Federal Court  Cour fédérale

Date: 20210426

Docket: T-2183-18

Citation: 2021 FC 367

Ottawa, Ontario, April 26, 2021

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

TEVA CANADA INNOVATION
AND
TEVA CANADA LIMITED

Plaintiffs

and

PHARMASCIENCE INC.

Defendant

and

YEDA RESEARCH AND DEVELOPMENT CO., LTD.

Patentee

and

COMMISSIONER OF PATENTS

and

ATTORNEY GENERAL OF CANADA

Third Parties to Motion

ORDER AND REASONS

I. Overview

[1] The Plaintiffs, Teva Canada Innovation and Teva Canada Limited [together, Teva], have brought a motion under s 50(1) of the *Federal Courts Act*, RSC 1985, c F-7, seeking a stay of the ongoing re-examination proceeding [the Re-examination Proceeding] related to Patent No. 2,760,802 [the 802 Patent] before the Re-examination Board of the Canadian Intellectual Property Office [the Board] until the conclusion of all appeals from the recent judgment in this Federal Court action. The Attorney General of Canada [the AG], on behalf of the Board, consents to the motion. The motion is opposed by the Defendant, Pharmascience Inc. [Pharmascience].

[2] As explained in more detail below, this motion is granted, because Teva has met the test for a stay of the Re-examination Proceeding. It has raised a serious issue in this action, and it has established irreparable harm though the risk that claims of the 802 Patent will be held invalid in a decision in the Re-examination Proceeding inconsistent with the recent judgment in this action. Considering the balance of convenience, this harm and the public interest in avoiding inconsistent decisions surrounding patent validity outweigh the more speculative costs that Pharmascience argues it and the public may suffer as an effect of the stay delaying market availability of its product.

II. **Background**

[3] The 802 Patent relates to a three times weekly injection of 40 mg glatiramer acetate used to treat multiple sclerosis. Teva is a licensee of the 802 Patent under the patentee, Yeda Research and Development Co., Ltd. [Yeda]. In the within Federal Court proceeding, Teva brought a patent infringement action pursuant to s 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the Regulations], against Pharmascience, a manufacturer of a glatiramer acetate product known as GLATECT, after Pharmascience served it with a notice of allegation under the Regulations. Teva sought, among other things, a declaration that dosing of GLATECT at 40 mg three times weekly would infringe claims 1-66 of the 802 Patent. Pharmascience denied infringement of the 802 Patent and argued that the patent is invalid due to obviousness and lack of utility or sound prediction of utility.

[4] On December 16, 2020, following the trial of this matter, Justice Kane issued a Confidential Judgment and Reasons [the Judgment], concluding that the 802 Patent is valid and that the asserted claims of the patent were not obvious and did not lack utility. Justice Kane also released a public version of the Judgment dated January 6, 2021. Pharamascience has filed an appeal of the Judgment.

[5] While the Federal Court action was underway, Pharmascience's counsel filed for re-examination of the 802 Patent by the Board pursuant to s 48.1(1) of the *Patent Act*, RSC 1985, c P-4. The re-examination request alleged that claims 1-66 of the 802 Patent were obvious in view of certain prior art that had not previously been examined by the Board.

[6] The Board has issued preliminary opinions that the claims in the 802 Patent were invalid due to obviousness. In response, Yeda (which is party to the Re-examination Proceeding) proposed new claims 67-78 and requested that the Board not issue a final decision until after the trial judgment in the Federal Court action was released. Yeda subsequently provided the Board with the public version of the Judgment. On February 22, 2021, the Board issued a further preliminary opinion, maintaining its preliminary view that the existing claims in the 802 Patent were invalid based on obviousness and also expressing the preliminary opinion that the proposed new claims are invalid due to obviousness and/or lack of utility. In response, Teva filed further submissions with the Board on March 22, 2021.

[7] In the meantime, on March 19, 2021, Teva also filed the present motion, seeking a stay of the Re-examination Proceeding until conclusion of all appeals from the Judgment. In the absence of a stay, s 48.3(3) of the *Patent Act* requires the Board to complete its re-examination and issue a decision within twelve months of commencement of the re-examination proceeding, in this case by May 29, 2021. Broadly speaking, Teva takes the position that a stay is necessary to prevent a finding of invalidity of claims of the 802 Patent, in a decision of the Board that is inconsistent with the result in the Federal Court action. As a purely procedural point, Teva also seeks to add the AG and the Commissioner of Patents [the Commissioner] as third parties to this motion, to ensure that they are bound by any resulting order.

