Federal Court  Cour fédérale

Date: 20131023

Docket: T-1194-12

Citation: 2013 FC 1066

Toronto, Ontario, October 23, 2013

PRESENT: The Honourable Mr. Justice Campbell

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

PFIZER CANADA INC. AND PFIZER INC.

Defendants

REASONS FOR ORDER AND ORDER

[1] In the present action pursuant to s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *Regulations*) the Plaintiff (Teva) argues that the Defendants (Pfizer) are liable for damages by keeping its drug RATIO-AMLODIPINE off the market between 2006 and 2009.

[2] By a decision dated April 5, 2013, Madam Prothonotary Milczynski denied Pfizer's motion to strike out Teva's Statement of Claim and dismiss the action. Presently under consideration is Pfizer's appeal of the Prothonotary's decision on an argument with respect to each feature of the two-part standard of review stated in paragraph 19 of the decision in *Merck & Co v Apotex Inc*, 2003 FCA 488 (*Merck*):

> Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless:
> a) the questions raised in the motion are vital to the final issue of the case, or
> b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

For ease of reference, the Prothonotary's decision is attached as ADDENDUM I to these reasons.

[3] With respect to the first part of the standard of review, Pfizer argues that each question addressed by the Prothonotary in dismissing the motion to strike must be considered *de novo* on the present appeal because each is vital to the final resolution of the present action. Pfizer's argument is grounded on the statement in paragraph 18 of *Merck* that "a decision which can thus be either interlocutory or final depending on how it is decided, even if interlocutory because of the result, must nevertheless be considered vital to the final resolution of the case". Pfizer also argues "to the extent that recent cases have come to a different view, they are based on an incorrect reading of the Federal Court of Appeal's reasons in *Merck"* (Pfizer's Written Representations, para. 53).

[4] The recent cases referred to by Pfizer have held that the issues under consideration by a Prothonotary leading to a dismissal of a motion to strike are not subject to being considered *de novo*

on appeal. An example of this line of authority is Justice Boivin's decision in *Seanautic Marine Inc (c.o.b. Union Africa Line) v Jofor*, 2012 FC 328 at paragraph 20:

> […] The Court recognizes that recent jurisprudence has held that an appeal from the dismissal of a motion to strike does not raise a question that is vital to the final issue of the case (see Ridgeview Restaurant Ltd. v Canada (Attorney General), 2010 FC 506 at para
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> 24, [2010] FCJ No 613; Chrysler Canada Inc. v Canada, 2008 FC 1049 at para 4, [2009] 1 CTC 145; Apotex Inc. v AstraZeneca Canada Inc., 2009 FC 120 at para 25, [2009] FCJ No 179; AYC Pharmacy Ltd. v Canada (Minister of Health), 2009 FC 554 at para 9, 95 Admin LR (4th) 265; and Horseman v Horse Lake First Nation, 2009 FC 368 at para 2, [2009] FCJ No 476; Lundbeck Canada Inc. v Canada (Minister of Health), 2008 FCA 265 at para 14, [2008] FCJ No 1275; and Peter G. White Management Ltd. v Canada, 2007 FC 686 at para 2, [2007] FCJ No 931). Therefore, the Court concludes that, given the context and nature of the questions raised in the appeal and in light of the case law above, this matter does not raise a question that is vital to the final issue of the case and thus should not be reviewed de novo.
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> [Emphasis added]

[5] Pfizer's "vitality" argument is based on a careful analysis of Justice Décary's decision in *Merck* and its application by Justice Simpson in *Sanofi-Aventis Canada Inc v Teva Canada Ltd*, [2010 FC 1210] (*Sanofi*). Pfizer's argument requires a back to basics review. The critical passages from *Merck* in this review are paragraphs 17 to 28 of the decision as quoted in ADDENDUM II to these reasons.

