Federal Court  Cour fédérale

Date: 20150612

Docket: T-823-15

Citation: 2015 FC 744

Ottawa, Ontario, June 12, 2015

PRESENT: The Honourable Madam Justice Gagné

BETWEEN:

HORIZON PHARMA PLC

Applicant

and

THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA

Respondents

ORDER AND REASONS

[1] Horizon Pharma plc brings an urgent motion, dated May 20, 2015 and amended May 28, 2015, for an Order, pursuant to sections 18(1), 18.1 and 18.2 of the *Federal Courts Act*, RSC 1985, c F-7, staying the issuance of a Notice of Compliance [NOC] for its own drug RAVICTI. The applicant asserts that the Minister of Health [Minister] is poised to issue the NOC as early as June 27, 2015 and thus seeks the stay pending judicial review of the Minister's decision to refuse data protection for RAVICTI.

[2] The applicant argues that without a stay, it will be left with no choice but to withdraw its New Drug Submissions [NDS] for RAVICTI in order to prevent generic competitors to use the information therein contained and enter the market immediately upon the expiry of its Canadian Patent Number 2, 212, 047 [047 Patent], on February 6, 2016. As a consequence, the applicant and Canadian patients will suffer irreparable harm.

[3] The respondents take no position in this motion.

[4] For the reasons discussed below I am of the view the application should be granted.

I. Background

[5] The applicant is a specialty biopharmaceutical company that markets a portfolio of products in arthritis, inflammation and orphan diseases. It acquired and merged with Hyperion Therapeutics Inc. [Hyperion] in May 2015. Hyperion was involved in a series of events leading to the present motion.

[6] Hyperion markets two drugs which became part of the applicant's orphan drug portfolio, BUPHENYL (sodium phenylbutyrate) and RAVICTI (glycerol phenylbutyrate), both of which are used to treat Urea Cycle Disorders [UCDs].

[7] Neither product has yet received a NOC or any form of data protection in Canada.

[8] Only BUPHENYL, which is offered in tablet or powder, has been available in Canada as part of Health Canada's Health Access Programme.

[9] RAVICTI is an oral liquid and a clinical improvement over BUPHENYL. It was only after the applicant has filed its Notice of Application before the Court that it became aware that Patent 047 was found to be eligible for listing on the Patent Register in Canada.

NDS for RAVICTI

[10] On April 25, 2014, Hyperion filed its NDS for RAVICTI. It also requested that RAVICTI be added to the Register of Innovative Drugs on the basis that it qualified as an "innovative drug" pursuant to section C.08.004.1 of the *Food and Drug Regulations*, CRC c 870 [*Regulations*]. A drug that satisfies the requirements and is added to the Register of Innovative Drugs automatically enjoys data protection. Otherwise, the drug may be copied immediately upon the issuance of a NOC as a result of the lack of data protection.

Initial Denial of Data Protection for RAVICTI

[11] On May 26, 2014, the Office of Patented Medicines Liaison [OPML] advised Hyperion of its preliminary position that RAVICTI was not an "innovative drug". However, after ongoing discussion and further submissions by the applicant, the OPML reversed its prior position and advised Hyperion that RAVICTI was eligible for data protection, subject to a final review of NOC issues.

Notice of Deficiency

[12] On November 13, 2014, Hyperion was notified that it failed to include the results of a drug-drug interaction study referenced in the NDS. It was also advised that its NDS would be placed at the back of the queue and that the approval clock would be re-set for 6 months.

The Generic Competitor and PHEBURANE

[13] Meanwhile, Medunik Canada, a generic competitor, received a NOC, pursuant to section C.08.002 of the *Regulations* for its PHEBURANE (sodium phenylbutyrate), a generic copy of BUPHENYL®. The applicant asserts Medunik was permitted to receive a NOC relying on data from Hyperion's European reference product AMMONAPS (BUPHENYL) and its market experience over the past 10 years.

[14] Medunik Canada had submitted its NDS after Hyperion in June 2014.

Decision Leading to Judicial Review

[15] On May 1, 2015 and after consultation and consideration of submissions, the OPML refused to add RAVICTI on the Register of Innovative Drugs and found that it was not eligible for data protection [Data Protection Decision]. Hyperion was advised that RAVICTI was not eligible because it was considered an ester variation of PHEBURANE (sodium phenylbutyrate) and that in the alternative it was "a second minor variation" of phenylbutyric acid, which was approved in PHEBURANE as a sodium salt. Given that PHEBURANE was approved prior to

RAVICTI, the OPML was of the view that RAVICTI could no longer be considered as an "innovative drug" under the *Regulations*.

[16] On May 20, 2015 the applicant filed a Notice of Application for judicial review of the Data Protection Decision.

II. Issues

[17] The sole issue raised by the applicant's motion is:

- Whether this Court should stay the Minister's decision to issue a NOC for RAVICTI pending the judicial review of the Data Protection Decision.