[8] As previously noted, the AG, acting on behalf of the Board, has consented to Teva's motion and has made submissions in support of the motion. The AG also seeks the following additional relief:

A. If the stay is granted, that the events triggering the expiry of the stay include any discontinuance or settlement by the parties;

B. If the stay is granted, that the Court direct the Board, upon the stay being lifted, to consider whether the doctrine of issue estoppel, or a similar legal principle, applies to preclude the re-litigation of issues previously decided by this Court; and

C. Regardless of whether the stay is granted, that the Court provide timelines for the continuation or resumption, and ultimate completion, of the Board's re-examination proceeding. The AG requests that the Court extend the deadline by which the Board must render its decision in the Re-examination Proceeding, as follows:

    i. if the stay is not granted, to 12 weeks from the date of the order that the Board complete its re-examination; or

    ii. if the stay is granted, to 12 weeks from the date of expiry of the stay.

[9] As explained in more detail below, Pharmascience opposes the motion, arguing that Teva has failed to satisfy the test for a stay of proceedings prescribed by *RJR-MacDonald v Canada*, [1994] 1 SCR 311 [*RJR-MacDonald*]. In relation to the AG's position, Pharmascience submits that, as no motion has been brought on behalf of the Board to stay the Re-Examination Proceeding that it is statutorily mandated to conduct, the AG is not properly situated to take positions or make submissions regarding the substantive merits of Teva's motion. Pharmascience

also argues that the AG has not provided the Court with any authority in support of much of the additional relief it requests.

III. **Issues**

[10] The principal substantive issue in this motion is whether the Court should stay the Re-examination Proceeding until the conclusion of all appeals from the Judgment. Depending on the outcome of that issue, the Court must also consider whether certain additional relief sought by the AG is available and appropriate.

IV. **Analysis**

A. *Test for a Stay of the Re-Examination Proceeding*

[11] There appears to be agreement among the parties that the Court has the authority to entertain a motion to stay a re-examination proceeding under the *Patent Act* (see *Prenbec Equipment Inc v Timberblade Inc*, 2010 FC 23 [*Prenbec*]; *Camso Inc v Soucy International Inc*, 2016 FC 1116 [*Camso*]) and that the applicable test is the conjunctive test prescribed by *RJR-MacDonald* (at para 43):

A. Whether there is a serious question to be tried on the merits;

B. Whether the applicant for the stay would suffer irreparable harm if the stay is refused pending a decision on the merits; and

C. Whether the balance of convenience (an assessment as to which of the parties would suffer greater harm from the granting or refusal of the stay pending a decision on the merits) favours the applicant.

[12] Pharmascience also emphasizes, and I accept, that the relief sought in the present motion falls into the category of unusual relief that requires satisfaction of a demanding test and a persuasive evidentiary basis, as it asks the Court to forbid a statutorily created body from exercising powers granted by Parliament (see *Mylan Pharmaceuticals ULC v Astrazeneca Canada, Inc*, 2011 FCA 312 [*Mylan*] at para 5).

B. *Serious Question to be Tried*

[13] The guidance in *Mylan*, that *RJR-MacDonald* sets out a demanding test, relates principally to the second and third elements of the test. It is common ground among the parties that the first element of the test, demonstrating a serious question to be tried on the merits, requires only that the case on the merits be neither frivolous not vexatious (see *RJR-MacDonald* at para 49).

[14] To demonstrate a serious question, Teva points to the Judgment, which upheld the validity of the asserted claims of the 802 Patent. It argues that, although the Judgment is under appeal, the fact that Teva's position on validity prevailed at the trial level demonstrates that its positon is neither frivolous nor vexatious.

[15] Pharmascience takes issue with Teva's position. It argues that, because the Judgment has already been issued, the question (i.e., the validity of the 802 Patent) that Teva asserts to be serious has already been answered. Pharmascience takes the position that the purpose of a stay of a proceeding is to allow a serious question to be answered in another proceeding, so that the answer may determine, benefit or influence the first proceeding. It submits that, because the question has already been answered, there is no outstanding serious question capable of supporting Teva's request for a stay.

