Federal Court  Cour fédérale

Date: 20200930

Docket: T-984-20

Citation: 2020 FC 938

Montréal, Québec, September 30, 2020

PRESENT: The Honourable Madam Justice St-Louis

BETWEEN:

CATALYST PHARMACEUTICALS INC and KYE PHARMACEUTICALS INC

Applicants

and

THE ATTORNEY GENERAL OF CANADA and MÉDUNIK CANADA

Respondents

ORDER AND REASONS

I. Overview

[1] The applicants, Catalyst Pharmaceuticals Inc [Catalyst] and KYE Pharmaceuticals Inc [KYE], seek an interlocutory injunction to stay the decision of the Minister of Health [the Minister's Decision or the Decision], rendered on August 10, 2020 and granting Médunik Canada [Médunik] a Notice of Compliance [NOC] for its amifampridine product, Ruzurgi.

[2] In their motion, the applicants essentially ask the Court for an order (1) staying the operation and effect of the Minister's Decision and (2) staying the operation of the NOC issued to Médunik on August 10, 2020, in respect of its New Drug Submission [NDS] for its Ruzurgi product, the whole pending the disposition of the underlying application for judicial review [the Underlying Application] they commenced on August 26, 2020.

[3] In their Underlying Application, the applicants challenge the Minister's Decision as contrary to section 3(b) of section C.08.004.1 of the *Food and Drug Regulations*, CRC, c 870. They seek a number of reliefs, including (1) quashing the Minister's Decision and the NOC issued to Médunik; (2) prohibiting the Minister from issuing a NOC to Médunik in respect of its Ruzurgi product until after August 1, 2028 (eight years after the date of issuance of Catalyst's NOC for its amifampridine phosphate product, Firdapse); and (3) in the alternative, referring the matter back to the Minister for redetermination in accordance with section 3(b) of section C.08.004.1 of the *Food and Drug Regulations*.

[4] As the applicants have not satisfied the applicable tripartite conjunctive test for injunctive relief, this motion will be dismissed.

II. Background

[5] As per the applicants' record, Catalyst is a Florida-based biopharmaceutical company focused on investing in leading-edge science to develop and commercialise innovative therapies for those who suffer from rare and ultra-rare diseases. KYE is a small Canadian company founded and incorporated in July of 2019, committed to bringing value to Canadians by bringing

medicines that fulfill clinically significant unmet needs to the Canadian market. KYE's first product to be commercially launched is Firdapse, as a result of an agreement with Catalyst.

[6] Médunik is a manufacturer and supplier of pharmaceutical products based in Blainville, Québec.

[7] Amifampridine treats an ultra-rare and debilitating autoimmune disorder called Lambert-Eaton myasthenic syndrome (LEMS). Currently, there are about 200 Canadians who suffer from LEMS. Until approval of Firdapse, amifampridine was not commercially available in Canada. It was only available through Health Canada's Special Access Program (SAP), which provides access to certain drugs that cannot otherwise be sold or distributed in Canada. Drugs accessed via the SAP are supplied directly by manufacturers to practitioners prescribing the drug, usually physicians. Amifampridine was supplied through the SAP by Jacobus Pharmaceuticals Co, the New Jersey based pharmaceutical company that ultimately licensed Ruzurgi to Médunik.

[8] On August 15, 2019, Catalyst requested "Priority Review" status for its NDS pertaining to its amifampridine product, Firdapse, and on October 18, 2019, Health Canada granted Catalyst's request, thus shortening the Minister's review period from the typical 300 days to 180 days.

[9] On October 18, 2019, Catalyst submitted its NDS for its Firdapse product. In its filing, it sought data protection, asking the Minister to classify Firdapse as an "innovative drug" under the data protection provisions of section C.08.004.1 of the *Food and Drug Regulations* introduced in

2006. On November 19, 2019, the Minister advised Catalyst that Firdapse appeared to be an "innovative drug", eligible for data protection.

