this statutory test. For an applicant to be considered "directly affected", the matter at issue must be one which would adversely affect its legal rights, impose legal obligations on it, or prejudicially affect it directly: see *Rothmans of Pall Mall Canada Ltd*, above.

[38] It is plain that the *Regulations* at issue aim to impose certain limitations on manufacturers seeking notices of compliance for new drugs. Accordingly, the only persons directly affected by the AVAMYS listing are manufacturers who would, if it were not for the listing, submit a drug submission for approval. Here, there is no evidence that the listing of AVAMYS actually affects any particular drug manufacturer, because there is no evidence that any manufacturer intends to submit a submission. If a member of the Association at some future time is affected by the listing of fluticasone furoate, that affected member, rather than the CGPA, would be the party with standing to bring an application challenging the listing.

[39] Mr. James Keon, president of the Association, filed an affidavit in response to GlaxoSmithKline's motion to strike. On cross-examination, he admitted that the Association 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, the Association has never filed a drug submission for fluticasone furoate. Clearly, the CGPA cannot therefore be directly affected by the Minister's decision to include a drug on the Register of Innovative Drugs.

[40] As for the decision of my colleague Justice Harrington upon which the CGPA relies, it has no application in the case at bar. There, the proceeding was a broad challenge to the constitutional validity of the *Regulations* as a whole. The Minister brought a motion to strike this application on the grounds that the CGPA lacked standing. Justice Harrington held that the CGPA had standing to challenge the legality of the data protection provisions of the *Regulations* as a person "directly affected" because the CGPA was "not an officious inter-meddler".

[41] However, this aspect of the decision was not considered on appeal. The Court of Appeal affirmed Justice Harrington's reasoning 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".

[42] At the hearing on the merits, Mandamin J. held that the CGPA was not directly affected by the *Regulations*, as it does not make drug applications or obtain NOCs. As a result, the matter at issue (the legality of the *Regulations*) would not adversely affect the CGPA's rights, impose any legal obligation, or cause it any direct prejudice. This aspect of the decision was not pursued on appeal: *Canadian Generic Pharmaceutical Association v Canada (Minister of Health)*, 2009 FC 725, at paras 138-139, aff'd 2010 FCA 334.

[43] If the CGPA cannot be considered to be directly affected by the limitations on drug manufacturers found in the *Regulations*, it is surely even less directly affected by the listing of a particular drug on the Register and by the Minister's refusal to remove it from the Register. The effect of that particular refusal is to prevent a drug manufacturer which seeks to market a generic

version of that particular drug from doing so. Since the Association is not such a manufacturer, its status as a person "directly affected" is even more tenuous than was the case in the context of its application challenging the regulatory regime as a whole.

[44] The CGPA's lack of standing is also evident from analogous circumstances under the *PM(NOC) Regulations*. Under that regime, a manufacturer does not have standing to challenge the Minister's decision to list a patent on the Patent Register unless that manufacturer has filed an Abbreviated New Drug Submission ("ANDS") referencing a drug to which the impugned patent relates. In one case, drug manufacturers brought an application for judicial review attacking the manner in which the Minister maintains the Patent Register, in general and without reference to any specific patent. In another case heard with the first one, the applicant manufacturers challenged a decision of the Minister to add a particular patent to the Patent Register. In both cases, the Court ruled that the applicants had no standing to bring the application. In the first case, the Court stated the following:

> [14] The applicants are generic drug manufacturers and, as such, are each regularly engaged in the process of making new drug submissions in accordance with the Regulations. Each is also regularly engaged in the litigation contemplated by those Regulations, litigation brought against them by "brand name manufacturers" or "first persons". However, there is no specific patent or patents on the Register that is or are identified in this proceeding and in relation to which either of the application has filed a new drug submission.
>
> (…)
>
> [16] On the evidence before me, I find no basis to conclude that the applicants are "anyone directly affected" by the Minister's course of conduct in maintaining the Register, within the meaning of subsection 18.1(1) of the *Federal Court Act*. The applicants are not "second person" with identifiable direct interests at stake under the

> Regulations under which the Minister maintains the Register. I conclude that while they are, or may some day become so, in respect of a specific entry or entries on the Register, that is insufficient to constitute a direct interest to support this application.
>
> (…)
>
> [18] I conclude that, even if the subject matter of this application is a proper subject of judicial review, the application nonetheless lack standing to bring this application.
>
> *Apotex Inc v Canada (Minister of National Health and Welfare)*, [1998] FCJ No 1096; 82 CPR(3d) 68, aff'd on other grounds [1999] FCJ No 1978, 3 CPR(4th) 1.