[16] I accept that the scenario identified by Pharmascience does represent one set of circumstances where a stay may be available. However, I do not agree that the purpose of a stay is as limited as Pharmascience suggests, or that such purpose necessarily informs the nature of the requirement to demonstrate a serious issue. Rather, the requirement to demonstrate a serious question exists so that a stay is not granted in the face of a laughably weak or hopeless case (see *Janssen Inc v AbbVie Corporation*, 2014 FCA 112 at para 23). In my view, the fact that the question has already been answered in the Judgment, and that such answer favours Teva, clearly supports the conclusion that its request for a stay is in support of a position on the merits that is neither frivolous nor vexatious.

[17] Even if I were to accept Pharmascience's position that a request for a stay of a proceeding must be for the purpose of obtaining an answer in a second proceeding so as to influence the first proceeding, the present circumstances satisfy that purpose. While the question of the validity of the 802 Patent has been answered by Justice Kane in the Judgment, Teva seeks a stay of the Re-

Examination Proceeding until it is known whether that answer will be upheld in the appeal of the Judgment.

[18] As will be addressed in more detail later in these Reasons, Teva argues that it requires an appellate decision in order to be able to invoke issue estoppel, *res judicata*, or like principles, in the Re-Examination Proceeding, in order to avoid a circumstance where the Board arrives at a decision that is inconsistent with the outcome of the Federal Court action. The present case therefore represents a scenario where a stay of the Re-Examination Proceeding is sought precisely for the purpose of determining the outcome of the Federal Court litigation so that it may influence the Re-Examination Proceeding.

[19] I therefore have no difficulty concluding that Teva's motion satisfies the first element of the *RJR-MacDonald* test.

C. *Irreparable Harm*

[20] Teva's principal argument on irreparable harm is that it faces risk that the 802 Patent will be invalidated by the Board in the Re-examination Proceeding, a result that is both harmful to its interests and inconsistent with the Judgment in its favour.

[21] In support of its arguments on irreparable harm, Teva relies substantially on the decisions in *Camso* and *Prenbec*, in which this Court granted stays of patent re-examination proceedings before the Board pending final judgment in Federal Court litigation surrounding the same patent. In *Prenbec*, Justice de Montigny held that the plaintiffs would suffer irreparable harm from the

continuation of the re-examination proceedings, as the Board would most likely ultimately invalidate the patent at issue (at para 42). In *Camso,* Justice Roy arrived at a similar conclusion (at para 40):

> 40. Conversely, the harm to Camso is irreparable. It would risk seeing the claims of its patent cancelled on the basis of a process where the evidence submitted can only be inferior to that in the previously initiated infringement proceeding when the request for re-examination was filed. Camso insisted at the hearing that things could be different if an infringement action had been initiated after a request for re-examination had been filed, as was the case for the 294 patent. The counsel did not elaborate on the difference that could make. What is certain is that parallel or consecutive proceedings must be avoided. That is what Justice Binnie stated on the Court's behalf in *Danyluk*:
>
> > 18 The law rightly seeks a finality to litigation. To advance that objective, it requires litigants to put their best foot forward to establish the truth of their allegations when first called upon to do so. A litigant, to use the vernacular, is only entitled to one bite at the cherry. The appellant chose the ESA as her forum. She lost. An issue, once decided, should not generally be re-litigated to the benefit of the losing party and the harassment of the winner. A person should only be vexed once in the same cause. Duplicative litigation, potential inconsistent results, undue costs, and inconclusive proceedings are to be avoided.

[22] I pause to note that it appears undisputed that the Re-examination Proceeding and the Federal Court litigation in this matter are, at least in part, duplicative. Teva submits that the issues on which the Board has expressed its preliminary opinions in the Re-examination Proceeding, i.e. whether the claims of the 802 Patent were obvious in view of the prior art at the claim date or lacked utility at the filing date, are the same issues that were resolved by Justice Kane in the Judgment, pending of course the outcome of the appeal therefrom. Teva explains that, of the 13 pieces of prior art reviewed by the Board in arriving at its preliminary opinions, all

but one were considered by Justice Kane. Teva also explains that this one other piece of prior art discloses much of the same information as a piece of art that was before Justice Kane (a point noted by the Board in one of its preliminary opinions).

[23] Teva therefore argues that the Re-Examination Proceeding is considering the same issue, the same patent, and substantially the same prior art as the Federal Court litigation, such that the two proceedings are duplicative and the re-examination should not proceed while the litigation remains underway.

