Federal Court of Appeal | Cour d'appel fédérale

**Date: 20200831**

**Docket: A-138-20**

**Citation: 2020 FCA 135**

**Present:** **RIVOALEN J.A.**

**BETWEEN:**

**THE MINISTER OF HEALTH**

**Appellant**

**and**

**GLAXOSMITHKLINE BIOLOGICALS S.A.**

**Respondent**

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on August 31, 2020.

REASONS FOR ORDER BY: RIVOALEN J.A.

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## REASONS FOR ORDER

**RIVOALEN J.A.**

### I. Introduction

[1] The Minister of Health (the appellant or the Minister) moves for a stay of the judgment of the Federal Court issued on April 7, 2020 (per Justice Barnes) (2020 FC 397) until this Court determines the appeal.

[2] It is useful to provide some background to these reasons.

[3] The respondent is the owner of Canadian Patent No. 2,600,905 (the ʻ905 Patent). It seeks a Certificate of Supplementary Protection (CSP) under Canada's CSP regime for its shingles vaccine SHINGRIX and the ʻ905 Patent. The CSP regime encompasses sections 104 to 134 of the *Patent Act*, R.S.C. 1985, c. P-4 and the *Certificate of Supplementary Protection Regulations*, S.O.R./2017-165. The origins of Canada's CSP regime lie in Chapter 20 of the *Canada-European Union Comprehensive Economic and Trade Agreement* (CETA) dealing with supplementary patent-like protection for certain eligible pharmaceutical patents.

[4] A CSP provides pharmaceutical patentees, like the respondent, with an additional period of "patent-like rights" capped at two years. The intent in allowing an additional two years is to compensate for the patent term lost during the research and regulatory approval of new drugs.

[5] The ʻ905 Patent will expire on March 1, 2026. The respondent applied to the Minister for a CSP to extend the expiration date of the ʻ905 Patent and the drug SHINGRIX to March 1, 2028. The Minister, by letter dated August 3, 2018, refused to issue the CSP.

[6] This motion and the substantive appeal arise in the context of the respondent's judicial review application of the Minister's decision of August 3, 2018, denying the CSP.

[7] The Federal Court allowed the respondent's judicial review application but did not order the issuance of the CSP. The Federal Court ordered that the matter be redetermined by the Minister on the merits and in accordance with its reasons. The Federal Court found that this was not an appropriate case to direct the Minister to issue a CSP to the respondent. The Federal Court

set aside the Minister's decision as unreasonable because it failed to take appropriate account of Canada's CETA commitments and the full scope and purposes of the applicable CETA provisions.

[8] On June 8, 2020, the appellant filed a Notice of Appeal of the Federal Court judgment and reasons. On June 15, 2020, the appellant filed her motion record, asking this Court to grant an order staying the judgment of the Federal Court until the appeal is determined. The appellant relies on paragraph 50(1)(*b*) of the *Federal Courts Act*, R.C.S. 1985, c. F-7, saying that the stay is in the interest of justice.

## II. Analysis

[9] To stay the Federal Court's judgment, the appellant must satisfy the tri-partite test outlined in *RJR –MacDonald Inc. v. Canada (Attorney General),* [1994] 1 S.C.R. 311, 111 D.L.R. (4th) 385, at page 334 [*RJRMacDonald*]. The appellant must establish to this Court's satisfaction that there is a serious issue to be tried, that she will suffer irreparable harm if the stay is not granted, and that the balance of convenience favours granting the stay. All three questions must be answered in the affirmative, and failure on any single question is fatal to the motion for the stay. The standard of proof is a balance of probabilities, and the burden of proof lies on the appellant throughout (*Novopharm Limited v. Janssen-Ortho Inc.*, 2006 FCA 406, 358 N.R. 155 at paras. 8, 11).

A. *Serious Issue to Be Tried*

[10] The rule on a motion for a stay is that the Court conducts a preliminary investigation of the merits. The threshold for seriousness is "a low one". The moving party needs only show that it is "neither vexatious nor frivolous" (*RJRMacDonald*, at p. 337).

[11] In the present case, the Notice of Appeal sets out several grounds for the appeal to this Court. The appellant asserts that the Federal Court erred in law in concluding that the decision of the Minister, in refusing to issue a CSP in respect of the respondent's '905 Patent and drug SHINGRIX, was unreasonable. Essentially, the appellant submits that the Federal Court improperly applied the reasonableness standard. She also argues that the Federal Court erred by interpreting the relevant provisions of the CETA *de novo*, without regard for the Minister's reasons; by interpreting those provisions incorrectly and by using those incorrect interpretations as the standard by which to assess the reasonableness of the Minister's decision. She advances the same argument regarding the Federal Court's interpretation of the relevant provisions of the *Patent Act* and the *Certificate of Supplementary Protection Regulations*.