[45] In the other case, the Court stated:

> [5] … I am not satisfied that the applicants have standing to bring this application for judicial review. Neither has filed for a notice of compliance by comparison or reference to a drug to which the Patent relates and neither has sent to the holder of the Patent a notice of allegation of non-infringement.
>
> (…)
>
> [6] If and when a notice of compliance submission is made, if then Glaxo Biochem Inc. brings an application for judicial review to determine whether the allegation of non-infringement is justified, the issue of whether the Patent is properly on the Register will be before this Court and the applicant or applicants in connection with the new drug submission will also be properly before this Court.
>
> *Apotex Inc v Canada (Minister of National Health and Welfare)*, [1998] FCJ No 1092, 82 CPR (3d) 65.

[46] In another case unrelated to the regulation of drugs, the Court of Appeal considered an application by an association of contractors. The application challenged a decision imposing new general terms and conditions for government construction contracts. The Court ruled that the contractors had standing, but the association did not:

> [30] … the Association simply lacks standing to attack that decision by way of judicial review. It is not itself in the construction business and is therefore in no position to bid on federal government contracts in British Columbia. It follows that the Association is not "directly affected" by the December 6, 1996 decision in the sense that it can neither benefit nor suffer any direct adverse impact from that decision.
>
> *Independent Contractors and Business Association*, above.

[47] The position of the CGPA is perfectly analogous to this case. The CGPA is not a drug manufacturer. The listing of AVAMYS on the Register cannot possibly affect it. It cannot adversely affect the Association's legal rights, impose legal obligations on it, or prejudicially affect it directly. The Association can neither benefit nor suffer any adverse impact from the listing of AVAMYS. At best, the interest of the CGPA in the litigation is merely indirect or contingent.

[48] The only case upon which the Applicant could rely to support its position is the decision of the Alberta Court of Queen's Bench in *Alberta Liquor Store Association v Alberta (Gaming & Liquor Commission)*, 2006 ABQB 904, at para 20. I am far from convinced, however, that this case is sufficient to displace the long line of authority described above. Furthermore, it appears from a close reading of that decision that the Court of Queen's Bench was not purporting to apply a "directly affected" test for standing, or for that matter any test at all. Indeed, the cases to which it refers to bolster its proposition that collective organisations should be granted standing come to that conclusion either on the basis of the public interest standing or of legislative provisions defining standing more broadly than section 18.1 of the *Federal Courts Act*.

[49] For all of the foregoing reasons, I am therefore of the view that it is plain and obvious that the CGPA is not directly affected by the matter in respect of which relief is sought. Accordingly, it has no standing under section 18.1 of the *Federal Courts Act.*

[50] In exceptional cases involving public rights, a party having no private interest in a matter may still have standing to bring it before the Courts. The CGPA's alternative argument, in the present case, is that the Association qualifies for such public interest standing.

[51] In a long series of cases, the Supreme Court of Canada developed a number of criteria for public interest standing. This jurisprudence culminated in *Canadian Council of Churches v Canada (Minister of Employment and Immigration)*, [1992] 1 SCR 236; [1992] SCJ No 5, where the Court set out a three-part test for public interest standing (at p. 253):

> It has been seen that when public interest standing is sought, consideration must be given to three aspects. First, is there a serious issue raised as to the invalidity of legislation in question? Second, has it been established that the plaintiff is directly affected by the legislation or if not does the plaintiff have a genuine interest in its validity? Third, is there another reasonable and effective way to bring the issue before the court?
>
> See also: *Thorson v Attorney General of Canada*, [1975] 1 SCR 138; *Nova Scotia Board of Censors v McNeil*, [1976] 2 SCR 265; *Minister of Justice of Canada v Borowski*, [1981] 2 SCR 575; *Finlay v Canada (Minister of Finance), supra.*

[52] The parties agree that this application raises a serious or justifiable issue and thus satisfies the first prong of the three-part test.