[24] I do not understand Pharmascience to be taking issue with the assertion that the proceedings are duplicative. Rather, it argues that such duplication does not give rise to irreparable harm, or indeed any harm, to Teva on the facts of this case. I will address those arguments shortly. However, for present purposes, I accept that the proceedings are largely duplicative. I say "largely", because Yeda has proposed new claims in the course of the Re-Examination Proceeding. While these new claims may give rise to issues to be resolved by the Board that are not addressed in the Federal Court litigation, this possibility does not detract from the conclusion that Teva faces risk that claims of the 802 Patent will be invalidated by the Board, in a result inconsistent with the result of the Federal Court litigation.

[25] This conclusion supports Teva's reliance on the reasoning in *Camso* and *Prenbec* for its argument that it would suffer irreparable harm if the requested stay is not granted. However, Pharmascience raises a number of arguments in an effort to distinguish those authorities, to which I now turn.

[26] Pharmascience notes that the Court cannot, and indeed is not being asked to, terminate the Re-Examination Proceeding. Rather, regardless of whether a stay is granted, the Board will in due course be required to complete the statutory re-examination process. Therefore, the question the Court must consider is whether Teva would suffer irreparable harm if the Board makes its decision before the appeal of the Judgment is decided, rather than afterwards.

[27] First, Pharmascience argues that any such harm is speculative. It submits that Teva is speculating that the Board will be unmoved by its submissions following the Board's most recent preliminary opinion and will therefore cancel the existing claims of the 802 Patent. Taking into account the fact the AG is now before the Court, raising concern about conflicting decisions related to the 802 Patent and supporting Teva's request for a stay, Pharmascience argues that it is speculative to assert that the Board is likely to invalidate the patent. Pharmascience would accordingly distinguish this case from the analysis in *Prenbec*, where the Court concluded the Board would most likely invalidate the patent in issue.

[28] As Pharmascience correctly asserts, harm that is speculative, hypothetical, or arguable at best does not qualify as irreparable harm (see *Laperriere v D & A MacLeod Company Ltd*, 2010 FCA 84 [*Laperriere*] at para 17). Rather, there must be persuasive, detailed and concrete evidence of irreparable harm (see *Mylan* at para 5). Of course, Teva cannot establish with certainty what the outcome of the Re-Examination Proceeding will be if the stay is not granted. However, the weight of the evidence favours a conclusion that invalidation of the 802 Patent is a likely result. Certainly, the Board's preliminary opinions support that conclusion. Indeed, I read the most recent Board opinion as indicating an intention to reach a decision based on the

evidence and jurisprudence before it, without considering the outcome of separate proceedings related to the 802 Patent.

[29] I acknowledge that Yeda's most recent submissions to the Board take issue with this preliminary opinion and argue that the Board should defer to the determinations by the Federal Court in the Judgment. However, it would be speculative to conclude that this submission will cause the Board to depart from its preliminary opinion on this point. I also do not interpret the position taken by the AG in this motion to support a conclusion that such departure is likely. While the AG, on behalf of the Board, supports Teva's request for a stay, it emphasized at the hearing of the stay motion that the Board adjudicates matters based on the record before it, not by incorporating findings of fact by another decision-maker.

[30] Moreover, the AG asks that the Court consider including in its decision on this motion ancillary relief in the form of a direction to the Board that, upon the requested stay being lifted, it should consider whether the doctrine of issue estoppel, or similar legal principle, applies to preclude the re-litigation of issues previously decided by the Court. I will consider later in these Reasons whether such ancillary relief is appropriate. In the meantime, I note that I interpret the AG's request as suggesting a possibility the Board may entertain arguments surrounding issue estoppel, once the appeal from the Judgment has been decided such that there is a final decision in this action. However, I do not interpret the AG's submission as suggesting a likelihood that the findings in the Judgment will influence the Board in the absence of a final appellate decision that would invoke the application of issue estoppel.

[31] I should also note that I have considered Pharmascience's position that, in the absence of a motion on behalf of the Board to stay the Re-Examination Proceeding that it is statutorily mandated to conduct, the AG is not properly situated to take positions or make submissions regarding the substantive merits of Teva's motion. However, I am persuaded by the submissions on this point advanced by Teva's counsel at the hearing of the motion. If the stay is not granted, such that the re-examination now proceeds and generates a decision inconsistent with the Judgment, and Yeda appeals that decision as permitted under s 48.5(1) of the *Patent Act*, it will fall to the AG to respond to that appeal on behalf of the Board. It is therefore not untoward for the AG to appear on the present motion and support Teva's position from a process perspective, in the interests of potentially pre-empting the issuance of inconsistent decisions.