[10] In December 2019, Médunik filed a NDS for its amifampridine product, Ruzurgi, and in the spring of 2020, the applicants learned about Médunik's NDS. Also in the spring of 2020, KYE began to seriously consider a partnership with Catalyst. The applicants thus initiated and pursued negotiations, knowing Médunik had filed its NDS.

[11] On July 31, 2020, the Minister granted Catalyst a NOC for its amifampridine product, Firdapse. As the first approved amifampridine product in Canada, Firdapse was recognized as an "innovative drug" and was thus entitled to data protection under the provisions of section C.08.004.1 of the *Food and Drug Regulations*.

[12] Section 3 of section C.08.004.1 of the *Food and Drug Regulations* provides that :

> (3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,
>
> (a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and
>
> (b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.

[13] On August 10, 2020, the Minister issued a NOC to Médunik for its amifampridine product, Ruzurgi.

[14] On August 14, 2020, knowing that the NOC had been issued to Médunik a few days before (see Mr. Douglas Reynolds' affidavit at para 12 and Mr. Reynolds' transcript on cross-examination at pages 87-89, 103-107), Catalyst and KYE signed a License Agreement. The respondent, the Attorney General of Canada, obtained a redacted copy of the License Agreement, which formed part of a filing by Catalyst with the United States Securities and Exchange Commission, from Catalyst's website, and filed it with his record. The applicants have refused to provide a complete copy of the License Agreement and to answer questions relating to its content, namely as to whether the risk was factored into the price negotiated between them.

[15] KYE filed for an administrative NDS, and on September 25, 2020, the Court was informed that the Minister had issued a NOC to KYE (earlier than the October 12, 2020 date KYE had anticipated). KYE could therefore potentially bring its product to the Canadian market earlier than anticipated. However, given my reasons for denying this motion, it is not necessary for me to consider this point.

III. The Applicable Test on a Stay Motion

[16] In this motion, the Court is not tasked with deciding the merits of the Underlying Application, but with assessing whether or not the applicants meet the test allowing for the issuance of interlocutory injunctive relief staying the operation and effects of the Minister's Decision and the operation of the NOC issued to Médunik.

[17] Hence, in order to succeed in their motion for an interlocutory injunction, the applicants must establish that they satisfy each prong of the conjunctive three-part test set forth by the Supreme Court of Canada [SCC] in *RJR-Macdonald Inc v Canada (Attorney General)*, [1994] 1 SCR 311 [*RJR-Macdonald*]. Under that test, the applicants must establish that: (1) a serious issue has been raised in the Underlying Application; (2) they will suffer irreparable harm if the stay is not granted; and (3) the balance of convenience, which examines the harm to the applicants and to the respondents, as well as the public interest, favours them.

[18] The injunction is an exceptional relief (*Aventis Pharma SA v Novopharm Ltd*, 2005 FCA 390 at para 4). In *Mylan Pharmaceuticals ULC v AstraZeneca Inc*, 2011 FCA 312, the Federal Court of Appeal confirmed the exceptional nature of injunctive relief and indicated: "As the Supreme Court recognized in *RJR-Macdonald Inc*., this is an unusual relief that requires satisfaction of a demanding test" (at para 5). In *Janssen v AbbVie Corporation*, 2014 FCA 112 [*Janssen*], the Federal Court of Appeal confirmed that the test "is aimed at recognizing that the suspension of a legally binding and effective matter – be it a court judgment, legislation, or a subordinate body's statutory right to exercise its jurisdiction – is a most significant thing" (at para 20). The burden imposed on the applicants is therefore onerous.

[19] The decision to grant or deny an interlocutory injunction is a discretionary one (*R v Canadian Broadcasting Corp, 2018 SCC 5* at para 27). As an interlocutory injunction is an exceptional remedy, compelling circumstances are required to justify the intervention of the courts and the exercise of their discretion to grant the relief. The burden is on the moving party to demonstrate that the conditions of this exceptional remedy are met (*The Ahousaht First*

Nation, the Ehattesaht First Nation, the Hesquiaht First Nation, the Mowachaht/Muchalaht First Nation, and the Tla-o-qui-aht First Nation v Canada (Minister of Fisheries and Oceans and Canadian Cost Guard), 2019 FC 1116 [*Ahousaht First Nation*]).