[12] The respondent does not agree with how the Minister has characterized the Federal Court's decision, but nonetheless accepts that the issues raised in this appeal, including the respondent's entitlement to a CSP for SHINGRIX, meet the standard of a serious issue pursuant to the test in *RJRMacDonald*.

[13] I agree that the appellant has met the first threshold requirement.

B. *Irreparable Harm*

[14] Turning to the second part of the test, in *RJRMacDonald*, at page 341, the Supreme Court has stated that "irreparable harm" refers to the nature of the harm suffered rather that its magnitude. It is harm either which cannot be quantified in monetary terms or which cannot be cured, usually because one party cannot collect damages from the other.

[15] To establish irreparable harm, the appellant must adduce clear and non-speculative evidence that irreparable harm will follow if the motion for the stay is denied. It may not be simply based on assertions (*United States Steel Corporation v. Canada*, 2010 FCA 200, 191 A.C.W.S. (3d) 707 at para. 7).

[16] Instead, "there must be evidence at a convincing level of particularity that demonstrates a real probability that unavoidable irreparable harm will result unless a stay is granted." (*Glooscap Heritage Society v. Canada (National Revenue)*, 2012 FCA 255, 440 N.R. 232 at para. 31 [Glooscap]; see also *Dywidag Systems International, Canada, Ltd. v. Garford Pty Ltd.*, 2010 FCA 232, 406 N.R. 304 at para. 14; *Canada (Attorney General) v. Canada (Information Commissioner)*, 2001 FCA 25, 268 N.R. 328 at para. 12; *Laperrière v. D. & A. MacLeod Company Ltd.*, 2010 FCA 84, 402 N.R. 341 at para. 17; *Janssen Inc. v. Abbvie Corporation*, 2014 FCA 176, 242 A.C.W.S. (3d) 11 at para. 46).

[17] In support of her motion, the appellant relies on the affidavit of Kendra Laurie Cann affirmed on June 11, 2020. Ms. Cann is a Patent Officer employed in the Health Products and

Food Branch of Health Canada. As part of her duties and direct involvement in the eligibility of the assessment of the CSP application in question, she reviewed and informed herself of the Certified Tribunal Record associated with the judicial review application.

C. *Evidence of Irreparable Harm*

[18] In her affidavit, Ms. Cann describes the effect of a redetermination of the matter by the Minister prior to the disposition of the appeal. She deposes that the Minister may decide to issue the CSP, rendering the appeal moot. She affirms that if this Court should decide not to hear the appeal because it is moot, the respondent will enjoy the benefit of an additional two years of *sui generis* protection, despite the Minister's concerns with the Federal Court's reasons for judgment. More specifically, she says that a CSP granted in this case would act as a barrier to prevent the authorization for sale and marketing of subsequent entry products for an additional two years, that is, until March 1, 2028.

[19] Alternatively, she deposes that should this Court allow the appeal and restore the Minister's decision, the Minister would need to address the CSP that she might issue pending the appeal. Ms. Cann adds that neither the *Patent Act* nor the CSP Regulations provide the Minister with express authority to revoke a CSP after it has been issued. In either event, Ms. Cann relies on a report of the Parliamentary Budget Officer dated April 26, 2018, and attached as an exhibit to her affidavit to depose that the cost of SHINGRIX for the Canadian public and other payers within the health care system will remain higher for two additional years. She says that a CSP would prevent competitors from entering the market for two years following the expiry of the

patent, allowing the respondent to maintain its market share and keeping the costs of SHINGRIX vaccine higher for Canadians.

[20] Ms. Cann asserts that the Canadian public and payers in the Health Care system would not be compensated for these higher costs, and therefore would suffer irreparable harm. She affirms that it is in the public interest for the Minister to delay the redetermination of this matter until after this Court has rendered a decision on the appeal.

[21] In addition, Ms. Cann says that there is a risk of compromising the public interest in the integrity and predictability of the Minister's statutory decision-making authority under the CSP regime because the Federal Court adopted a broad definition of "medicinal ingredient". There are currently a number of pending CSP applications, and the Minister may have to address multiple CSP applications without the benefit of guidance from this Court in this novel area. Without a stay, the Minister will be compelled to make decisions that may be subsequently found to be inconsistent with the views of this Court, leading to unjustified expansion of the eligibility for CSPs and creating uncertainty for drug manufacturers by jeopardizing the orderly administration of the CSP regime.