[6] In the decision in *Sanofi*, after reviewing the decision in *Merck*, and, in particular Justice MacGuigan's statements in *Aqua-Gem*, Justice Simpson provides the following conclusion at paragraphs 31 and 32:

> Merck 2003 was a case in which Apotex sought to make fundamental amendments to its Statement of Defence. The motions judge who reviewed the Prothonotary's decision to allow the

> amendment declined to treat the proposed amendments as vital and did not conduct a de novo review. He upheld the Prothonotary's decision to allow the Apotex amendments.
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> The Court of Appeal found that the proposed amendments were vital and conducted its own de novo review. In the end, it declined to permit the amendments. The importance of this decision for present purposed [sic] is that the restatement and the Court's subsequent
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> analysis makes it clear that, as Sanofi submits, it is the question before the Prothonotary that is the focus of the "vitality" analysis.
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> [Emphasis added]

[7] In my opinion, two principles are communicated by the decision in *Merck*. First, a Judge sitting on an appeal from a Prothonotary's order is required to consider the vitality of the questions raised in the motion before the Prothonotary. In this respect, I agree with Justice Simpson's analysis. But second, the requirement to consider does not impose a certain response or outcome. That is, as clearly expressed in paragraphs 22 and 23 of *Merck*, for good reason, not all impugned findings made by a Prothonotary require *de novo* consideration. Thus, whether a *de novo* hearing is engaged depends on the substantive issue under consideration and, as expressed in paragraphs 27 and 28 of *Merck*, the importance of that issue to the litigation. That is, context is important.

[8] In my opinion, the analysis of the substantive issues undertaken in *Merck* must be considered as merely an example of how the principles communicated in the decision can be applied. And, apart from the principles stated, neither the decision in *Merck* nor *Sanofi* is a precedent for the outcome of the present motion. Each case turns on its own merits.

[9] For example, the decision in *Merck* addressed whether a motion to amend by the defendant raised questions vital to the final issues of that claim. The Court of Appeal found that the

amendments would add a completely new defence that would go to the heart of the claim, so they were considered to be vital. In the present claim, Pfizer brings a motion to strike Teva's claim in its entirety. Therefore, given this fundamental distinction, I find that the "vitality" reasoning on the merits in *Merck* is distinguishable and is only relevant to the merits of the motion under consideration in that claim.

[10] In my opinion, the jurisprudence of this Court that holds that issues considered by a Prothonotary leading to the dismissal of a motion to strike are not subject to being considered *de novo* on appeal is a proper well-established application of the second principle I have discerned from the decision in *Merck*. Generally speaking, because on a motion to strike the focus of a Prothonotary is on the test as to whether it is plain and obvious that the claim cannot succeed, and because the dismissal of a motion to strike allows the full merits of the claim advanced by a plaintiff to be determined on a trial, it cannot be said that that the issues considered by a Prothonotary in dismissing a motion to strike are vital to the final resolution of the claim. However, the general can be made specific in a situation where it can be established that the dismissal of a strike motion will have an impact on the litigation that compels *de novo* consideration of certain issues argued to be vital to the litigation. In my opinion, this is not such a situation.

[11] In addition to adhering to the jurisprudence of this Court with respect to vitality, in my opinion there is good reason to send this claim to trial without *de novo* consideration of the issues considered by the Prothonotary. Albeit with respect to quantum of damages, Teva makes the following key allegation at paragraph 49 of the Statement of Claim:

> The Defendants knew, or ought to have known, both when the application for the 393 Patent was filed, and when the T -1350-04 Prohibition Application was commenced and pending, that there was no basis in fact to support the statements in the 393 Patent that besylate is sufficiently superior to the other salts, for instance tosylate and mesylate so as to make it "unique" or "outstanding" or "particularly suitable" (Impeachment Judgment at para. 179). The selection of words such as unique, outstanding and particularly
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> suitable were the work of patent draftsmanship not of the inventors (Impeachment Judgment at para. 199). The Defendants' misleading assertion that the besylate salt had these "special advantages" was central to their ultimately successful argument that Ratiopharm's allegations of anticipation, double-patenting, and invalid selection were not justified, and was in contravention of s. 53 of the Patent Act.

If the allegation is proved at trial, given the evolution of the interpretation of s. 8 of the *Regulations*, the impact of such a finding on liability for damages is uncertain. Justice Evans in *Apotex Inc. v. Eli Lilly and Co.*, 2004 FCA 358 at paragraph 16 cautions that difficult questions involving the interpretation of s. 8 can only be satisfactorily resolved in the context of a trial. In my opinion, this caution certainly applies to the present litigation.

