Federal Court  Cour fédérale

Date: 20170106

Docket: T-1537-15

Citation: 2017 FC 22

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR AN ORDER dated December 28, 2016

SIMPSON J.

[1] Alexion Pharmaceuticals Inc. [Alexion] appeals from the Order and Reasons of Prothonotary Aalto dated June 23, 2016 [the Decision]. The Prothonotary allowed the Respondent's motion to strike Alexion's constitutional challenge to the price regulation scheme found in sections 83-86 and the words "in any proceeding under s 83" in section 87(1) of the *Patent Act*, RSC 1985, c P-4 [the Act and the Impugned Provisions]. Alexion had challenged the Impugned Provisions as *ultra vires* of Parliament in a Notice of Application dated September 11, 2015 [the Challenge]. This appeal is brought pursuant to section 18.1 of the *Federal Courts Act*, RSC, 1985 c F-7.

I. Background

[2] Alexion is a Delaware company headquartered in New Haven, Connecticut.

[3] Through its Canadian affiliate, Alexion Canada Pharma Corp., Alexion markets the drug Soliris (eculizumab), which is used to treat rare and devastating blood and genetic conditions.

[4] Alexion began to market Soliris in Canada in 2009.

[5] On January 15, 2015, staff of the Patented Medicine Prices Review Board [the Board Staff and the Board] commenced proceedings against Alexion by delivering a Statement of Allegations [the Allegations]. The Allegations assert that, between 2012 and 2014, Alexion sold Soliris at an excessive price. The Allegations anticipate that any "excessive" revenues found by the Board will be confiscated and forfeited to the Crown.

[6] On January 20, 2015, the Board issued a Notice of Hearing. At the hearing the Board will determine whether, under sections 83 and 85 of the Act, Alexion is selling or has sold Soliris in Canada at an excessive price [the Hearing].

II. The Challenge

[7] In the Challenge, Alexion sought both a declaration that the Impugned Provisions are unconstitutional and an order prohibiting the Board from proceeding with the Hearing. It is presently scheduled to start in mid-January 2017.

[8] Alexion asserts that the price regulation scheme and confiscatory powers created by the Impugned Provisions are *ultra vires* of the powers granted to Parliament to regulate patents of invention and discovery under section 91(22) of the *Constitution Act, 1867*.

[9] Alexion argues that the Impugned Provisions are not elements of patent law. Rather, they constitute pure price control and confiscatory measures falling within exclusive provincial jurisdiction over property and civil rights under section 92(13) of the *Constitution Act, 1867*.

[10] The Challenge is supported by expert affidavit evidence and a brief which traces the history of the Impugned Provisions.

III. The Respondent's Motion to Strike

[11] The Respondent's motion to strike the Challenge alleges that it is bereft of any chance of success because there is a line of jurisprudence that has fully and finally determined that the Impugned Provisions are *intra vires* of the powers granted to Parliament. Most recently, in *Canada (Attorney General) v. Sandoz Canada Inc.*, 2015 FCA 249 [*Sandoz*], the Federal Court of Appeal confirmed that the Impugned Provisions are constitutional.

[12] In response, Alexion argued that while the constitutionality of the Impugned Provisions has been referred to in several cases including the *Sandoz* decision, the discussion has been peripheral, and has not involved a pith and substance analysis or a complete and careful division of powers analysis. Alexion says that such analyses are needed because the Act has been

amended so that control of excessive pricing under the Act is now achieved by a price control scheme rather than by the former compulsory licencing scheme.

IV. Prothonotary's Aalto's Decision

[13] In reaching his Decision, Prothonotary Aalto undertook an extensive review of the cases relied on by the Respondent in support of its position that the constitutionality of the Impugned Provisions is settled law. (See: *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 DLR (4th) 485 (QB), aff'd (1992), 96 DLR (4th) 606 (CA) [*Manitoba Society*] and *Smith, Kline & French Laboratories Ltd. v. Attorney General of Canada*, [1986] 1 FC 274). The Prothonotary also considered *Sandoz*.

[14] In *Sandoz*, after discussing the Manitoba Court of Appeal decision in *Manitoba Society*, the Chief Justice of the Federal Court of Appeal wrote as follows at paragraph 116:

> In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act, 1867* when applied to a patent holder or owner. The respondents recognize as much when they state that the Federal Court judge's interpretation of "patentee" maintained the connection to the federal head of power, such that the reasoning in *Manitoba Society* remained intact (respondents' respective replies to the response by the Attorney General of Canada to the Notice of Constitutional Question (respondents' replies) at para. 46).

[15] In the result, the current price control scheme in sections 79 to 103 of the Act was upheld as constitutional.

[16] Since *Sandoz* is binding authority, the Prothonotary concluded that the Challenge was bereft of any chance of success.

[17] In *Sandoz*, leave was sought to appeal to the Supreme Court of Canada. At the time of the Prothonotary's decision, leave had not been decided. However, a Notice of Discontinuance was filed on September 8, 2016. This leaves the Federal Court of Appeal's unanimous decision in *Sandoz* as the ultimate authority.

V. Issues

[18] The sole issue is whether the Prothonotary was correct when he struck out the Challenge as being bereft of any possibility of success because the *Sandoz* decision is binding authority.

[19] In *Sandoz*, the Federal Court of Appeal [the Court] indicated in paragraph 2 of its decision that the "central issue" in both appeals was whether Sandoz Canada Inc. and Ratiopharm Inc. [the Respondents], who are generic drug manufacturers, were patentees as that term is defined in subsection 79(1) of the Act. If they were patentees, the Court indicated that the next question was whether sections 79 to 103 of the Act were constitutional. These are the current price control provisions.

[20] The Court found that the Respondents were patentees as defined in subsection 79(1) of the Act and then turned to the constitutional question. The Court noted in paragraph 112 of its decision that the theory behind the Respondents' constitutional attack was that, unlike the prior

scheme of compulsory licencing which used patent rights to control prices, the current regime is one of pure price regulation which intrudes into the sphere of property and civil rights.

[21] In paragraphs 112 and 113 of the *Sandoz* decision, the Court also noted the Respondents' arguments that the Amendments to the Act in 1992, which repealed the compulsory licensing provisions, mean that the decision in *Manitoba Society* is no longer good law.

[22] These are among the arguments that Alexion now advances in the Challenge. Alexion submits that it has expert evidence which was not before the Court in *Sandoz* and that it should be entitled to a fresh opportunity to more fully litigate the constitutionality of the Impugned Provisions.

[23] However, since the Court in *Sandoz* clearly understood that the method of price control had changed from compulsory licensing to pure price control involving the power to confiscate excessive revenues, there is in my view no basis for revisiting the constitutionality of the Impugned Provisions.

VI. Conclusion

[24] My conclusion is that *Sandoz* is binding authority. The Prothonotary's Decision was therefore correct and, accordingly, the appeal from his Decision was dismissed.

"Sandra J. Simpson"
Judge

Ottawa, Ontario
January 6, 2017

FEDERAL COURT

SOLICITORS OF RECORD

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