III. Analysis

[18] The applicant argues that a stay is necessary and appropriate and that this case satisfies the criteria for granting a stay (*RJR-MacDonald Inc v Canada (Attorney General)*, [1994] 1 SCR 311 [*RJR-MacDonald Inc*]; *Jamieson Laboratories Ltd v Reckitt Benckiser LLC et al*, 2015 FCA 104 at para 22 [*Jamieson Laboratories Ltd*]):

(i) it presents a serious issue to be tried;

(ii) the applicant and Canadian patients will suffer irreparable harm if no stay is granted; and

(iii) the balance of convenience favours the requested relief.

[19] The test for granting a stay is conjunctive and each factor needs to be assessed.

Serious issue to be tried

[20] The applicant argues that in the present case, an incorrect, unreasonable and inconsistent interpretation of the *Regulations* is a serious issue to be tried. It is of the view that:

- The Minister incorrectly found RAVICTI to be an ester variation of sodium phenylbutyrate;
- The Minister's "second minor variation" argument is an error of law;
- The Minister erred in ignoring the significant and substantial data of the RAVICTI NDS;
- Denying RAVICTI data protection is inconsistent with the policy behind data protection;
- The Minister capriciously and inconsistently applied the data protection regulations.

[21] As has been held repeatedly, the threshold that the applicant must meet in establishing a serious issue, in most circumstances, is a low one; unless it can be shown that the arguments put forth are frivolous or vexatious, a serious issue will be made out. As has been held recently, this question must be answered on the basis of no more than an "extremely limited review of the case" (*Jamieson Laboratories Ltd*, at paras 21-26). Without deciding the merits of the judicial review of the Data Protection Decision, I am satisfied that in the present case there is a "serious issue" of potential errors committed by the Minister, such as, for example, in connection to interpreting and applying the definition of "variation" within the meaning of subsection C.08.004.1(1) of the *Regulations* and/or on classic administrative law principles. The applicant

has offered the Affidavit of Dr. Bruce Scharschmidt in support of its motion; Dr. Scharschmidt now serves as a consultant for the applicant and had served as Senior Vice President and Chief Medical & Development Officer at Hyperion. Dr. Scharschmidt discusses Health Canada's initial denial of data protection and subsequent reversal. It seems that Health Canada essentially agreed with the submissions and would have afforded RAVICTI data protection but for the delay and subsequent result—which was that Medunik got its NOC first. He goes on to discuss the analogous case of AVAMYS, for the proposition that two separate variations of the same medical ingredient have received data protection, as long as the medical ingredient itself has not been previously approved. This, for example, raises a question of interpretation or application of "variation" in subsection C.08.004.1(1) of the *Regulations*.

[22] I am of the view that the first part of the test is met and that the applicant has shown a serious issue to be tried.

Irreparable Harm

[23] Turning to irreparable harm, on the basis of the affidavit evidence submitted, it must be shown that the applicant will suffer incalculable and non-compensable losses should it not succeed in its judicial review application. The evidence adduced must be clear and not speculative (*T.W.U. v Canadian Industrial Relations Board*, 2005 FCA 83 at para 8).

[24] The applicant argues that it, and the public, will suffer irreparable harm if the stay is not granted: it will have to withdraw from the Canadian marketplace and suffer non-compensable losses, while irreparably harming patients.

A. Non-compensable losses

[25] The applicant argues the evidence adduced is clear: it will not be able to market RAVICTI in Canada and will simply have no recourse to seek compensation for lost profits. As the applicant is not yet in the marketplace, the Court can draw inferences that logically there can be no evidence of harm that has already occurred (*Ciba-Geigy Canada Ltd v Novopharm Ltd*, [1994] FCJ No 1120). While it is the applicant making the decision to withdraw its NDS, it is submitted that Health Canada's actions of failing to properly consider data protection prior to the issuance of an NOC is the cause giving rise to the harm.

[26] Before the merger, Hyperion consistently told Health Canada that it would have to withdraw its NDS for RAVICTI because without data protection, it cannot recoup the investments needed to offer RAVICTI for sale on the Canadian marketplace. That is, the brief market exclusivity period of time enjoyed in the event of an issued NOC without data protection would fall short of enabling the applicant to come close to recouping these investments.

[27] The applicant claims that this assertion does not change in view of the fact that RAVICTI is eligible for listing on the Patent Register. It argues that the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 can only prevent generic competition until February 6, 2016 when the 047 Patent expires. This brief period of exclusivity is not long enough to recoup substantial investments – it is roughly equivalent to six months – Health Canada's target period of exclusivity for generic drug submissions.

[28] In his affidavit, Dr. Scharschmidt refers to the extensive clinical studies taken in developing RAVICTI, since approximately 2006, which was included in the data package that formed part of the RAVICTI NDS. It further specifies at paragraph 20, "these clinical trials included a Canadian site at the University of Toronto and required substantial investment in Canada from Hyperion."