D. *Appellant's Position*

[22] Relying on Ms. Cann's affidavit, the appellant advances four arguments outlining why a failure to grant a stay would result in irreparable harm.

[23] First, there is a substantial risk that the appeal will be rendered moot, resulting in the Minister and the public being denied the opportunity to obtain guidance from this Court on the issues raised in this appeal.

[24] Second, if this Court declines to hear the appeal because it is moot, Canadians will be denied the opportunity to pay lower prices for competitors' biosimilar versions of SHINGRIX during the two-year term of the CSP.

[25] Third, the revocation of a CSP issued in error is difficult and uncertain. The Minister has no legislative authority to revoke or cancel a CSP issued in the interim. Even if the Minister were to bring an application to declare the CSP invalid or void, the outcome of such an application is unpredictable.

[26] Finally, there is a risk that contradictory decisions will compromise the public interest in the integrity of the Minister's decision-making authority and in the certainty and predictability of the CSP regime. On this fourth point, the appellant argues that the Federal Court's expansive interpretation of the CSP regime, and in particular, the meaning of "medicinal ingredient" to any ingredient that has "biological activity" is an expression that is absent from both the CETA and the CSP regime. She relies on this Court's decision of *Commissioner of Patents v. Belzberg*, 2009 FCA 275, 396 N.R. 342, at paragraph 22 [*Belzberg*] where it was accepted that there might be cases for which a stay is desirable, in order to avoid confusion, additional delay and inconsistency. The appellant does point out that in *Belzberg*, the motion for the stay was denied because of a failure to adduce specific evidence of the irreparable harm. However, the appellant

submits that in the present case, the Minister has provided the affidavit of Ms. Cann to demonstrate irreparable harm.

E. *Respondent's Position*

[27] The respondent argues that the evidence of alleged irreparable harm is hypothetical and unsupported. It says that the Minister's submissions on irreparable harm rest on a series of faulty assumptions that have not been borne out.

[28] First, it rightfully points out that Ms. Cann says that *if* the Minister redetermines the matter and decides to issue a CSP, the appeal *could* become moot. It argues that as a prerequisite, a CSP for SHINGRIX *must* be issued before any of the irreparable harm alleged by the Minister can occur. Importantly, the Federal Court did not order the Minister to issue a CSP in this case. The Minister's allegations on irreparable harm therefore do not arise from the Federal Court's judgment.

[29] Furthermore, the Minister has not submitted any evidence that she intends to reconsider or issue a CSP for SHINGRIX in the near future, or at all.

[30] Second, on the allegations that there will be harm to the public interest if the Minister in her redetermination decides to issue the CSP, the respondent argues that there is no evidence of Canadians facing increased costs for the purchase with respect to the vaccine SHINGRIX. The authors of the Parliamentary report relied upon by Ms. Cann state that their findings are not applicable to patented drugs without generics. The vaccine market is unique even amongst

biologics. There are no so-called “generic” vaccine products, and the general market-entry assumptions found in the report bear no relevance to the unique development and marketing of vaccine products like SHINGRIX. The appellant’s evidence on this point is therefore speculative and should be rejected.

[31] Third, there is no evidence that the integrity of the CSP regime will be impacted. In her affidavit, Ms. Cann concludes that in the absence of a stay, the Minister will be compelled to make decisions that may be inconsistent with the views of this Court. There is no concrete evidence however provided on how the Minister will be compelled to make such a decision. Furthermore, the Minister herself has conceded that “[e]ven if this Court grants the stay in this case, the Minister will still be required to consider new applications for CSPs made based on the Reasons of the Federal Court Judgment.” (Minister’s written representations, at para. 68, p. 157 of the Motion Record of the appellant). In other words, the stay itself will not prevent alleged irreparable harm from occurring.

[32] Finally, the respondent argues that the Minister’s delay in pursuing the appeal and this motion for a stay should weigh against any finding that there is actual irreparable harm that needs to be mitigated by a stay.

[33] On this fourth point, the respondent says that the Federal Court released its confidential decision on March 20, 2020. It took the Minister three months to bring this motion. Despite prompting from the respondent, there were further delays before the Minister took the necessary

steps to have this matter designated a Selected File in accordance with this Court's Notice to the Parties and the Profession.

