Federal Court  Cour fédérale

Date: 20140311

Docket: T-1963-13

Citation: 2014 FC 235

Ottawa, Ontario, March 11, 2014

PRESENT: The Honourable Madam Justice Mactavish

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Applicant

and

THE MINISTER OF HEALTH
ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR ORDER AND ORDER

[1] Hospira Healthcare Corporation (Hospira) has brought an application for judicial review with respect to a decision of the Minister of Health refusing to issue a Notice of Compliance for a drug that Hospira identifies as "Drug A" until the expiry of the period of data protection granted to an unidentified third party under the *Food and Drugs Regulations*, C.R.C., c. 870.

[2] While not admitting this to be the case, for the purposes of this appeal I understand Hospira not to dispute that the unidentified third party referred to in its Notice of Application is

sanofi-aventis Canada Inc. (Sanofi) and that “Drug A” refers to oxaliplatin. Oxaliplatin is an oncology drug sold by Sanofi under the Eloxatin brand name pursuant to a Notice of Compliance issued by the Minister of Health.

[3] Following a motion brought by Sanofi, Prothonotary Tabib ordered Hospira to add Sanofi as a party respondent in this proceeding. Hospira appeals that decision, asserting that the Prothonotary erred in finding that Sanofi was “directly affected” by Hospira’s application for judicial review.

[4] As the Federal Court of Appeal observed in *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, at paragraphs 18-19, 30 C.P.R. (4^{th}) 40, discretionary orders of Prothonotaries ought not to be disturbed on appeal unless the question raised by the motion is vital to the final issue in the case, or the order is clearly wrong in the sense that the exercise of discretion was based upon a wrong principle or a misapprehension of the facts.

[5] The final issue in the case is the reasonableness of the Minister’s decision to refuse to issue a Notice of Compliance to Hospira for its “Drug A” until the expiry of the data protection period granted to Sanofi under the *Regulations* on the basis that Hospira’s New Drug Submission involved a direct or indirect comparison with Eloxatin.

[6] Hospira’s substantive right to have the issues identified in its Notice of Application determined have not been affected by the Prothonotary’s Order. Moreover, Hospira has not persuaded me that the decision whether or not to add Sanofi as a respondent in this proceeding is

a matter that is vital to these issues: see *Savanna Energy Services Corp. v. Technicoil Corp*., 2005 FC 842 at para. 18, 40 C.P.R. (4th) 237; *Sierra Club of Canada v. Canada (Minister of Finance)*, [1999] 2 F.C. 211 at para. 21, [1998] F.C.J. No. 1761 (T.D.). As a consequence, I am not persuaded that I should review Prothonotary Tabib's decision on a *de novo* basis.

[7] Hospira has not asserted that Prothonotary Tabib's decision was based upon a misapprehension of the facts. As a consequence, the only question for me is whether the exercise of her discretion was based upon a wrong principle.

[8] Prothonotary Tabib provided careful and detailed reasons for concluding that Sanofi was indeed "directly affected" by Hospira's application for judicial review within the meaning of Rule 303 of the *Federal Courts Rules*, SOR/98-106. She had regard to the test articulated by the Federal Court of Appeal in *Forest Ethics Advocacy Assn. v. Canada (National Energy Board)*, 2013 FCA 236, 450 N.R. 166, and explained how Sanofi was able to satisfy that test: see paras. 16 to 20 of Prothonotary Tabib's decision. I have not been persuaded that the exercise of her discretion was based upon a wrong principle in this regard.

[9] Hospira also asserts that Prothonotary Tabib misconstrued the data protection scheme established by sections C.08.001 to C.08.004 of the *Food and Drug Regulations*. The Prothonotary further erred, Hospira says, in failing to follow this Court's decision in *Lundbeck Canada Inc. v. Canada (Minister of Health)*, 2008 FC 1379, 338 F.T.R. 145, aff'd 2009 FCA 134, 392 N.R. 9, and other decisions which establish that innovator companies do not have standing to challenge decisions made by the Minister of Health under the *Food and Drugs Act* or

Regulations in examining drug submissions made by generic drug manufacturers. According to Hospira, *Lundbeck* was binding on the Prothonotary and was dispositive of Sanofi's motion.

[10] I do not accept this submission.

[11] As noted by the Prothonotary, this case arises out of unusual circumstances and raises novel issues. The cases relied upon by Hospira (which are identified at paragraph 30 of Hospira's memorandum of fact and law and paragraph 13 of Prothonotary Tabib's decision) are clearly distinguishable from the present case. They do not deal with the rights of innovators under the data protection provisions of the *Regulations*, but instead address the ability of innovators to challenge findings by the Minister of Health with respect to health and safety issues.

[12] In particular, this Court's decision in *Lundbeck* deals with a fundamentally different situation than that which arises in this case. In *Lundbeck*, the innovator company's drug was *not* listed on the Health Canada Register of Innovative Drugs. The company was seeking a declaration that it should be so listed, and was also seeking orders preventing the Minister of Health from reviewing and acting upon drug submissions from two generic companies.

[13] Of particular significance was the finding in *Lundbeck* that because the innovator company's drug was not listed on the Register, the data protection regime in the *Food and Drug Regulations* did not apply: see para. 46. In contrast, Sanofi's Eloxatin drug is in fact listed on the Register and is indeed subject to the data protection regime under the *Regulations*.

[14] The effect of this listing is that for the first six years of the data protection period, generic manufacturers are prohibited from filing an abbreviated new drug submission relating to Eloxatin: *Teva Canada Ltd. v Canada (Minister of Health)*, 2012 FCA 106 at para. 49, 101 C.P.R. (4^{th}) 425.

[15] As a consequence, I have not been persuaded that Prothonotary Tabib erred in principle in her treatment of the jurisprudence (including this Court's decision in *Lundbeck*) such that her decision to add Sanofi as a respondent to this proceeding was clearly wrong.

Conclusion

[16] For these reasons, Hospira's appeal is dismissed. Sanofi is entitled to its costs, which are fixed in the amount of $2,500, inclusive of disbursements.

ORDER

THIS COURT ORDERS that Hospira Healthcare Corporation's appeal is dismissed, with costs to Sanofi fixed in the amount of $2,500, inclusive of disbursements.

"Anne L. Mactavish"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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