[53] As for the second prong, the CGPA argues that in order to have a genuine interest, a party need not be directly affected, contrary to the findings of the Prothonotary. Like other associations who have succeeded on this prong of the test, the CGPA may have a genuine interest in the validity of the legislation in question, argues the Association, regardless of whether it is directly affected. I

agree with that proposition, since it is the very purpose of public interest standing to grant standing in cases where a party is not, strictly speaking, directly affected.

[54] The Applicant also disputes another finding made by the Prothonotary, namely that the CGPA cannot be said to have a genuine interest in removing fluticasone furoate from the Register as it does not represent the public at large but rather represents the interests of its members. According to the CGPA, courts frequently grant public interest standing to trade associations that represent the interests of their members. In support of that proposition, the CGPA cites a number of cases in which professional associations of lawyers, accountants, architects, and even the CGPA itself have been granted public interest standing on behalf of their members.

[55] As already mentioned, the CGPA was indeed granted public interest standing to challenge the validity of the *Regulations*. But the case in which it was granted standing is very different from the case at bar, where the challenge concerns a particular decision made by the Minister to list a particular drug product on the Register of Innovative Drugs. Therein lies an important distinction for the purposes of granting public interest standing, in my view.

[56] Public interest standing has always been linked to the need to ensure that constitutional principles are upheld and followed by public officials and legislators. Such a preoccupation can be traced back to the earliest public interest standing cases where the doctrine was developed as an alternative to the notion that only those directly affected by a legislation or governmental decision could submit a matter to the courts. In *Thorson*, above, for example, Justice Laskin declared that it "would be strange and, indeed, alarming, if there was no way in which a question of alleged excess

of legislative power, a matter traditionally within the scope of the judicial process, could be made the subject of adjudication" (at p. 145). Justice Martland, writing for the majority, came to a similar conclusion in *Minister of Justice of Canada v Borowski*, above, where the question was whether the abortion provisions of the Criminal Code were rendered inoperative by conflict with the *Canadian Bill of Rights*. Having reviewed the *Thorson* and *Nova Scotia Board of Censors* decisions (where the challenge was to the constitutionality of federal and provincial legislation respectively), Justice Martland wrote as follows (at p. 598):

> I interpret these cases as deciding that to establish status as a plaintiff in a suit seeking a declaration that legislation is invalid, if there is a serious issue as to its invalidity, a person need only to show that he is affected by it directly or that he has a genuine interest as a citizen in the validity of the legislation and that there is no other reasonable and effective manner in which the issue may be brought before the Court. In my opinion, the respondent has met this test and should be permitted to proceed with his action.

[57] The wording of the first and second prong of the three-part test for public interest standing set out by the Supreme Court in *Council of Churches* reiterates that the validity of a statute is at the core of the reasoning behind this expanded concept of standing. The furthest the Supreme Court has been prepared to go in this respect was to extend the public interest standing to challenge an exercise of administrative authority. In *Finlay*, above, a resident of Manitoba and a "person in need" within the meaning of the Canada Assistance Plan, sued for a declaration that the continued payments of contributions under the Plan by Canada to Manitoba were illegal. He asked for an injunction to stop them as long as the provincial system of assistance to persons in need failed to comply with the conditions and undertakings imposed by the Plan. In coming to the conclusion that Mr. Finlay had public interest standing to bring this action, the Court stated the following:

> [31] … the judgments of this Court in Thorson, McNeil and Borowski cannot be regarded as providing clear and direct authority for the recognition of public interest standing, as a matter of judicial discretion, to bring a non-constitutional challenge by an action for a declaration to the statutory authority for public expenditure or other administrative action. It is fair to say, however, that they do not clearly exclude such recognition. The issue, then, as I see it, is whether the principle reflected in Thorson, McNeil and Borowski should be extended by this Court to such cases. This question raises again the policy considerations underlying judicial attitudes to public interest standing, and in particular, whether the same value is to be assigned to the public interest in the maintenance of respect for the limits of administrative authority as was assigned by this Court in Thorson, McNeil and Borowski to the public interest in the maintenance of respect for the limits of legislative authority.
>
> [32] In my view an affirmative answer should be given to this question. The recognized standing of the Attorney General to assert a purely public interest in the limits of statutory authority by an action of his own motion or on the relation of another person is a recognition of the public interest in the maintenance of respect for such limits. For the reasons indicated in Thorson, I do not think that his refusal to act in such a case should bar a court from the recognition, as a matter of discretion in accordance with the criteria affirmed in Borowski, of public interest standing in a private individual to institute proceedings. The traditional judicial concerns about the expansion of public interest standing may be summarized as follows: the concern about the allocation of scarce judicial resources and the need to screen out the mere busybody; the concern that in the determination of issues the courts should have the benefit of the contending points of view of those most directly affected by them; and the concern about the proper role of the courts and their constitutional relationship to the other branches of government. These concerns are addressed by the criteria for the exercise of the judicial discretion to recognize public interest standing to bring an action for a declaration that were laid down in Thorson, McNeil and Borowski. …