[20] The applicants submit that they satisfy each prong of the test, while the respondents contend that the applicants satisfy none.

IV. Analysis

A. *The Serious Issue*

(1) The Parties' Positions

[21] On the serious issue component, the applicants appropriately present the low threshold and contend that the issues raised in the Underlying Application easily meet this threshold, as they are neither vexatious nor frivolous. The applicants contend that the Minister's Decision was incorrect, unreasonable and prohibited by the data protection regulations. They point to the fact that, at the time the Minister decided to approve and grant a NOC for Médunik's Ruzurgi product, Catalyst had already been granted its own NOC for its Firdapse product, which had been designated as an "Innovative Drug" under the data protection regulations. The applicants add that Médunik had directly compared Ruzurgi to Firdapse in seeking its NOC, which, under section 3(b) of the *Food and Drug Regulations*, prohibited the Minister from approving Médunik's submission and issuing the NOC to Médunik. The applicants thus question (1) whether the Minister has the discretion to purportedly ignore the data protection regulations and issue a NOC to Médunik for Ruzurgi when its NDS relied on data that was the subject of data

protection in respect of an innovative drug; and (2) the correctness and reasonableness of the Minister's interpretation and application of the data protection regulations. Finally, in response to Médunik's argument regarding standing, they submit that the case law cited by the respondents does not apply, as it does not deal with data protection. They rely on the Court's decision in *Hospira Healthcare Corporation v Canada (Minister of Health and Attorney General)*, 2014 FC 179.

[22] The Attorney General essentially responds that the applicants advance an interpretation that is unsupported by a plain reading of the provision, and that would lead to an absurd result. He argues that the applicants therefore fail to raise a serious issue as to the reasonableness of the Minister's Decision.

[23] Médunik submits that the motion raises no serious issue, even on this low threshold, as (1) the applicants are not directly affected and have no standing, as the holder of a NOC for a medicine does not have any right to raise non-compliance of the Minister with the *Food and Drugs Act* or the regulation adopted thereunder regarding the issuance or proposed issuance of a NOC to another drug manufacturer (citing, *inter alia*, *Merck Frost Canada Inc v Canada (Minister of Health and Welfare)*, (1998) 146 FTR 249 at paras 10 and 11); (2) the applicants have no statutory cause of action; and (3) deference is owed to the Minister on a reasonableness standard.

(2) The Court Will Assume that a Serious Issue Exists

[24] On the serious issue component, I agree with the parties on the low applicable threshold. However, given my conclusion on the two other components of the conjunctive tripartite test, I need not decide, and I will thus assume without deciding that a serious issue exists.

B. *Irreparable Harm*

(1) The Parties' Positions

[25] The applicants submit that they must adduce evidence at a convincing level of particularity that demonstrates, on a balance of probabilities, a real probability that unavoidable irreparable harm will result unless a stay is granted (*Canada (Health) v GSK*, 2020 FCA 135 at para 16; *Bombardier Recreational Products Inc v Artic Cat Inc*, 2020 FCJ No 798). The applicants stress that this does not amount to a "beyond a reasonable doubt" or "absolute certainty" standard, and contend that, particularly in the absence of any evidence to the contrary, they have easily met their burden.

[26] In response to the respondents' arguments that KYE's alleged harm was of its own making and that the alleged harm was avoidable (*Western Oilfield Equipment Rentals Ltd v M-1 LLC*, 2020 FCA 3 at paras 11-12; *Glooscap Heritage Society v Minister of National Revenue*, 2012 FCA 255 [*Glooscap*]), the applicants submit that the case law does not apply to their case and relates to a different type of conduct.