[32] Returning to Pharmascience's argument that it is speculative to assert that the Board will invalidate the 802 Patent, it is also my view that the mere fact of subjecting Teva to duplicative litigation on the same issue, with the associated risk of inconsistent decisions, is itself a non-speculative form of irreparable harm. As noted earlier in these Reasons, Justice Roy's analysis of irreparable harm in *Camso* explained that an issue, once decided, should not generally be re-litigated to the benefit of the losing party and the harassment of the winner. Duplicative litigation and potential inconsistent results are to be avoided (at para 40).

[33] Pharmascience also seeks to distinguish the authorities on which Teva relies, as turning significantly on the inferiority of the evidentiary record before the Board in those cases. I agree that the reasoning in *Camso*, that irreparable harm results from the risk of patent claims being cancelled through a re-examination proceeding notwithstanding the existence of an infringement

action, turns in part on the Justice Roy's characterization of the re-examination proceeding as a process in which the evidentiary basis is "inferior" to that in the action. For instance, the Board does not have the benefit of expert testimony (see *Camso* at para 33). To similar effect, *Prenbec Equipment Inc v Timberblade Inc*, 2009 FC 584 notes that no cross-examination of witnesses or indeed any hearing of oral testimony is contemplated in the re-examination process (at para 17).

[34] Pharmascience argues that, unlike in *Camso* and *Prenbec*, Teva is not in a position to complain about the evidentiary record before the Board in the present case, because it had the opportunity (through Yeda) to provide the Board with the trial record from this action. Indeed, Pharmascience submits that Yeda has self-selected those components of the record that it considered favourable to its position and has omitted others. Pharmascience further argues that *Prenbec* in particular is distinguishable, as the reasoning in that case turned on the significance of credibility findings surrounding the prior art, which the Board was not well equipped to make. It submits that there is no evidence that the present matter requires significant credibility findings.

[35] I agree that the prominent role of credibility is a feature of the *Prenbec* reasoning that does not appear to be present in the case at hand. However, in my view this distinguishing feature does not undermine the general application of the reasoning in both *Prenbec* and *Camso* to the present matter. It remains the case that Federal Court litigation generates a more comprehensive evidentiary record than does a re-examination proceeding. As described in *Genencor International Inc v Canada*, 2008 FC 608, the re-examination process is a relatively summary and inexpensive alternative to a full-blown litigation process (at para 4). The extent to

which the full panoply of fact-finding tools afforded to the Court by the litigation process is significant to the outcome of a dispute will of course vary from case to case. However, in a circumstances where it is necessary to consider whether to grant a stay of one of the two processes to avoid inconsistent results, preference should be given to the more comprehensive of the two (see *Prenbec* at para 48).

[36] Moreover, in my view the fact that the Federal Court litigation has already produced a result, albeit still subject to the outcome of the appeal, militates in favour of the Re-examination Proceeding giving way to the litigation. This is because, with a first instance result delivered in one of the two processes, it is only the other process that can be stayed, pending final appellate review in the first process, in the interests of potentially avoiding inconsistent results. I note that Pharmascience argues the contrary position, i.e. that the fact the Judgment has already been issued and provided to the Board distinguishes this matter from *Prenbec* and *Camso* and therefore favours denying the stay. It submits that the purpose of the stays granted in those cases was to allow the Board to have the benefit of the Court's decision when making its re-examination decision. Pharmascience argues that, because the Judgment is already available to the Board, no stay is necessary. However, in my view, it is the availability of the <u>final</u> decision in the litigation (following conclusion of appeals) before the re-examination process concludes that potentially serves to mitigate the risks of inconsistent results.

[37] Neither *Prenbec* nor *Camso* expressly states that the stay of the Board's proceeding in those cases applies until conclusion of all appeals in the related Federal Court litigation. Teva's counsel submits that this is how the judgments in those decisions should be interpreted. In

Prenbec, the judgment orders that the re-examination proceeding "…be stayed until the final judgment of this Court in the present action …". Similarly, in *Camso*, the judgment orders that the re-examination "…be stayed until final judgment is rendered regarding the action launched in this Court under docket number T-2338-14 …". It may be that Teva is correct, that the reference to final judgment in those matters means judgment following conclusion of available appeals. Regardless, taking into account the particular arguments advanced by the parties in the case at hand, I am satisfied that it is issuance of a decision by the Board prior to the appellate decision in the litigation that gives rise to the irreparable harm.