[12] As a result, I dismiss Pfizer's vitality argument.

[13] With respect to the second part of the standard of review expressed in paragraph 19 of *Merck*, Pfizer argues that the exercise of discretion by the Prothonotary was based upon a wrong principle or upon a misapprehension of the facts. However, during the course of the hearing of the present appeal, Counsel for Pfizer confirmed that the Prothonotary was correct in applying both the "but for" approach and the "plain and obvious" test in reaching a conclusion on the strike motion. With respect to the abuse of process argument advanced by Pfizer on the motion, I find that the

Prothonotary was correct in applying the "clearly abusive" test (see: *Blencoe v British Columbia (Commission)*, 2000 SCC 44 at para. 120).

[14] In my view, Pfizer's error argument is based on simply a disagreement with the conclusions reached in opposition to the arguments advanced on the motion. It is clear that the Prothonotary's

points of disagreement with Pfizer's arguments are only directed towards determining whether it is plain and obvious that Teva's action cannot succeed on its merits or is an abuse of process and, thus, do not impact in any way on the conclusions that might be expressed by the trial judge following a trial on the evidence.

[15] In my opinion, the Prothonotary approached the motion to strike on correct legal principles, and on a full apprehension of the facts, and, thus, I find that there is no basis for interfering with the Prothonotary's clear reasons for allowing the claim to proceed to trial.

[16] As a result, I dismiss Pfizer's error argument.

ORDER

THIS COURT ORDERS that for the reasons provided, the present appeal is dismissed.

I award costs of the appeal to the Plaintiff.

"Douglas R. Campbell"
Judge

"ADDENDUM I"

Date: 20130405

Docket: T-1194-12

Toronto, Ontario, April 5, 2013

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

PFIZER CANADA INC. AND PFIZER INC.

Defendants

ORDER

UPON Motion, dated the 20th day of August, 2012, on behalf of the Defendants (collectively "Pfizer"), for an order:

1. Striking out the statement of claim and dismissing this action; and

2. Granting Pfizer its costs of this action, or in alternative of the motion, on an elevated scale; or such order as may seem just.

AND UPON reviewing the motion records filed on behalf of the parties and hearing submissions of counsel;

The within action is a claim for damages, commenced pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations ("PMNOC Regulations" or "Regulations*"). Section 8 provides that liability arises upon the dismissal or discontinuance of an application for an order of prohibition, brought under section 6 of the *PMNOC Regulations*, to compensate the respondent drug manufacturer in the section 6 proceeding for having been kept off the market by virtue of the operation of the *Regulations*, namely the "first person" brand-name pharmaceutical having commenced an application in response to receipt of the "second person" generic's Notice of Allegation:

> 8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
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> (a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that….
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> (ii) a date other than the certified date is more appropriate; and
>
> (b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.
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> (2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

The determination of the nature, scope and quantum of damages (if any) payable in a section 8 case requires the judge hearing the trial to construct a "but for" universe, within which findings must be made about the presumed conduct and actions of various players, including the brand-name first person pharmaceutical company, the second person generic who argues it was delayed in obtaining a notice of compliance for its product, the Minister of Health, other generics, customers of these pharmaceutical manufacturers - and as is evident in the within action, determinations might also need to be made as to what the Federal Court or Federal Court of Appeal might or might not have done (and/or when) in the particular circumstances of this case.

To the extent that there may be (as there are in this case) multiple section 6 proceedings, a patent impeachment action and the expiry of I.P to factor into this "but for" universe, it can quickly become populated with many "what-ifs" relating to various scenarios or outcomes. Final disposition of a section 8 action may require a great deal in the way of the parties' and judicial resources, and many years of litigation to conclude.

Nonetheless, the *PMNOC Regulations* have established this regime within which brand name and generic pharmaceuticals are to resolve these disputes relating to the approval process, market entry and damages.

In the within action, the chronology and relevant facts are as follows:

On January 23, 2004 ratiopharm Canada Inc. filed an Abbreviated New Drug Submission ("ANDS") for Ratio-Amlodipine with the Minister of Health, based on demonstrated bioequivalence to Pfizer's Norvasc tablets.

