Federal Court  Cour fédérale

Date: 20140226

Docket: T-1963-13

Citation: 2014 FC 179

Ottawa, Ontario, February 26, 2014

PRESENT: Madam Prothonotary Tabib

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Applicant

And

THE MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Respondents

REASONS FOR ORDER AND ORDER

[1] The present motion raises the issue of an innovator's standing and right to be made a party to a judicial review of the Minister of Health's administration of that part of the *Food and Drugs Regulations*, CRC, c. 870 implementing a data protection regime pursuant to Canada's obligations under the North American Free-Trade Agreement ("NAFTA") and the Trade-Related Aspects of Intellectual Property Rights ("TRIPS").

Background

[2] Sanofi-Aventis Canada Inc. ("Sanofi") manufactures and sells in Canada the drug Eloxatin, which contains oxaliplatin as an active pharmaceutical ingredient. On June 15, 2007, the Minister of Health determined that Eloxatin and oxaliplatin were innovative drugs and placed them on the Register of Innovative Drugs (the "Register"), maintained pursuant to subsection C.08.004.1(9) of the *Food and Drugs Regulations*.

[3] The data protection regime set out in section C.08.004.1 aims to protect the data submitted in support of an application for approval to market innovative drugs containing a new chemical entity, by preventing others from using the innovator's data in support of their own applications for drug approval. When a drug is placed on the Register of Innovative Drugs, the Minister is precluded from receiving from another manufacturer an application for a Notice of Compliance entitling it to market that drug in Canada for a period of six years, where that application is based on or refers to the data provided by the innovator. The Minister may not, either, issue an NOC for such an application for a further period of two years.

[4] On October 27, 2006, before oxaliplatin was listed on the Register, Hospira filed a New Drug Submission (NDS) seeking an NOC for a drug containing "Chemical Entity A" as its active ingredient. Sanofi has good reason to believe that "Chemical Entity A" is, in fact, oxaliplatin. On this motion, Hospira does not admit that "Chemical Entity A" is oxaliplatin, but does not deny that Sanofi has reasonable grounds to believe that it is. Hospira has undertaken, if the Court finds that the innovator whose drug is listed as "Chemical Entity A" has a right to be added as a

respondent to this application, to notify and name that innovator. For the purposes of the hearing and of these reasons, and for ease of understanding, the assumption has been made that "Chemical Entity A" is oxaliplatin, although it is not necessary, and the Court does not, determine that this is in fact the case.

[5] The Minister initially rejected Hospira's NDS, for reasons that have nothing to do with data protection. Following Hospira's successful judicial review of the Minister's initial refusal, the Minister resumed his examination of Hospira's NDS. By then, Eloxatin and oxaliplatin had been listed on the Register. As is often the case, the Minister sought additional information from Hospira to assist in his assessment of the drug's safety and efficacy. In one of its answers, Hospira made reference to the product monograph for Eloxatin. The Minister considered that Hospira had thereby made "direct or indirect comparison" between its drug and Eloxatin, and advised Hospira that, pursuant to section C.08.004.1, it would not issue Hospira's NOC for the drug until the expiration of the data protection period, even though Hospira's ANDS was otherwise approvable.

[6] Hospira brings this application to judicially review the Minister's decision, challenging the Minister's interpretation and application of section C.08.004.1 of the *Food and Drugs Regulations*. It says that the data protection provisions do not apply to its NDS because it was filed before Eloxatin was entered on the Register. In any event, it argues that it did not directly or indirectly compare its product to Eloxatin, that if it did, the reference did not appear in its initial NDS and that post-filing amendments are excluded from the scope of the relevant section, and that the reference was mandated by the Minister without due notice that it would be deemed to

trigger the application of data protection. Hospira's notice of application for judicial review does not name, and was not served on Sanofi or any party other than the Minister.