[27] The applicants contend that the harmful effects of having to compete with Ruzurgi in the next few weeks or months will be visited on them for years, even if the Underlying Application is successful.

[28] They also allege that the irreparable harm they will suffer until the adjudication of the Underlying Application lies in (1) unrecoverable loss of profits; and (2) irreversible price erosion.

[29] Regarding unrecoverable profits, the applicants essentially contend that the loss of exclusivity, even in the short term, will lead to lost market share, sales, revenues and profits, for the period that Firdapse is on the market as a competing drug to Ruzurgi, that they will not be able to recover. They particularly point to the fact that Médunik is now in a unique position of having instant access to the patients on the SAP and to their prescribing physicians. The applicants outline that these harms will be singularly acute for KYE, which is a new company in its pre-revenue stage and that the short-term losses will affect its projected revenues, ability to be cash-flow positive on its projected timeline, future valuation and current and future fundraising activities. They add that it will cause KYE to have to raise more capital than it would have if Firdapse had received the exclusivity it deserves due to its data protection as an innovative drug.

[30] Regarding price erosion, the applicants submit that having to compete with Ruzurgi in the next weeks or months will lead to price erosion for Firdapse that will persist in the long term. They add that, without exclusivity, Ruzurgi will likely enter the market on the same timeline as

Firdapse, driving down prices because of competition. They outline that once a lower price has been established, it will be difficult, if not impossible, to raise.

[31] The applicants adduced two affidavits sworn by Mr. Douglas Reynolds, Co-Founder and President of KYE, and the transcript of his cross-examination, and one affidavit sworn by Dr. Gary Ingenito, Chief Medical Officer and Head of Regulatory Affairs at Catalyst, and the transcript of his cross-examination.

[32] With his first affidavit, Mr. Reynolds introduced six (6) exhibits: (1) a letter from Health Canada to Catalyst dated November 19, 2020 indicating that "[a]t this time, Firdapse appears to be an 'innovative drug' and is therefore eligible for data protection;" (2) an extract from Health Canada's Register of Innovative Drugs dated August 13, 2020, listing Firdapse as an innovative drug and outlining the dates of data protection; (3) the pre-NDS meeting minutes for Firdapse dated May 7, 2019 outlining Health Canada's indication that "one carcinogenicity study would be the absolute minimum required;" (4) an approval letter from the US Food and Drug Administration to Jacobus Pharmaceuticals outlining the studies that must be conducted; (5) an extract from Health Canada's Drug Product Database dated September 8, 2020; and (6) Médunik's press release dated August 18, 2020 announcing that it had received market authorisation for Ruzurgi.

[33] With his second affidavit, Mr. Reynolds introduced two additional exhibits: (1) a September 8, 2020 email alert call for patient input from the Canadian Agency for Drugs and

Technologies in Health (CADTH); and (2) a CADTH website update indicating that the anticipated filing date for Ruzurgi is October 5, 2020.

[34] The applicants rely heavily on Mr. Reynolds' testimony, particularly on (1) paragraphs 13 and 14 of his first affidavit, where he outlines that patients currently receiving Ruzurgi under the SAP are expected to transition to the first approved amifampridine drug product, Firdapse; (2) paragraph 27, where he affirms that the licensing and supply agreement with Catalyst "contemplates a fairly equitable split of net sales between the two companies;"; and (3) paragraphs 37-52, where he outlines the allegations of lost profits and price erosion resulting from competition, and why these losses will not be recoverable.

[35] The applicants do not point to any documentary evidence on this prong of the test, and have not provided information relating to their License Agreement.

[36] With his affidavit, Dr. Gary Ingenito introduced 9 exhibits: (1) a listing of all clinical studies required to obtain regulatory approval in the US and Canada; (2) a listing of all non-clinical studies required to obtain regulatory approval in the US and Canada; (3) a letter dated December 19, 2018 sent on behalf of Catalyst to Health Canada; (4) pre-NDS meeting minutes for Firdapse dated May 7, 2019; (5) a letter from Health Canada to Catalyst dated September 13, 2019 assigning priority review status to Firdapse; (6) the NOC for Firdapse; (7) Médunik's press release dated August 18, 2020; (8) Postmarket Requirements and Commitments for Ruzurgi; and (9) Ruzurgi's Product Monograph.