F. *Decision*

[34] I have considered the appellant's main submissions and her reply submissions. I cannot accept her arguments on the demonstration of irreparable harm.

[35] The judgment of the Federal Court is not time-limited and does not order that the Minister issue a CSP. Although the Minister may not ignore the judgment pending appeal and must follow her normal procedures and timeframes to make a fresh decision in accordance with the Federal Court judgment, at this point it remains that no CSP has been issued or ordered.

[36] I am not satisfied on the record before me that the Minister has established irreparable harm. I have no concrete evidence on this point. At best, the evidence proffered by the appellant is hearsay evidence, in the form of a Parliamentary Report attached as an exhibit. Much of the irreparable harm alleged by the appellant and described in the affidavit of Ms. Cann is argumentative and speculative.

[37] The evidence proffered by the appellant has not satisfied me that she will suffer irreparable harm if the stay of the Federal Court judgment is not granted. On this record, I am not persuaded that the public interest will be impacted. Whether or not biosimilar manufacturers will be prevented from entering the market for an additional two years, from March 1, 2026, to March 1, 2028, remains to be seen. The Parliamentary Report does not assist me in my analysis

of this question, as it does not consider vaccines such as SHINGRIX. In short, I agree with the respondent's submissions as set out in paragraph [30] above on this point.

[38] The crux of the appellant's appeal is a disagreement with respect to the Federal Court's interpretation of "medicinal ingredient", the CSP regime and CETA. This Court held in *Belzberg* that *RJRMacDonald* does not generally relieve the Crown from her burden of establishing irreparable harm, including specifically where the Crown "is seeking a stay of an order in which there was no challenge to the validity of a law, but only a dispute as to its interpretation." (*Belzberg* at paras. 17-19).

[39] As stated earlier, I find that the appellant has failed to overcome the irreparable harm hurdle. Because the appellant has failed to demonstrate that she will suffer irreparable harm if her motion for a stay of the judgment of the Federal Court is dismissed, I need not consider the third step of the test, the balance of convenience.

[40] With respect to the respondent's argument that the Minister herself has delayed the appeal and the motion for a stay by waiting more than three months to bring matters before the Court, I am satisfied that on April 22, 2020, the Minister advised the Court by letter of her intention to appeal and her motion requesting an extension of time to be filed during the week of May 11th, 2020. In light of the COVID-19 pandemic, this Court established a program of selecting a limited number of files to proceed by way of a Notice to the Parties and the Profession dated June 11, 2020, entitled "Gradual phase-out of Suspension Period: COVID-19".

These are unprecedented times and I am satisfied that the Minister acted promptly in the circumstances.

[41] I find that there is merit in having the appeal set down in a timely manner. This appeal raises a serious issue and will be this Court's first opportunity to consider Canada's newly enacted CSP regime. Furthermore, I note in the appellant's reply submissions that the Agreement on the Contents of the Appeal Book was filed on August 5, 2020, and the parties have now agreed upon a timetable for the hearing of the appeal.

## III. Conclusion

[42] The appellant has provided no concrete evidence of any irreparable harm it would suffer if the Court denied the order for a stay of the Federal Court judgment. The evidence provided in support of their request for an order to stay the judgment has not met the tri-partite test outlined in *RJRMacDonald.*

[43] For these reasons, the motion for stay of the Judgment of the Federal Court issued on April 7, 2020 (2020 FC 397) is dismissed.

[44] The appellant's motion for an expedited hearing is granted, and the timetable for the hearing of the appeal shall be as set out in Schedule A to the appellant's reply submissions, save for the due date of the filing of the Agreement on Contents of the Appeal Book, which was filed on August 5, 2020.

[45] This motion is brought in the context of an appeal from a Federal Court judgment disposing of an application for judicial review of the Minister's decision under the *Patent Act*. As such, pursuant to section 131 of the *Patent Act*, I find that the Minister shall not be ordered to pay the costs of the respondent. The respondent's request for costs is denied.

"Marianne Rivoalen"

J.A.

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

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| **DOCKET:** | A-138-20 |
| **STYLE OF CAUSE:** | THE MINISTER OF HEALTH V. GLAXOSMITHKLINE BIOLOGICALS S.A.. |

**MOTION DEALT WITH IN WRITING WITHOUT APPREARANCE OF PARTIES**

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|---|---|
| **DATED:** | AUGUST 31, 2020 |

**APPEARANCES:**

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