[58] All the cases cited by the Applicant to argue that courts frequently grant public interest standing to trade associations relate to challenges brought against the constitutional validity of legislative provisions or the legality of administrative decisions. In *Federation of Law Societies of*

Canada v Canada (Attorney General), [2002] O.J. No. 17 and *Law Society of British Columbia v Canada (Attorney General)*, 2001 BCSC 1593, the applicants were granted standing to challenge the constitutional validity of certain provisions of the *Proceeds of Crime (Money-Laundering) and Terrorist Financing Act*, S.C. 2000, c. 17 on the basis that they imposed unconstitutional duties on legal counsel in that they violated the protected right of an independent bar pursuant to ss. 7, 8 and 10(b) of the *Canadian Charter of Rights and Freedoms*. Similarly, an association representing the economic and professional interests of businesses in the province of Quebec was granted standing to challenge the constitutional validity of legislative provisions prohibiting the hiring of replacement workers during a strike on the basis that these provisions infringe the *Canadian Charter of Rights and Freedoms*. Finally, the Canadian Bar Association and the Law Society of British Columbia were given standing to challenge a provincial legislation placing an obligation on lawyers to collect a tax on the purchase of legal services, both on the grounds of the *Constitution Act, 1867* and the *Canadian Charter of Rights and Freedoms*: see *Canadian Bar Association v British Columbia (Attorney General)*, [1993] BCJ No 407 (BCSC).

[59] The other two cases cited by the Applicant do not convince me that the Association is eligible for public interest standing because they present situations not analogous to the case before me. One case, *Ontario Association of Architects v. Association of Architectural Technologists of Ontario*, 2002 FCA 218, does not even discuss the issue of public interest standing but rather deals with the right of appeal in the context of section 56 of the *Trade-marks Act*, R.S.C. 1985, c. T-13. The other case, *Certified General Accountants Association of Canada v Canadian Public Accountability Board*, [2008] OJ No 194, is much closer to the situation described in *Finlay*, above, than to the case at bar. In that latter case, the Divisional Court of the Ontario Superior Court of Justice found that a professional self-regulatory body has the standing to challenge matters affecting

the profession that it regulates and for which it sets standards. Accordingly, it was granted standing to bring a declaratory action that the Canadian Public Accountability Board is subject to rules of natural justice and that the Board's structure does not meet the requirements of natural justice and procedural fairness.

[60] In sum, the rationale behind the public interest standing has nothing to do with the interest pursued by the CGPA in this case, namely to represent the generic manufacturers and, allegedly, to provide the public with generic alternatives. Once again, the whole purpose of granting status to parties who are not directly affected is to prevent the immunization of legislation or public acts from any challenge. As stated by the Supreme Court in *Canadian Council of Churches*, above, it is the increasing recognition of the importance of public rights in our society that has led the courts to award public interest standing as a means of maintaining respect for the limits of statutory authority.

[61] Granting public interest standing in the case at bar would not respond to such a rationale. What the CGPA wishes to challenge is a discrete decision of the Minister in the exercise of the powers conferred upon him by regulations which have been found to be *intra vires* the federal Parliament and rationally connected to its enabling provision. This is a far cry from all the cases in which public interest standing has been granted on the basis of a genuine concern for the constitutionality or validity of a legislative provision or of an administrative decision.