[37] Dr. Ingenito's only reference to any harm to Catalyst appears at the last paragraph of his affidavit where he states:

> In addition, I understand that Douglas Reynolds has also provided an affidavit on behalf of KYE, setting out the harms that will ensue to KYE if the motion is not granted. I have read his affidavit. If this motion is not granted, given the partnership between Catalyst and KYE, I expect that the lost of profits and revenues caused by the loss of market exclusivity for Firdapse, as discussed by Mr. Reynolds, and the effects of the price erosion that he describes, will also cause harm to Catalyst as well.

[38] The Attorney General responds that the applicants have failed to provide a legitimate and supported claim of irreparable harm, as the only irreparable harm alleged is that of KYE. He adds that (1) KYE's alleged irreparable harm arises entirely from circumstances that KYE voluntarily accepted when it entered into the License Agreement with Catalyst. Having entered into the License Agreement with the understanding that the value of its business opportunity would be greater if it successfully brought the Underlying Application, and having assessed its chances of success, KYE now asserts that it cannot wait for the adjudication of the Underlying Application because it will suffer irreparable harm if it is not immediately permitted to operate as if it already had won. The Attorney General also argues that (2) the harm was avoidable and (3) in any event, KYE has failed to provide clear, non-speculative evidence of the alleged financial impacts of failing to issue a stay.

[39] Médunik responds that the applicants have not met the recognized test in this Court. It submits that (1) the applicants' affidavits are replete with suggestions of "possible" or "likely" harm rather than "actual" harm that will be suffered if a stay is not granted; (2) the applicants' witnesses admitted that they knew about certain potential of risks relating to data protection for

Firdapse, but still chose to move forward with the NDS and License Agreement; (3) the likelihood of irreparable harm arising between now and the disposition of the Underlying Application is undermined by the effective admissions - that Catalyst does not sell Firdapse in Canada, and does not intend to, and that KYE does not expect to sell Firdapse in Canada until late October at the earliest and does not know if it will be eligible for either private insurer reimbursement or listing on public drug benefit formularies; (4) KYE's witness admitted that the allegations of irreparable harm arising from potential generic drug submissions and physicians' cost-sensitivity are speculative; and (5) KYE's witness refused to tell Médunik whether the issuance of the Ruzurgi NOC will have any effect on the milestone payments under the License Agreement, while the Catalyst witness had no personal knowledge of the License Agreement.

(2) Irreparable Harm Has Not Been Established

[40] Under the second prong of the test, the question is whether the applicants have provided sufficiently clear, convincing and cogent evidence that, on a balance of probabilities, they will suffer irreparable harm between now and the time the Underlying Application is decided, should the stay be denied. The Court may find the applicants have not met their burden, whether or not the respondents have adduced contrary evidence.

[41] At para 63 of *RJR-Macdonald*, the SCC described the duties of the Court in assessing irreparable harm as follows: "At this stage the only issue to be decided is whether a refusal to grant relief could so adversely affect the applicants' own interests that the harm could not be remedied if the eventual decision on the merits does not accord with the result of the interlocutory application."