[7] To the extent "Chemical Entity A" is in fact oxaliplatin, Sanofi argues that it is a person directly affected by the order sought by Hospira in this judicial review application, and that as such, Hospira ought to have, and should be ordered to, name it as a party respondent.

Analysis

[8] Rule 303 of the *Federal Courts Rules* requires an applicant to a judicial review to name as a respondent "every person directly affected by the order sought in the application". Hospira in this application seeks "an Order quashing and setting aside the Minister's decision (…) which refused to issue the applicant a notice of compliance for Drug A (…) and an Order of *mandamus* requiring the Minister to forthwith issuance [sic] a notice of compliance to Hospira for Drug A". The question before the Court is therefore simply whether Sanofi would be directly affected by such an order.

[9] The parties are *ad idem* that the appropriate test for determining whether a party has a direct interest is the same whether the party is a proposed applicant or a proposed respondent, and that it was most recently articulated by the Federal Court of Appeal in *Forest Ethics Advocacy Assn. v Canada (National Energy Board)*, 2013 FCA 236 as follows:

> "20. A party has a "direct interest" under subsection 18.1 (1) of the *Federal Courts Act* when its legal rights are affected, legal obligations are imposed on it, or it is prejudicially affected in some direct way : *League for Human Rights of B'Nai Brith Canada v. Odynsky*, 2010 FCA 307 at paragraphs 57-58; *Rothmans of Pall Mall Canada Ltd. v. Canada (M.N.R.)*, [1976] 2 F.C. 500 (C.A.); *Irving Shipbuilding Inc. v. Canada (A.G.)*, 2009 FCA 116."

[10] There is no case directly on point, that is, a case where an innovator's standing has been determined in the context of a review of the Minister's decision that the data protection regime applied or did not apply to a specific submission in respect of a listed Innovative Drug.

[11] The only decision involving the data protection regime in which standing was discussed is *Lundbeck Canada Inc. v. Canada (Minister of Health)* 2008 FC 1379, aff'd 2009 FCA 134. In that case, Lundbeck, whose drug was not listed as an Innovative Drug on the Register, was seeking a declaration that it should be so listed, and orders preventing the Minister from accepting, reviewing and acting upon drug submissions filed by two generics, on the basis that there was no existing "Canadian Reference Product" as well as on the basis that its product should be listed on the Register. The Court found that Lundbeck's application was bereft of any merit. On the issue of the data protection regime, it found that Lundbeck's drug was not, and clearly could not be, listed on the Register, and that the new data protection regime therefore could not apply to it. The trial Judge also made a general finding that Lundbeck lacked standing to interfere with the Minister's consideration of an ANDS under the *Food and Drugs Regulations*. Hospira notes that the Judge included in his conclusion on standing reference to Lundbeck's challenges under the data protection provisions (at paragraph 25). There is, however, no discussion of the principles of standing as they might apply to the new data protection regime.

Further, if the trial Judge's decision were to be interpreted as a determination of law that innovators have no standing whatsoever when it comes to the data protection regime, it would deny to a manufacturer the standing to even challenge the Minister's determination as to whether or not to list its own drug on the Innovative Drug Register. This would clearly be wrong, given that Sanofi's standing was accepted on that very issue in *Teva Canada Ltd. v Canada (Minister of Health)*, 2011 FC 507, 2012 FCA 106. In any event, the Federal Court of Appeal in *Lundbeck* expressly upheld the conclusions of the trial judge that the applications had no merit, and declined to consider the issue of standing. I therefore conclude that the *Lundbeck* case is not determinative of this matter.

[12] All parties have noted two clear and constant lines of jurisprudence on the issue of standing in respect of the regulations made under the *Food and Drugs Act*.