[62] In many respects, this case is akin to the decision reached by the Federal Court of Appeal in *Canwest Mediaworks*, above. In that case, Canwest applied for judicial review and requested an order of *mandamus* to require the respondents to investigate and prosecute American media

corporations which, it alleged, distributed in Canada advertisements for prescription drugs which contravene the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Food and Drug Regulations*, C.R.C., c. 870. Writing for a unanimous court, Evans J.A. upheld a decision of the Federal Court granting a motion by the respondents to dismiss for lack of standing the application brought by the applicant. As part of his reasoning, Justice Evans states:

> [14] The fact that CanWest's interest in the enforcement of the DTCA [Direct to Customer Advertising] prohibition is commercial also indicates that it does not have "a real and continuing interest" for the purpose of being afforded public interest standing. Private interests are primarily relevant to determining whether persons are "directly affected" by the impugned administrative action and therefore have standing as of right.
>
> [15] In this case, the Motions Judge concluded that CanWest was not "directly affected" because the harm that it alleged that the respondents' failure to enforce the law has caused to its commercial interests was too speculative and indirect. CanWest surely cannot rely on the same interest that did not qualify it for "private interest standing" to establish that it has a "genuine interest" for the purpose of public interest standing.

[63] The Applicant not having met the second prong of the three-part test set out in *Canadian Council of Churches*, above, I am of the view that this Court, in the exercise of its discretion, ought not to grant public interest standing to the CGPA.

[64] There is another compelling reason to come to this conclusion: the Applicant also fails to meet the third prong of the test because there is another reasonable and effective way to bring the issue before the Court. This last criterion has been described by the Supreme Court as being "at the heart of the discretion to grant public interest standing": *Hy and Zel's Inc v Ontario (Attorney General)*, [1993] 3 SCR 675, at para 16.

[65] As already mentioned, 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*, above, at p. 256. The burden of proof is on the CGPA to show that there are no other, more appropriate litigants available who could litigate the issue raised on this application.

[66] Counsel for the Applicant argued that there is no other reasonable and effective way to bring the issue before the Court. He took issue with the Prothonotary's finding that the reasonable and effective manner of litigating this issue is by way of a generic manufacturer seeking to submit an ANDS for fluticasone furoate. He based this argument essentially on the following points:

- Requiring a generic manufacturer to prepare and submit an ANDS for a generic version of a drug listed on the Register is both costly to the generic manufacturer and extends the time that a drug is improperly listed on the Register while that ANDS is prepared;

- Prohibiting a coalition of generic manufacturers from bringing a single proceeding to delist a drug from the Register results in redundant litigation, since each manufacturer is required to bring its own application for judicial review;

- C.08.004.1 does not set out a mechanism for any party to challenge the listing of drugs improperly listed on the Register; and

- Pursuant to C.08.004.1(3), a generic manufacturer's attempt to submit an ANDS for a generic version of a drug listed on the Register is an illegal act and the penalty for doing so can include three months imprisonment (by application of s. 31 of the *Foods and Drugs Act*).

[67] As for the argument that it would be costly and time-consuming for a generic manufacturer to prepare an ANDS before being allowed to bring an application for judicial review to challenge a decision by the Minister, it is at best speculative and is not supported by the evidence before me. Other than Mr. Keon's affidavit which argues this point without offering any specific support for this contention, there is nothing in the record supporting this assertion. More importantly, the level of "investment" in a drug submission that a manufacturer would have to make, if any, to achieve standing in such a case has not yet been established in the jurisprudence. Indeed, it appears that this issue is currently raised for the first time in a listing challenge brought by a generic manufacturer in *Teva Canada Limited v the Minister of Health and Sanofi Aventis Canada Inc*, T-1172-10.

[68] The CGPC's argument assumes that this Court would not provide to a drug manufacturer with a reasonable and effective means to challenge a decision affecting its rights. It is true that when pushed on that question, counsel for the Minister of Health refused to take a position as to what his client would consider sufficient circumstances for a manufacturer to have the standing to bring an application for judicial review. That being said, and without in any way wanting to prejudge the Court's decision in *Teva*, above, a judge may well be prepared to determine that a manufacturer can establish standing merely through persuasive evidence of a genuine intention to file a drug submission.

[69] This brings me to another argument raised by the Applicant. The Applicant notes that the *PM(NOC) Regulations* expressly provide a process whereby generic manufacturers can obtain relief in the event that they are prejudiced by the inclusion of ineligible patents on the Patent Register. In this regard, s. 6(5)(a) of the *PM(NOC) Regulations* provides that a generic manufacturer may bring a motion to dismiss a proceeding in whole or in part in respect of those patents that are not eligible

for inclusion on the Patent Register. Furthermore, section 8 provides a remedy in costs when unnecessary proceedings have taken place due to an ineligible patent.