[42] As my colleague Justice Gascon outlined at paragraph 85 of the *Ahousaht First Nation* decision, the FCA has frequently insisted on the attributes and quality of the evidence needed to establish irreparable harm in the context of injunctive reliefs such as stays or interlocutory injunctions. The evidence must be more than a series of possibilities, speculations, or hypothetical or general assertions (*Gateway City Church v Canada (National Revenue)*, 2013 FCA 126 [*Gateway City Church*] at paras 15-16). Assumptions, hypotheticals and arguable assertions unsupported by evidence carry no weight (*Glooscap* at para 31). There needs to be "evidence at a convincing level of particularity that demonstrates a real probability that unavoidable irreparable harm will result unless a stay is granted" (*Gateway City Church* at para 16, citing *Glooscap* at para 31). It is not enough "to enumerate problems, call them serious, and then, when describing the harm that might result, to use broad, expressive terms that essentially just assert – not demonstrate to the Court's satisfaction – that the harm is irreparable" (*Stoney First Nation v Shotclose*, 2011 FCA 232 [*Stoney First Nation*] at para 48). In other words, to prove irreparable harm, the moving party must "demonstrate in a detailed and concrete way that it will suffer real, definite, unavoidable harm – not hypothetical and speculative harm – that cannot be repaired later" (*Canada (Attorney General) v Oshkosh Defense Canada Inc*, 2018 FCA 102 at para 25, which also cites Janssen at para 24).

[43] As indicated at the hearing, I also agree with my colleague's analysis and conclusion regarding the precedent of this Court citing *Vancouver Aquarium Marine Science Centre v Charbonneau*, 2017 BCCA 395 (*Ahousaht First Nation* at paras 87 and 88).

[44] In *Canada (Attorney General) v United States Steel Corp*, 2010 FCA 200, the Federal Court of Appeal stated: "The jurisprudence of this Court holds that the party seeking the stay must adduce clear and non-speculative evidence that irreparable harm will follow if the motion for a stay is denied. It is not sufficient to demonstrate that irreparable harm is "likely" to be suffered. The alleged irreparable harm may not be simply based on assertions" (at para 7, emphasis added).

[45] With regards to applicant Catalyst, the evidence that irreparable harm will occur rests on the information Dr. Ingenito conveys in the last paragraph of his affidavit, which can easily be qualified as a very general assertion, and which unequivocally fails to meet the test. This conclusion is not displaced by considering Mr. Reynolds' general affirmation that the agreement between the parties "contemplates a fairly equitable split of net sales between the two companies."

[46] Regarding applicant KYE, I agree with Médunik that the affidavit is replete with suggestions of "possible" or "likely" harm rather than actual harm that will be suffered if a stay is not granted. In addition, Mr. Reynolds relies on his own experience, and on what counsel described as common sense, to support his allegations of lost profits and market share and price erosion, and provides no documentary evidence to support these allegations.

[47] Therefore, on irreparable harm, I conclude that the applicants have not met their burden, as they have not submitted clear, convincing and non-speculative evidence that irreparable harm will occur if a stay is not granted. The evidence is simply insufficient to meet the stringent test

set by the Supreme Court of Canada and applied with the guidance of the Federal Court of Appeal.

[48] As mentioned earlier, given this conclusion on the insufficiency of the evidence, I need not address the other issues raised by the respondents.

C. *Balance of Convenience*

(1) The Parties' Positions

[49] Finally, on the last component of the test, the applicants submit that the balance of convenience favours them, as they will suffer the harm. Conversely, they argue that Médunik suffers no harm if the Court stays the effects of the Minister's Decision. They emphasize that they have provided an appropriate undertaking to compensate Médunik for any relevant damages should the applicants be unsuccessful in the Underlying Application. The applicants submit that this stands in contrast with the harm they will suffer if the stay is not granted, harm which they allege will be significant, permanent and unrecoverable.

[50] The Attorney General responds that the balance of convenience lies in his favour as (1) the harm to the applicants, if any, would arise from risks voluntarily assumed; (2) third parties would be irrevocably impacted by paying more; (3) a stay would unjustifiably interfere with the exercise of statutory power in the public interest; and (4) a stay would be inconsistent with the scheme of the data protection regulations.

[51] Médunik stresses the public interest considerations and the prudence of preserving the *status quo*. It submits that the balance of convenience strongly militates against granting a stay and in favour of preserving the *status quo*, when considering what would happen to patients if the Médunik NOC is stayed in contrast to what will happen to those patients if the stay is denied.