Since that time ratiopharm Canada Inc. and ratiopharm Inc. amalgamated with Teva Canada Ltd (on August 10, 2010), and so for the balance of this order, reference to "Teva" will be used to refer to either Teva or ratiopharm.

Following the filing of the ANDS, on June 5, 2004, Teva delivered its Notice of Allegation ("NOA") in respect of the two patents listed on the Patent Register against the Norvasc tablets at that time. Teva acknowledged that a Notice of Compliance ("NOC") for the Ratio-Amlodipine product would not issue until the expiry of Canadian Patent No. 1,253865 (the "865 Patent") on May 9, 2006, but alleged that the second patent on the Patent Register, Canadian Patent No. 1,321,393 (the "393 Patent") was invalid.

On July 19, 2004, Pfizer commenced an application under s.6 of the *PMNOC Regulations*, T-1350-04 for an order prohibiting the Minister of Health from issuing an NOC until the expiry of the 393 Patent, on the grounds that Teva's allegations of invalidity were unjustified.

On October 20, 2004, the Minister advised Teva that its ANDS for Ratio-Amlodipine was satisfactory. Thus, but for the commencement of T-1350-04, Teva could obtain its NOC and enter the market with its product upon expiry of the 865 Patent.

By order dated February 17, 2006, Pfizer's application for prohibition in T-1350-04 was dismissed. However, Teva could not just wait until the May 9, 2006 expiry of the 865 Patent to obtain its NOC. Prior to T-1350-04 being dismissed, on January 20, 2006, Pfizer caused a new patent to be listed on the Patent Register in respect of its Norvasc tablets, Canadian Patent No. 2,355,493 (the "493 Patent").

On February 15, 2006, to address the 493 Patent, Teva delivered its second NOA, alleging that Teva's Ratio-Amlodipine would not infringe the 493 Patent.

On March 31, 2006, Pfizer commenced its second application for an order of prohibition: T-586-06, requesting that the Court prohibit the Minister from issuing an NOC to Teva until the expiry of the 493 Patent.

While the application in T-586-06 was proceeding, on May 9, 2006 the 865 Patent expired.

Also, while the application was proceeding, on February 19, 2007, Norvasc related prohibition applications (Pfizer's section 6 prohibition proceedings against Pharmascience and Cobalt) were dismissed. In the Pharmascience and Cobalt matters, the Federal Court held that it was "plain and obvious" that the 493 Patent should not be listed under the provisions of the *PMNOC Regulations*, as against Notice of Compliance questions.

Pfizer's application in T-586-06 in respect of the 493 Patent was dismissed on April 26, 2007. However, Teva did not obtain its NOC at that time. Despite the expiry of the 865 Patent by this time, the matter of the 393 Patent had not yet concluded.

Pfizer had appealed the dismissal of the application for a prohibition order in T-1350-04, and on June 9, 2006 the Federal Court of Appeal reversed the dismissal. In its place, the Court of Appeal issued an order prohibiting the Minister of Health from issuing a NOC to Teva for Ratio-Amlodipine until the expiry of the 393 Patent.

Teva brought a motion to the Federal Court of Appeal seeking to have the Court set aside its judgment of June 9, 2006, dismiss the application and set aside the 393 prohibition order. That motion was dismissed.

Teva then, on September 21, 2007, commenced an action to impeach the 393 Patent, and on July 8, 2009, the Federal Court voided the 393 Patent on several grounds.

On July 9, 2009 Teva received the NOC for its Ratio-Amlodipine product.

Pfizer appealed the July 8, 2009 decision voiding the 393 Patent, but the appeal was dismissed by the Federal Court of Appeal on July 29, 2010.

Against this factual backdrop, Teva now seeks to claim damages from Pfizer for having been kept off the market as a result of the operation of the *PMNOC Regulations*. The issues on this motion are:

(i) Is it plain and obvious that Teva's action cannot succeed?

(ii) Is it plain and obvious that Teva's action is an abuse of process; and

(iii) Is it plain and obvious that Teva's allegation that Pfizer engaged in fraudulent and oppressive conduct is an abuse of process?