[38] I arrive at this conclusion in part because, to the extent the result in the litigation has any potential to influence the Board's decision, the Board faces a "moving target" until the final appellate decision in the litigation is available. However, I am also taking into account Teva's submission that the availability of the appellate decision, representing a final decision in the Federal Court litigation, will equip it to argue before the Board that issue estoppel, *res judicata*, or like principles should preclude the Board ruling on patent validity issues that have already been determined in the litigation. The AG emphasizes that in order for issue estoppel to apply, the prior judicial decision that creates the estoppel must be final (see, e.g., *Danyluk v Ainsworth Technologies Inc*, 2001 SCC 44 at para 25).

[39] It appears that this particular argument was not advanced, at least not in any express detail, in either *Prenbec* or *Camso*. Indeed, at the hearing of this motion, Pharmascience's counsel took issue with Teva's counsel relying on this argument, as it was not set out in Teva's written submissions in support of its position on irreparable harm. I agree with Pharmascience

that issue estoppel is not referenced in the written representations in Teva's motion record. However, I do not consider this to have resulted in any unfairness to Pharmascience, as the potential relevance of issue estoppel or like principles to the resolution of the concern about duplicative proceedings in this matter was clearly raised by the other parties' written submissions.

[40] As previously noted, the AG asks that the Court consider including in its decision on this motion ancillary relief in the form of a direction to the Board that, upon the requested stay being lifted, it should consider whether the doctrine of issue estoppel, or similar legal principle, applies to preclude the re-litigation of issues previously decided by the Court. This request was included in the AG's written submissions filed in advance of the hearing. Those written submissions also argued that, upon the conclusion of the appeal from the Judgment, the preconditions to the operation of issue estoppel will likely be met.

[41] In its own written submissions, Pharmascience responded to the AG's representations about issue estoppel. Pharmascience questioned whether issue estoppel would apply and made substantive submissions in support of that position. Pharmascience also argued that the AG had provided no authority for its position that the Court should direct the Board to consider issue estoppel and that, in any event, the AG's request was redundant, because Yeda had asked the Board to consider the application of issue estoppel and like principles before it issues its final decision.

[42] Pharmascience also made substantive submissions, at the hearing of this motion, on the potential application of issue estoppel in this matter. It argues that the other parties have provided no authority for the application of issue estoppel. However, it also submits that, if the Board declines to be influenced by the Judgment, the ability to appeal the Board's decision to the Federal Court represents an avenue to determine whether or not the Board should have applied the principle of issue estoppel.

[43] I am therefore of the view that the question of the relevance of issue estoppel, or like principles, to Teva's request for a stay was squarely raised in advance of the hearing, including by Pharmascience itself, and the question was capably argued by all parties at the hearing. As will be explained in more detail later in these Reasons, I decline to accept the AG's invitation to direct the Board to consider these principles in making its decision. I also will not make any finding on the potential application of such principles to the present facts. However, Yeda has raised this issue for the Board's consideration. I find compelling Teva's argument that it will suffer irreparable harm, resulting from the risk and indeed the likelihood of a finding of invalidity of the 802 Patent in a decision by the Board inconsistent with the result on the Federal Court litigation, if Yeda does not have the benefit of a final decision in that litigation when the Board is considering the issue estoppel argument.

[44] Pharmascience also argues that the availability of an appeal from the Board's decision will prevent Teva from suffering any harm if a stay is not granted and that, even if harm was suffered, the appeal would serve to repair such harm. Pharmascience notes that, if Yeda is dissatisfied with the Board's decision and launches a timely appeal, s 48.4(4) serves to stay the

effect of that decision until the outcome of the appeal. Pharmascience also takes issue with an argument by Teva that such an appeal would be subject to the reasonableness standard of review and that such deference detracts from the effectiveness of the appeal right as a remedy for the risk of inconsistent decisions.

[45] With respect to the standard of review, I agree with Pharmascience that Teva's argument is based on the jurisprudential position pre-dating the decision by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65, which explained that, where the legislature has provided for a statutory appeal from an administrative decision to a court, the typical appellate standard prescribed by *Housen v Nikolaisen*, 2002 SCC 33 [*Housen*] (as opposed to the more deferential reasonableness standard) will apply (at para 37).