[13] On the one hand, it has been held that an innovator drug manufacturer does not have standing to bring or respond to an application to judicially review a decision of the Minister of Health under the *Food and Drugs Act* or the *Food and Drugs Regulations* in respect of the issuance or proposed issuance of an NOC to another drug manufacturer (*Merck Frosst Canada Inc v Canada (Minister of Health)*, [1997] FCJ No 1847, *Glaxo Canada Inc v Canada (Minister of Health & Welfare)*, [1988] 1 FC 422, aff'd (1990) 31 CPR (3d) 29, *Pfizer Canada Inc v Canada (Minister of National Health and Welfare)*, (1986), 12 CPR (3d) 438). The rationale for these cases has consistently been that the Minister alone is charged with the protection of the public's health and safety, that issues of the safety and efficacy of drugs are of no concern to

third-party manufacturers and that the economic and competitive impact on them is not sufficient to hold that they are "directly affected" by the issuance of an NOC to a competitor.

[14] On the other end of the spectrum, there is equally constant jurisprudence that an innovator whose patents are listed against a drug on the register maintained under the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 ("*PM(NOC)Regulations*") does have standing where the issue in a judicial review is whether or not the rights and protections afforded to it under the *PM(NOC)Regulations* are engaged by another manufacturer's application for an NOC (*Ferring Inc v Canada (Minister of Health)*, [2007] FCJ No 1138, *Apotex Inc v Canada (Attorney General)*, [1994] FCJ No 879, *Apotex Inc v Canada (Minister of Health)*, 2006 FC 846, *Nu-Pharm Inc v Canada (Attorney General)*, 2001 FCT 973, *Apotex Inc v Canada (Minister of Health)*, [2000] FCJ No 248). The Courts have generally distinguished these cases from cases related to the Minister's administration of the *Food and Drugs Regulations* on the basis that the *PM(NOC)Regulations* do recognize and afford protection for innovators' patent rights: generic drug manufacturers who, for the purpose of establishing safety and efficacy, compare their products to an innovator's product against which a patent is registered are required to either await the patent's expiry before obtaining an NOC, or to address why the patents are invalid or would not be infringed. This triggers specific legal rights for the innovator.

[15] Contrary to Hospira's submissions, one cannot draw from these two lines of cases simple and absolute propositions that are determinative of the matter at issue here, such as that innovators have standing where the *PM(NOC)Regulations* are engaged but none when only the

Food and Drugs Regulations are involved, that an economic or competitive prejudice is always too remote to "directly affect" a person, or that the only kinds of interests that can give rise to standing in administrative proceedings under the *Food and Drugs Act* are those for which the regulations contemplate a legally enforceable right or legal recourse. In the end, it always comes down to whether the order sought affects the legal rights of the innovator, imposes legal obligations on it, or prejudicially affects it in some direct way. In the circumstances of the cases cited above where the administration of the *Food and Drugs Regulations* was at issue, no legal rights were affected and no legal obligations imposed, and the Courts found that the competition resulting from the issuance of an NOC did not, of itself, affect the innovator in a direct way. In cases involving the *PM(NOC) Regulations*, legal rights were affected. These were the factors considered by the Court, not some arbitrary distinction between the *Food and Drugs Regulations* and the *PM(NOC) Regulations*.

[16] In the case before me, assuming that "Chemical Entity A" is oxaliplatin, it is clear that an order reversing the Minister's determination that the data protection regime was engaged and ordering the issuance of an NOC to Hospira would prejudicially affect Sanofi in a direct way, and not merely because it would suffer economic or competitive prejudice.

[17] The data protection regime established by section C.08.004.1 specifically recognizes and intends to protect the interests of innovative drug makers by guaranteeing them exclusivity in the market place for the designated period of data protection against those who may refer to or use the data they have generated to establish the safety or efficacy of their drug. The purpose and

intent of the data protection regime as a direct benefit to innovators whose products are listed on the Register is explicitly set out in the Regulatory Impact Analysis Statement that introduced the new regime:

> "The amendments to section C.08.004.1 of the *Food and Drug Regulations* ("Regulations") are intended to provide new drugs with an internationally competitive, guaranteed minimum period of market exclusivity of eight years."
> (…)
> "The obligations in TRIPS require that signatories provide protection against the unfair commercial use of the data, whereas NAFTA requires that signatories provide a reasonable period of time during which a subsequent manufacturer is prohibited from relying on the originator's data for product approval.
> (…)
> In keeping with the provisions, the government has decided to provide this protection by allowing the innovator, or the originator of the data submitted for regulatory approval, to protect investments made in the development of the product by providing a period of market exclusivity."