I am satisfied that so long as there is any temporal window within which Teva may reasonably assert attracts liability for damages, the action must be permitted to continue. The "but for" world without operation of the *PMNOC Regulations* must take into account that at first instance, Pfizer's application in T-1350-04 was dismissed, the 865 Patent had expired and had Pfizer not commenced the application in T-586-06 in respect of the 493 Patent (which was dismissed), Teva could have received its NOC and entered the market with its Ratio-Amlodipine tablets between May 9, 2006 and June 9, 2006.

Teva submits that the fact that the Federal Court of Appeal issued the prohibition order one month after the expiry of the 865 Patent in respect of the 393 Patent (which was subsequently found invalid) does not alter the fact that "but for" Pfizer's application in T-586-06, Teva would have received an NOC and commenced selling on May 9, 2006. As at May 9, 2006, the prohibition order had not yet been issued by the Court of Appeal. There is a possibility for this one month window because of the dismissal of T-586-06. In addition, there may be further "what ifs" based on plausible arguments relating to the 393 Patent and the fact that it was declared to be void – can a void patent have any impact on the calculation of damages under section 8 of the PMNOC – despite or independent of the Federal Court of Appeal decision on appeal and on reconsideration?

With respect to the decision of the Federal Court of Appeal on reconsideration, the Court did not make any determination about Teva's ability to pursue a section 8 damage claim based on the dismissal of T-586-06 with respect to the 493 Patent, and made no determination with respect to Pfizer's liability under the Regulations in light of the dismissal of T-586-06. The Court of Appeal addressed the subject of the motion for reconsideration, namely its decision to reverse T-1350-04 which Teva urged the Court of Appeal to reconsider in light of the Federal Court's findings that the 493 Patent ought not to have been listed. The Court of Appeal refused to set aside its decision to issue a prohibition order in respect of the 393 Patent because what Teva was advancing in support of the motion was "too speculative":

> Beyond this, the course of events proposed by Ratiopharm is too speculative to give rise to a new "matter" within the meaning of Rule 399(2)(a) or to justify the invocation of this Court's inherent jurisdiction in order to set aside this Court's prior decision. Ratiopharm assumes, amongst other things, that if the 493 patent had not been improperly listed, the Minister would have issued a NOC with respect to its Besylate tablets prior to the time when Pfizer's appeal before this Court was to be heard and in any event, before the Court rendered its decision with the result that the Court would have exercised its discretion against disposing of the appeal and a prohibition would not have been issued.
>
> There are an infinite number of intervening events which could have altered the scenario painted by Ratiopharm. It is simply impossible to assume that the events would have unfolded as Ratiopharm suggests or to give this scenario the certainty that would be required in order to justify the setting aside of the earlier decision of this Court.

Accordingly, whatever the final outcome of this action may be, I am not satisfied that the allegations and claim for damages made by Teva can be found to be an abuse of process or an attempt to re-litigate the 393 Patent prohibition proceedings. Teva does not seek to overturn the prohibition order issued by the Court of Appeal, but have the fact that the 393 Patent was subsequently found void to be included as a factor in its section 8 damage claim.

Thus, but for T-586-06, Teva may have obtained the NOC on May 9, 2006 and Teva may (or may not) succeed in having these considerations related to the delisting of the 493/dismissal of T-586-06 taken into account, together with other factors related to the 393 Patent in either asserting some claim for damages for the one month or attempting to enlarge the window or otherwise in calculating damages. Either way, the outcome cannot be certain.

It is open to the Court to take into account a wide variety of factors in a section 8 proceeding:

> s.8(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to

> in that subsection, make any order for relief by way of damages that the circumstances require.
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> s.8(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

Finally, I note that the jurisprudence relating to section 8 proceedings is still evolving and is not fully settled. The Regulations by their very nature give rise to the construction of complex scenarios, such that the "what ifs" unless clearly abusive or doomed to fail, must be permitted to proceed to be adjudicated on a full evidentiary record and legal argument at trial. As noted in *Apotex Inc. v Pfizer*, 2009 FC 631 at para.29:

> These cases involved the construction of s.8 to answer questions of law raised by the parties…I agree that where there are difficult legal questions requiring the legal construction of a complex statutory framework, summary judgment is not appropriate.

Accordingly, as Pfizer has not established that Teva's claim is either entirely without merit and doomed to fail or constitutes an abuse of process, the motion must be dismissed.