[46] However, in my view, the availability of Yeda's s 48.4(4) appeal right, even on the less deferential standard, does not serve to eliminate the harm to its licensee, Teva. It is of course possible that, depending on the details of the Board's decision, an appeal could serve to eliminate any inconsistency between the results of the Re-examination Proceeding and the final outcome of the Federal Court litigation. However, an appeal, even on the *Housen* standard, is not a hearing *de novo* and therefore does not necessarily represent a means of remedying inconsistencies resulting from the duplicative litigation.

[47] In conclusion, having considered the parties' respective arguments on the element of irreparable harm, I am satisfied that Teva has satisfied this element of the *RJR-MacDonald* test.

D. *Balance of Convenience*

[48] The third element of the test, assessment of the balance of convenience, requires Teva to demonstrate that it would suffer greater harm if the stay is refused than Pharmascience, and potentially others, would suffer if the stay is granted. As Pharmascience submits, at this stage of the inquiry, the public interest must be factored into the balancing exercise (see *Laperriere* at para 25).

[49] Pharmascience submits that if the stay is granted, this will delay the final determination of the Re-Examination Proceeding (following any appeal by Yeda) by at least several months. In the event that such final determination invalidates the 802 Patent, Pharmascience will then receive a notice of compliance under the Regulations for its 40mg GLATECT product, and it will be able to commence marketing that product. However, the commencement of that marketing will have been delayed by the duration of the stay. Pharmascience submits that it will therefore suffer lost revenue and multiple sclerosis patients (and provincial payors) will for a period be denied the cost savings represented by its product compared to that of Teva.

[50] In support of this argument, Pharmascience relies on an expert report from the trial before Justice Kane, which explains that, upon issuance of a notice of compliance for its product, Pharmascience would seek and obtain listing on all provincial drug plans by offering a cost saving compared to Teva's product. I do not understand Teva to be contesting this evidence.

[51] I accept that, depending on how the Re-examination Proceeding (including any appeal of the Board's decision) and the appeal of the Judgment play out, one possible result is that the 802 Patent will be invalidated, Pharmascience will receive its notice of compliance, and the marketing of its product will have been delayed by the issuance of the requested stay. In that scenario, Pharmascience will incur loss of income, and members of the public will be financially disadvantaged by the delay in the availability of the less expensive product. However, this is only one possible result. It is also possible that, consistent with the Judgment, the validity of the 802 Patent will be upheld. I express no opinion on the likelihood of either of these possible results, other than to say that there is clearly a significant element of speculation to the harm to it and the public on which Pharmascience relies.

[52] In contrast, as explained in my analysis of the irreparable harm element, the harm to Teva if the stay is refused is not speculative. Again, whether Teva and Yeda will ultimately prevail in upholding the validity of the 802 Patent is unknown. However, in the absence of the requested stay, the harm represented by the fact of duplicative proceedings and the resulting potential for inconsistent results is, at least in part, independent of which party prevails. Indeed, I consider the prevention of such inconsistent results itself to be in the public interest. As explained in *Camso*, duplicative proceedings must be avoided (at para 40).

[53] I therefore conclude that the balance of convenience favours granting the stay. As Teva has satisfied all three elements of the applicable test, my Order will grant Teva's motion and stay the Re-Examination Proceeding. As to the precise duration of the stay, and any ancillary terms

that should be included in the Order, I now turn to consideration of the requests for ancillary relief.

E. *Requests for Ancillary Relief*

[54] As an initial point, Teva seeks to add the AG and the Commissioner as third parties to this motion, to ensure that they are bound by the Order. This approach was adopted in both *Prenbec* and *Camso*, and I do not understand either Pharmascience or the AG to oppose it. I consider the requested addition to be appropriate, and my Order will therefore so provide.

[55] The AG's requests for ancillary relief differ depending on whether the stay is granted or refused. As I have made the decision to grant Teva's motion, I need to consider only the relief sought ancillary to the granting of the stay.

[56] While Teva's Notice of Motion seeks an order staying the Re-Examination Proceeding until conclusion of all appeals from the Judgment, the AG proposes an additional nuance, that the expire of the stay also be triggered by any discontinuance or settlement between the parties. Teva agrees with this proposal, and Pharmascience takes no position thereon. I consider this addition to be appropriate.