(2) Balance of Convenience Favours the Respondents

[52] Under the third component of the three-part test, the balance of convenience assessment, the Court must determine which of the parties will suffer the greatest harm from the granting or denial of the injunction pending the adjudication of the Underlying Application (*RJR-Macdonald* at para 67). Of particular relevance to these proceedings is the SCC's recognition that the role of public authorities in protecting the public interest is an important factor in assessing the balance of convenience.

[53] The SCC, again in *RJR-Macdonald* (at para 73), indicates: "When a private applicant alleges that the public interest is at risk that harm must be demonstrated." On the other hand, in the case of a public authority, the SCC teaches us that the onus of demonstrating irreparable harm to the public is less than that of a private applicant (*RJR-Macdonald* at para 76) and states: "[The test will] nearly always be satisfied simply upon proof that the authority is charged with the duty of promoting or protecting the public interest and upon some indication that the impugned legislation, regulation or activity was undertaken pursuant to that responsibility. Once these minimal requirements have been met, the court should in most cases assume that irreparable harm to the public interest would result from the restraint of that action" (*RJR-Macdonald* at para 76).

[54] The Court is satisfied that the Minister is indeed charged with the promotion of the public interest, as outlined by the Attorney General at paras 80 and 81 of his written representations, and that the Minister's Decision was made pursuant to that responsibility. Irreparable harm to the public interest has thus been established. It tilts the balance of convenience in favour of the Minister, especially in a context where, conversely, the applicants have not met their burden or demonstrated that they will suffer irreparable harm.

[55] The Court is also mindful of the fact that KYE entered into the License Agreement knowing that a NOC had been issued to Médunik (see paragraph 14), which further tilts the balance of convenience towards the respondents.

[56] On the issue of the *status quo*, the Court concludes that granting the relief sought by the applicants would upset the current state of affairs, and that prudence weighs in favour of declining to issue an interlocutory injunction.

[57] The applicants have not convinced the Court that the harm they expect to suffer in the absence of a stay outweighs the harm that will be caused to the public interest by a suspension of the Minister's Decision and the NOC issued to Médunik. In the circumstances of this case, the balance of convenience therefore does not favour granting the stay requested by the applicants.

V. Conclusion

[58] In conclusion, I will dismiss the applicants' motion, as I am not satisfied that they have met the three parts of the conjunctive test set forth by the SCC in *RJR-Macdonald*.

[59] Finally, the parties have confirmed having reached an agreement as to costs, and I will decide accordingly.

ORDER in T-984-20

THIS COURT'S ORDER that:

1. The applicants' motion is dismissed;

2. Costs are granted in favour of the respondents, as per the agreement of the parties.

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	**T-984-20**
STYLE OF CAUSE:	**CATALYST PHARMACEUTICALS INC and KYE PHARMACEUTICALS INC. and THE ATTORNEY GENERAL OF CANADA and MÉDUNIK CANADA**
PLACE OF HEARING:	**MONTRÉAL (QUEBEC) – BY VIDEOCONFERENCE**
DATE OF HEARING:	**SEPTEMBER 23, 2020**
ORDER AND REASONS:	**ST-LOUIS J.**
DATED:	**SEPTEMBER 30, 2020**

APPEARANCES:

Mr. Andrew Shaughnessy **Ms. Yael Bienenstock** **Ms. A. Peterson**	**FOR THE APPLICANTS**
Mr. Jason Markwell	**FOR THE RESPONDENT – MÉDUNIK CANADA**
Mr. John Lucki **M. Lovell** **Ms. Leah Bowes**	**FOR THE RESPONDENT - AGC**

SOLICITORS OF RECORD:

Torys LLP **Toronto (Ontario)**	**FOR THE APPLICANTS**
Fasken Martineau **Toronto (Ontario)**	**FOR THE RESPONDENT- MÉDUNIK CANADA**
Attorney General of Canada **Toronto (Ontario)**	**FOR THE RESPONDENT AGC**