THIS COURT ORDERS that:

1. The motion be and is hereby dismissed.

2. In the event the parties cannot agree on costs, the matter may be spoken to on a case management teleconference.

"Martha Milczynski"

Prothonotary

"ADDENDUM II"

Paragraphs 17 to 28 of the decision in *Merck & Co v Apotex Inc*, 2003 FCA 488 read as follows:

> The standard of review
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> 17 This Court, in Canada v. Aqua-Gem Investment Ltd., [1993] 2 F.C. 425 (F.C.A.), set out the standard of review to be applied to discretionary orders of prothonotaries in the following terms:
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> > [...] Following in particular Lord Wright in Evans v. Bartlam, [1937] A.C. 473 (H.L.) at page 484, and Lacourcière J.A. in Stoicevski v. Casement (1983), 43 O.R. (2d) 436 (Div. Ct.), discretionary orders of prothonotaries ought not to be disturbed on appeal to a judge unless:
> >
> > (a) they are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts, or
> > (b) they raise questions vital to the final issue of the case.
> >
> > Where such discretionary orders are clearly wrong in that the prothonotary has fallen into error of law (a concept in which I include a discretion based upon a wrong principle or upon a misapprehension of the facts), or where they raise questions vital to the final issue of the case, a judge ought to exercise his own discretion de novo.
> > [MacGuigan J.A., at pp. 462-463]
> > [footnote omitted]
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> 18 MacGuigan J.A. went on, at pp. 464-465, to explain that whether a question was vital to the final issue of the case was to be determined without regard to the actual answer given by the prothonotary:
>
> > [...] It seems to me that a decision which can thus be either interlocutory or final depending on how it is decided, even if interlocutory because of the result, must nevertheless be considered vital to the final resolution of the case. Another way of putting the matter would be to say that for the test as to relevance to the final issue of the case, the issue to be decided should be looked to before the question is answered by the prothonotary,

> whereas that as to whether it is interlocutory or final (which is purely a pro forma matter) should be put after the prothonotary's decision. Any other approach, is [sic] seems to me, would reduce the more substantial question of "vital to the issue of the case" to the merely procedural issue of interlocutory or final, and preserve all interlocutory rulings from attack (except in relation to errors of law).

This is why, I suspect, he uses the words "they (being the orders) raise questions vital to the final issue of the case", rather than "they (being the orders) are vital to the final issue of the case". The emphasis is put on the subject of the orders, not on their effect. In a case such as the present one, the question to be asked is whether the proposed amendments are vital in themselves, whether they be allowed or not. If they are vital, the judge must exercise his or her discretion de novo.

19 To avoid the confusion which we have seen from time to time arising from the wording used by MacGuigan J.A., I think it is appropriate to slightly reformulate the test for the standard of review. I will use the occasion to reverse the sequence of the propositions as originally set out, for the practical reason that a judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would now read:

> Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless:
> a) the questions raised in the motion are vital to the final issue of the case, or
> b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

20 With respect to the test to be applied by this Court on an appeal from a judge's decision, the Supreme Court of Canada, in Z.I. Pompey Industrie v. ECU-Line N.V. (2003), 224 D.L.R. (4th) 577, held at para. 18 that the Federal Court of Appeal may only interfere with the decision of the applications judge where the judge "had no grounds to interfere with the prothonotary's decision or, in the event such grounds existed, if [the judge's] decision was arrived at on a wrong basis or was plainly wrong".

Whether the proposed amendments are vital to the final issue of the case

21 The first argument raised by the appellants is that the judge erred in finding that the amendments sought were not vital to the issue of the case and in not, therefore, exercising de novo his discretion.

22 The test of "vitality", if I am allowed this expression, which was developed in Aqua-Gem, is a stringent one. The use of the word "vital" is significant. It gives effect to the intention of Parliament, as so ably described by Isaac C.J. at pages 454 and 455 of his minority reasons in Aqua-Gem (I pause here to note that the learned Chief Justice's analysis of the role of the prothonotaries in the Federal Court remains basically unchallenged in the majority opinion written by MacGuigan J.A.):

> [...] such a standard [of review] is consistent with the parliamentary intention embodied in section 12 of the [Federal Court] Act, that the office of prothonotary is intended to promote "the efficient performance of the work of the Court".