[57] As previously noted in these Reasons, the AG also requests that, if the stay is granted, the Court direct the Board, upon the stay being lifted, to consider whether the doctrine of issue estoppel, or similar legal principle, applies to preclude the re-litigation of issues previously decided by this Court. Teva supports this request, and Pharmascience opposes it, arguing that the

AG has identified no authority or precedent for the Court to presently give directions to the Board as to what it should or should not be considering in completing its statutory role.

[58] Pharmascience also submits that the question of the application of issue estoppel is already before the Board, as Yeda raised it in its most recent submissions. I agree with Pharmascience's position on this point. It may be that a time will come, on appeal from the Board's eventual decision, when the Court will be called upon to consider the question of the application of issue estoppel to the circumstances before the Board. However, as a matter of basic administrative law, the Court should not weigh into that question until it has a mandate to do so, with the benefit of whatever reasoning and conclusion on that question may be included in the Board's decision.

[59] Finally, the AG asks that the Order provide a time frame, following the expiry of the stay, within which the Board must completed the Re-Examination Proceeding and issue its decision. The AG proposes 12 weeks from expiry of the stay, and Teva supports this request. Pharmascience does not dispute that some time period following the expiry of the stay is required for the Board to complete its work, but it proposes that this period be set at a duration equivalent to the time remaining between the date of issuance of the stay and the Board's current deadline of May 29, 2021.

[60] Neither the AG nor Teva has provided any particular evidence or argument in support of the proposed 12 week time period. This is a longer duration than the period that was remaining to

the May 29, 2021 deadline when Teva filed its stay motion on March 19, 2021. I see little basis to adopt an arbitrary 12 week time period.

[61] On the other hand, I am conscious that the time remaining between the issuance of the Order granting the stay and the previous May 29, 2021, deadline is in part a function of the time it has taken the Court to rule on the motion, and I am reluctant to see the Board pressed for time as a result of the Court's timing. I therefore consider it rational to select roughly the time between Teva's filing of the stay motion on March 19, 2021 and the previous May 29, 2021 deadline (i.e. roughly 10 weeks) as the period to be afforded the Board following the expiry of the stay. My Order will so provide.

V. **Costs**

[62] Each of Teva and Pharmascience seeks costs of this motion against the other, payable forthwith. At the hearing, Teva proposed costs in the lump sum amount of $5,000.00, and Pharmascience agreed that this was an appropriate figure, payable to whichever party was successful. The AG takes the position only that no costs should be awarded against it. I do not understand either of the other parties to be seeking costs against the AG.

[63] I consider the proposed figure of $5,000.00 appropriate and will therefore award costs in that amount to the successful party, Teva, payable by Pharmascience forthwith.

ORDER IN T-2183-18

THIS COURT ORDERS that:

1. The Commissioner of Patents and the Attorney General of Canada are added as third parties to this motion.

2. The re-examination of Patent No. 2,760,802 before the Re-examination Board (file no. RX-131/19) is stayed until final judgment is rendered, discontinuance filed, or settlement achieved, in Court file number T-2183-18 including any appeals.

3. The Re-Examination Board shall complete the re-examination of Patent No. 2,760,802 within 10 weeks of expiry of the stay.

4. Lump-sum costs in the amount of $5,000.00, inclusive of taxes and disbursements, are awarded to the Plaintiffs against the Defendant, to be paid forthwith.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2183-18
STYLE OF CAUSE:	TEVA CANADA INNOVATION AND TEVA CANADA LIMITED and PHARMASCIENCE INC. and YEDA RESEARCH AND DEVELOPMENT CO., LTD. and COMMISSIONER OF PATENTS and ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	HEARD BY VIDEOCONFERENCE VIA TORONTO
ORDER AND REASONS:	SOUTHCOTT, J.
DATED:	APRIL 26, 2021

APPEARANCES:

Bryan Norris Lesley Caswell Jessica Sudbury	FOR THE PLAINTIFFS
Harry Rodomski Jordan Scopa Jaclyn Tilak	FOR THE DEFENDANT
Bryan Norris Lesley Caswell Jessica Sudbury	FOR THE PATENTEE
Lynn Marchildon	FOR THE THIRD PARTIES TO MOTION

SOLICITORS OF RECORD:

Aitken Klee LLP Ottawa, Ontario	FOR THE PLAINTIFFS
Goodmans LLP Toronto, Ontario	FOR THE DEFENDANT
Aitken Klee LLP Ottawa, Ontario	FOR THE PATENTEE
Attorney General of Canada Toronto, Ontario	FOR THE THIRD PARTIES TO MOTION