[18] The Federal Court of Appeal has further recognized that the data protection regime, as implemented by section C.08.004.1, did intend to confer on an innovator market exclusivity as the chosen means to give effect to Canada's obligations to protect the innovator's data under NAFTA and TRIPS. *Canadian Generic Pharmaceutical Assn. v Canada (Minister of Health)*, 2010 FCA 334, at para 76:

> "76 In my view, the DPR is in clear accord with the enabling provision. It is a regulation, the purpose of which is to implement, in relation to drugs, article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS. Market exclusivity, conferred by the DPR on an innovator, is the means chosen by the Governor in Council to give effect to the relevant provisions of NAFTA and TRIPS. More

> particularly, the DPR is, in my view, a step taken by the Governor in Council "... to ensure that the data is protected against unfair commercial use".

[19] Sanofi's Eloxatin and oxaliplatin have been listed on the Register of Innovative Drugs. Sanofi is therefore entitled to benefit from the market exclusivity promised by section C.08.004.1 and to the protection of its data against direct or indirect comparison by others. The Minister has determined, in the decision under review, that Hospira has made such a comparison and impinged upon the protection extended to Sanofi. He has determined that market exclusivity has been triggered against Hospira's product and in favour of Sanofi. Hospira's application seeks to reverse that decision and withdraw the protection and benefits to which the Minister has determined Sanofi was entitled. It is beyond question that the order sought will directly prejudice Sanofi, as it will remove the protection and its right to the exclusion of Hospira's product from the market, both of which were intended for Sanofi's direct benefit.

[20] The fact that the *Food and Drugs Regulations* do not contemplate the participation of Sanofi in the Minister's initial determination or a specific legal recourse in the event the data protection regime is triggered or breached does not negate Sanofi's standing. As formulated in *Forest Ethics Advocacy*, above, the test for standing does not require that legal rights or obligations flow to a person from the order sought; it is sufficient that it be prejudicially affected in a direct way.

[21] For these reasons, I am satisfied that the innovator whose product is listed on the Register of Innovative Drugs as corresponding to "Chemical Entity A" is a person directly affected by the order sought and that it is to be added by Hospira as a respondent to the Application.

[22] Much of Hospira's arguments were directed to the merits of the Minister's decision, presumably in an attempt to demonstrate that the decision was so clearly ill-founded that the benefit of the data protection regime could not, on the facts, have accrued to Sanofi and that Sanofi therefore cannot be a party affected by the order sought. The merits of the Minister's decision are not relevant to the determination of whether Sanofi would be directly affected by the order sought. The Minister's decision is valid, effective and provides benefits to Sanofi, until reversed, notwithstanding Hospira's argument that it should not have been made. The order sought by Hospira would remove those benefits. In any event, I have not been satisfied that the Minister's interpretation of the *Regulations* is clearly without merit.

ORDER

THIS COURT ORDERS that:

1. Hospira shall, no later than 20 days from the date of this order, amend its Notice of Application to add, as a respondent, the innovator whose drug is listed on the Register of Innovative Drugs as containing "Chemical Entity A".

2. The delays for the steps to be taken in this Application shall thereafter follow the provisions of the Federal Courts Rules.

3. Costs of this motion, in the amount of $2,000.00 shall be paid by Hospira to Sanofi.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1963-13
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DATED:	FEBRUARY 26, 2014

APPEARANCES:

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Me Judith Robinson Me Brian Capogrosso	FOR THE PROPOSED RESPONDENT SANOFI-AVENTIS CANADA

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