Federal Court  Cour fédérale

Date: 20150508

Dockets: T-1693-14
T-1694-14

Citation: 2015 FC 610

Ottawa, Ontario, May 8, 2015

PRESENT: The Honourable Mr. Justice Barnes

Docket: T-1693-14

BETWEEN:

GILEAD SCIENCES, INC. AND
GILEAD SCIENCES CANADA, INC.

Applicants

And

THE MINISTER OF HEALTH AND
APOTEX INC.

Respondents

Docket: T-1694-14

AND BETWEEN:

GILEAD SCIENCES, INC. AND
GILEAD SCIENCES CANADA, INC.

Applicants

And

THE MINISTER OF HEALTH AND APOTEX INC.

Respondents

ORDER AND REASONS

[1] Apotex Inc. [Apotex] brings this motion under paragraph 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended by SOR/2006-242 [Regulations] seeking an Order dismissing this proceeding in respect of Canadian Patent No. 2,298,059 [the 059 Patent] as an abuse of process.

[2] The underlying basis for this motion is my decision in *Gilead Sciences, Inc v Teva Canada Limited*, 2013 FC 1272, 236 ACWS (3d) 470, where I found Claims 3 and 4 of the 059 Patent invalid on the ground of obviousness. Apotex argues that the Applicants' [collectively Gilead] attempt to relitigate the validity of the 059 Patent on obviousness grounds in this proceeding should not be permitted.

[3] In the earlier Notice of Compliance [NOC] proceeding in *Gilead v Teva*, above, Teva submitted a Notice of Allegation [NOA] putting in issue the validity of Claims 1 through 7 of the 059 Patent. Gilead responded with a Notice of Application asserting the validity of those claims. Gilead's pleading included the following additional assertions:

> 87. None of the "teachings of the prior art" discussed by Teva in the Letter, nor the references provided by Teva in Schedule B, alone or in combination, show that any aspect of the claims of the '059 Patent are obvious pursuant to section 28.3 of the *Patent Act*.
>
> 88. Moreover, Teva has not adequately detailed the elements of the common general knowledge in support of its allegation of obviousness, nor how these elements are said to render obvious the claims of the '059 Patent.
>
> 89. The Applicants do not accept that the prior art references, chosen by Teva, are a complete list of the relevant prior art and further assert that Teva has unfairly and inaccurately characterized the state of the art at the relevant time.
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> 90. Further, the Applicants do not accept that the Schedule B references would have been located during a reasonable search conducted by a person skilled in the art at the relevant date.
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> 91. The claims of the '059 Patent, and specifically claims 1-7 thereof were not obvious to a person skilled in the art at the relevant date. As such, Teva's allegations of obviousness are not justified and are denied by the Applicants.

[4] When the *Teva* matter came before me for argument, Gilead elected to assert only the validity of Claims 3 and 4 of the 059 Patent and thereby abandoned its prosecution of Claims 1, 2, 5, 6 and 7. In the result, only the validity of Claims 3 and 4 was assessed in that case.

[5] In this proceeding Apotex served a NOA on Gilead challenging all of the 059 Patent claims on the ground, *inter alia*, of obviousness. It also raised the issue of abuse of process. The Apotex NOA describes the inventive concept of the Patent as the fumarate salt form of tenofovir disoproxil, in its amorphous and crystalline forms, for treating a patient infected with a virus or at risk of viral infection.

[6] Gilead's Notice of Application in this proceeding challenges Apotex's abuse of process allegation with a bare denial and with an argument that it intends to fill an evidentiary gap from the *Teva* proceeding concerning the history of the invention [see para 112 of the Gilead Memorandum and the affidavit of Dr. John Rohloff]. Gilead has also pleaded in considerable detail why it maintains the 059 Patent to be non-obvious [see paras 115-130 of the Notice of Application].

[7] Gilead has also filed the affidavit of Dr. Nair Rodriguez-Hornedo in support of its proposed obviousness case. That affidavit describes the inventive concept of the 059 Patent as the fumarate salt of tenofovir disoproxil and its superior properties for use in pharmaceutical formulations. Dr. Rodriguez-Hornedo also offers an extensive rationale for why the 059 Patent invention would not have been considered obvious by the person of skill [see paras 112-132 of his affidavit].

[8] Gilead opposes this motion on several grounds. It says the form of requested relief is discretionary and, among other things, the Court should take account of Apotex's supposed delay in bringing the issue forward. Gilead also argues that the validity issues resolved in the *Teva* proceeding are not the same as those under present consideration. In the *Teva* case only Claims 3 and 4 were asserted by Gilead and in this proceeding all of the claims are in play. In the result, a different evidentiary record will be before the Court in this case which could, according to Gilead, support a different outcome.

[9] In my view, Gilead's attempt to relitigate the validity of the 059 Patent in this proceeding represents a clear abuse of process. The law in this area is well settled.

[10] Under section 6(5) of the Regulations, the second person may move to strike an application for prohibition "in whole or in part" on the basis of an abuse of process. The burden of proof, of course, rests with the moving party – in this case Apotex.