[70] It is true that there is no comparable scheme in C.08.004.1. But this is not to say that generic manufacturers are left without any recourse. Health Canada's *Guidance Document on Data Protection* outlines a specific procedure whereby a generic drug manufacturer seeking an NOC on the basis of a comparison with an innovative drug can make representations to the OPML to challenge the designation:

> Where a manufacturer seeks an NOC on the basis of a direct or indirect comparison with an innovative drug, the manufacturer will not be permitted to file the submission for six years from the date of issuance of the NOC for the innovative drug. The manufacturer will be provided with a preliminary decision by letter informing it of the intent to reject the submission and granting a 30-day period to make representations in response. If, following consideration of the representations, the OPML remains of the view that the submission cannot be filed, then the submission will be returned to the manufacturer at its expense.
>
> *Health Canada, Guidance Document: Data protection under C.08.004.1 of the Food and Drug Regulations* (March 1, 2010), at pp. 6-7.

[71] This, in my view, is a clear answer to the argument made by the CGPA that drug manufacturers would be required to commit illegal acts in order to directly challenge the Minister's decision. Indeed, the *Regulation* does not strictly speaking create an offence for the generic manufacturer filing an ANDS while a drug is listed on the Register. Rather, it is clear from the procedure outlined above in the *Guidance Document on Data Protection* that it is not a criminal offence for a generic drug manufacturer to file an abbreviated new drug submission during the pendency of the data protection period.

[72] I note, moreover, that the CGPA wrote to the Minister in the present case to request that fluticasone furoate be removed from the Register. Even if no ANDS was submitted, and without any indication that a generic manufacturer had any intention to file an ANDS, the OMPL replied to that letter and provided substantive reasons for refusing to remove fluticasone furoate from the Register. I fail to see why a generic drug manufacturer could not have done the same, and could not eventually have sought judicial review of that decision.

[73] Finally, I do not accept that prohibiting a coalition of generic manufacturers from bringing a single proceeding to delist a drug from the Register would result in redundant litigation. First of all, there is absolutely no evidence to that effect, and such a claim intuitively runs counter to the previous argument according to which the preparation of an ANDS is costly and time-consuming. Indeed, we do not even know if any of the drug manufacturers represented by the CGPA intends to file an ANDS for fluticasone fuorate.

[74] Moreover, the argument of the Applicant can easily be turned on its head. If the CGPA is granted standing in the present case, it may well open the floodgates for further challenges to decisions under the data protection regulations by trade associations. The CGPA should not be allowed to use the public interest exception to standing in order to shield their members from public disclosure and cross-examination, and to gain access to confidential information.

[75] For all of the foregoing reasons, I am therefore of the view that it is plain and obvious that the CGPA's application is bereft of any chance of success and should be dismissed. The CGPA is not directly affected by the Minister's decision. It has no genuine interest in the issue raised and

does not speak on behalf of a broader public interest in this case. Other more reasonable and effective means exist for bringing this matter before the Court. As a result, the appeal will be dismissed, with costs.

ORDER

THIS COURT ORDERS that the appeal be dismissed, with costs.

"Yves de Montigny"

_____

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-152-10
STYLE OF CAUSE:	CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION v. THE MINISTER OF HEALTH AND GLAXOSMITHKLINE INC.
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	February 9, 2011
REASONS FOR ORDER AND ORDER:	de Montigny J.
DATED:	April 15, 2011

APPEARANCES:

Mr. Jonathan Stainsby Mr. Mark Edward Davis	FOR THE APPLICANT
Mr. Rick Woyiwada	FOR THE RESPONDENT MINISTER
Mr. Jason Marwell Ms. Amy E. Grenon	FOR THE RESPONDENT GSK INC.

SOLICITORS OF RECORD:

Heenan Blaikie LLP Lawyers Toronto, Ontario	FOR THE APPLICANT
Myles J. Kirvan Deputy Attorney General of Canada	FOR THE RESPONDENT MINISTER
Ogilvy Renault LLP Toronto, Ontario	FOR THE RESPONDENT GSK INC.