[29] As the applicant could not recoup its investment and would have no recourse or means to be compensate in respect of lost sales, I am satisfied that the applicant would suffer irreparable harm if a stay is not granted and that the second part of the test is met, at least as regard the applicant.

B. Harm to patients

[30] The applicant further argues that the Court should also consider irreparable harm that the Canadian patients would suffer. It contends that, if it does not enter the Canadian market, Canadian patients suffering from UCDs will not have access to RAVICTI, which is significantly superior to other drugs on the market. The public will be denied a life-changing and life-saving drug - significant in light of Health Canada's refusal to accept requests for RAVICTI by way of its Health Access Programme.

[31] The applicant admits that typically the moving party is to be the focus of the irreparable harm inquiry while it is more appropriate to consider third parties when assessing the balance of convenience (*RJR-MacDonald Inc*, at para 342). However, according to the applicant the "issue remains an open one" (*Janssen Inc v AbbVie Corporation*, 2014 FCA 112 at para 35 [*Janssen*];

Edmonton Northlands v Edmonton Oilers Hockey Club, [1993] AJ No 1001). The applicant argues that this Court should consider the impact on third parties in failing to grant a stay, because of the "unique circumstances" of this motion.

[32] Thus, the question is whether it would be appropriate to consider the submission, in light of the following passages from Stratas J in *Janssen*, wherein Janssen brought a motion for a stay of the remedy phase of the trial, pending two appeals to the Federal Court of Appeal and an upcoming trial on injunctive relief:

> 33. In its submissions on irreparable harm, Janssen emphasized the suffering of patients who will not be able to use its medication, Stelara. But at present, patients can still use Stelara. That may change depending on how the Federal Court determines the issue of injunction.
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> 34. The Federal Court might grant an injunction on terms that protect patients. It might grant an injunction on other terms that reduce or eliminate the harm to patients or, for that matter, other harms that Janssen could suffer. Or it might not grant the injunction at all. Right now, any harm to patients, or for that matter to Janssen, is speculative and hypothetical.
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> 35. On the issue of harm to patients, AbbVie submits that the only admissible irreparable harm is that suffered by the moving party: see, e.g., *Manitoba (Attorney General) v. Metropolitan Stores (MTS) Ltd.*, [1987] 1 S.C.R. 110 at page 128. Janssen disagrees and submits that such harm is admissible because the patients are dependent upon it, the moving party: see, e.g., *Holy Alpha and Omega Church of Toronto v. Attorney General of Canada*, 2009 FCA 265 at paragraph 17; *Glooscap Heritage Society*, supra at paragraph 34. Given my comments, above, I need not resolve this issue.

[33] Stratas J leaves the question open. However if it were to be answered in favour of considering the harm on patients that depend on the applicant, it could be said that the facts of this case differ from those in *Janssen*. In the present case, the harm to the patients would not be

speculative or hypothetical: the applicant has unequivocally asserted that it would withdraw its NDS should it be denied data protection and the evidence presented shows, at least *prima facie*, that RAVICTI is a clinical improvement over BUPHENYL and thus PHEBURANE.

[34] However, as I found that the applicant would suffer irreparable harm if no stay is granted, I will leave the impact on the Canadian patients to the analysis of the balance of convenience.

Balance of Convenience

[35] The applicant submits the balance of convenience favours maintaining the status quo.

[36] In considering which of the two parties would suffer greater harm, the applicant submits failure to grant a stay would cause the applicant infinitely greater harm than granting a stay would cause to the Minister. There is no harm in maintaining the status quo—that is simply being required to delay the issuance of the NOC.

[37] In determining where the balance lies, I find there is a compelling public interest in granting the stay, an important factor: Canadian patients with UCDs will have access to what could be a life-saving drug. The Supreme Court of Canada has held that public interest includes both the concerns of society generally and the particular interests of identifiable groups (*RJR-MacDonald Inc*, at paras 343-344).

[38] In my view, given that the respondents take no position in this matter, it is an indicator that there is no harm in staying the issuance of the NOC for RAVICTI, which is the applicant's own drug.

IV. Conclusion

[39] For the foregoing reasons, I would order a stay of the Minister's issuance of the NOC for RAVICTI, pending the disposition of the application for judicial review of the Data Protection Decision.

ORDER

THIS COURT'S ORDER is that:

1. The applicant's motion is granted;

2. The issuance of a Notice of Compliance to the applicant, pursuant to the *Food and Drug Regulations*, CRC, c 870, with respect to its New Drug Submission #174219 for RAVICTI is stayed until the earlier of:

   a) Ten (10) days following final judgment on the underlying application for judicial review of the Data Protection Decision and expiry of all deadlines for appealing such final judgment; or

   b) Ten (10) days following discontinuance, for any reason, of the underlying application for judicial review;

3. No costs are granted.

"Jocelyne Gagné"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-823-15
STYLE OF CAUSE:	HORIZON PHARMA PLC v THE MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	JUNE 8, 2015
ORDER AND REASONS:	GAGNÉ J.
DATED:	JUNE 12, 2015

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