[11] The general rationale for summarily disposing of unwarranted applications of this sort was expressed in *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 59 CPR (4th) 416 (FCA), 2007 FCA 163, at paras 36-38:

> 36 Proceedings in which the case for the patent holder is clearly futile or plainly has no chance of success because of an earlier, binding authority continue to be impermissible as abuses of process because such proceedings will waste judicial resources and impose hardship on generic drug manufacturers without any corresponding benefit such as a more accurate result. However, applying the principles outlined by Arbour J., it is evident that the types of proceedings that constitute abuses of process go beyond those that are clearly futile to include cases such as the one at present. Many of the concerns raised by Arbour J. are applicable to this appeal. Allowing Sanofi-Aventis to proceed with its application will give rise to the possibility of inconsistent judicial decisions, with one judge holding that the inventors of the '206 patent lacked a sound basis for predicting the utility of their invention and another holding that there was sound prediction. Thus one generic would receive an NOC because of invalidity based on lack of sound prediction while another would be refused an NOC even though its NOA raised the same allegation. As Arbour J. identified, permitting that type of inconsistency would threaten the credibility of the adjudicative process. Likewise, as Arbour J. noted, there is no reason to think that a second proceeding under section 6 of the NOC *Regulations* will lead to a more accurate result than the first. This scenario is in contrast to an action for a declaration of patent invalidity, where because the parties have the benefit of a full trial and all the attendant procedural safeguards, a more accurate result may arise. That is

> why the courts have on numerous occasions stated the principle that decisions rendered under the NOC *Regulations* are not binding on actions for patent infringement or to declare a patent invalid (see e.g. *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209; *Novartis A.G. v. Apotex Inc.*, [2002] F.C.J. No. 1551, 2002 FCA 440 at paragraph 9; *Pfizer Canada Inc. et al. v. Apotex Inc. et al.* (2001), 11 C.P.R. (4th) 245 at paragraph 25).
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> 37 In the context of the NOC *Regulations*, encouraging the efficient use of scarce judicial resources is also of particular concern. Judicial resources are already taxed considerably by the voluminous proceedings brought under the regulations. An attempt to further strain the resources of parties and of the courts through repetitious litigation without any compelling justification strongly favours a finding of abuse of process.
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> 38 Therefore, despite the fact that Mactavish J.'s decision would not dictate the outcome of the present application and consequently, that it is not possible to say that Sanofi-Aventis has no chance of success, I nevertheless am compelled to hold that the application in respect of the Novopharm NOA is an abuse of process and therefore should be dismissed.

[12] The argument that either party to a NOC proceeding can selectively present evidence from one proceeding to another was firmly rejected by the Court in *Sanofi*, above, as can be seen from the following passage taken from paragraph 50:

> 50 …All parties are held to the same standard: they must each put forward their entire case, complete with all relevant evidence, at first instance. The innovator is prevented from relitigating an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings. Generics likewise must put forward their full case at the first opportunity. Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. However, where one generic has made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give

> rise to the possibility of an inconsistent result, this concern is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate. In each situation, it is necessary to balance the effect of a proceeding on the administration of justice against the unfairness to a party from precluding it from bringing forward its case.

Also see *Alcon Canada Inc v Cobalt Pharmaceuticals Company*, 2014 FC 525, 240 ACWS (3d) 569 at para 118, *Pfizer Canada Inc v Novopharm Ltd*, 2008 FC 674, 328 FTR 315 (Eng) at paras 8, 16 and 40.

[13] It seems to me that an abuse of process finding in the NOC context is not dependant on the evidence to be called but, rather, on the issues presented to the Court for determination. Once the second person puts a validity issue into play, the patentee proceeds at its subsequent peril by not fully responding. In other words, it must live with the consequences of not fully joining issue in the first proceeding.

[14] A patentee cannot avoid an abuse of process finding by asserting the validity of only a select number of claims in an initial NOC proceeding, only to assert the validity of different claims in a subsequent NOC proceeding involving a different generic challenger. Where the initial NOA puts in issue the validity of certain patent claims, it is not open to the patentee to concede some of the claims but later resile from that position. If it were otherwise, the patentee could effectively split its case and unilaterally compel subsequent generic challengers to litigate claims, the invalidity of which the patentee had effectively conceded. This would amount to a manipulation of the system and it would violate the principle that the patentee is required to put its strongest case forward in the first instance.

[15] The situation may well be different where the initial generic challenger declines to put the validity of certain claims in issue in its NOA, perhaps relying solely on an allegation of non-infringement. There the patentee could presumably rely on the presumption of validity in the first instance without compromising its right to assert validity in the face of a subsequent challenge.

[16] There is no merit to Gilead's argument that the Court ought to exercise its discretion to deny the relief requested by Apotex. It would be a waste of judicial resources to permit this argument to go forward. If Gilead is aggrieved by the earlier finding in the *Teva* proceeding, it always has the option of bringing an infringement action.

[17] In the result, the motion is allowed and Gilead's Notice of Application is struck out insofar as it concerns the validity of the 059 Patent.

[18] Costs are payable to Apotex at the mid-point of Column 5.

ORDER

THIS COURT ORDERS that this motion is allowed and Gilead's Notice of Application is struck out insofar as it concerns the validity of the 059 Patent.

THIS COURT FURTHER ORDERS that Apotex will have its costs at the mid-point of Column 5.

"R.L. Barnes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1693-14
STYLE OF CAUSE:	GILEAD SCIENCES, INC. AND GILEAD SCIENCES CANADA, INC. v THE MINISTER OF HEALTH AND APOTEX INC.
AND DOCKET:	T-1694-14
STYLE OF CAUSE:	GILEAD SCIENCES, INC. AND GILEAD SCIENCES CANADA, INC. v THE MINISTER OF HEALTH AND APOTEX INC.
PLACE OF HEARING:	OTTAWA, ONTARIO
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ORDER AND REASONS:	BARNES J.
DATED:	MAY 8, 2015

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