In my respectful view it cannot reasonably be said that a standard of review which subjects all impugned decisions of prothonotaries to hearings de novo regardless of the issues involved in the decision or whether they decide the substantive rights of the parties is consistent with the statutory objective. Such a standard conserves neither "judge power" nor "judge time". In every case, it would oblige the motions judge to re-hear the matter. Furthermore, it would reduce the office of a prothonotary to that of a preliminary "rest stop" along the procedural route to a motions judge. I do not think that Parliament could have intended this result.

23 One should not, therefore, come too hastily to the conclusion that a question, however important it might be, is a vital one. Yet one should remain alert that a vital question not be reviewed de novo merely because of a natural propensity to defer to prothonotaries in procedural matters.

24 In Aqua-Gem, at p. 464, MacGuigan J.A. distinguished on the one hand between "routine matters of pleadings", words used by Lord Wright in Evans v. Bartham, [1937] 2 All E.R. 646 (H.L.) at 653, and "a routine amendment to a pleading", words used by Lacourcière J.A. in Stoicevski v. Casement (1983), 43 O.R. (2d) 436

(Ont. C.A.) at 438, and, on the other hand, between "questions vital to the final issue of the case, i.e. to its final resolution".

25 When is an amendment a routine one as opposed to a vital one? It would be imprudent to attempt any kind of formal categorization. It is much preferable to determine the point on a case by case basis (see Trevor Nicholas Construction Co. v. Canada (Minister for Public Works), [2003] F.C.J. No. 357, 2003 FCT 255, per O'Keefe J. at para. 7, aff'd, [2003] F.C.J. No. 1706, 2003 FCA 428). I note that amendments that would advance additional claims or causes of action have consistently been found, in the Federal Court of Canada, to be vital for the purposes of the Aqua-Gem test (see Scannar Industries Inc. et al v. Minister of National Revenue (1993), 69 F.T.R. 310, Denault J., aff'd (1994), 172 N.R. 313 (F.C.A.); Trevor Nicholas Construction Co., (supra); Louis Bull Band v. Canada, [2003] F.C.J. No. 961, 2003 FCT 732 (Snider J.).

26 In the case at bar, counsel for Apotex has opined that since the proposed amendments do not raise a new defence but simply set out an alternative factual basis for an existing non-infringement defence, they are routine amendments. Counsel for the appellants, on the other hand, invite the Court to determine that the proposed amendments were vital amendments as they are an attempt to withdraw an admission which would have had an important impact on the final issue of the case and to raise a new defence.

27 The proposed amendments, in my view, represent a dramatic departure from the position until now advanced by Apotex in its pleadings. Its defence of non-infringement was essentially based on the fact that it had acquired lisinopril made prior to the issuance, on October 16, 1990, of the '350 Patent and on the fact that it had acquired lisinopril made under a Compulsory Licence issued to its supplier, Delmar. Apotex' pleadings in these and other proceedings has always assumed that were it not for those facts, there would be infringement of the '350 Patent. The construction of the Patent and the chemical composition of lisinopril has never been an issue.

28 The proposed amendments, clearly, would add a totally new defence to the Statement of Defence, a new defence that would go to the heart of the claim of the '350 Patent and require expert evidence that could not have been contemplated by the appellants at the discovery stage in view of the admissions already made in the pleadings and in the proceedings. They are, in my view, vital to the final issue of the case. A de novo review of the decision of the prothonotary was therefore warranted and the applications judge

erred in finding that it was not. I must, therefore, exercise de novo the discretion the applications judge failed to exercise.

[Emphasis added]

FEDERAL COURT

SOLICITORS OF RECORD

Docket: **T-1194-12**

STYLE OF CAUSE:	TEVA CANADA LIMITED v PFIZER CANADA INC. AND PFIZER INC.
PLACE OF HEARING:	TORONTO, ONTARIO
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APPEARANCES:

Marcus Klee Devin Doyle	FOR THE PLAINTIFF
John B. Laskin W. Grant Worden	FOR THE DEFENDANTS

SOLICITORS OF RECORD:

AITKEN KLEE LLP Ottawa, Ontario	FOR THE PLAINTIFF
TORYS LLP Toronto, Ontario	FOR THE DEFENDANTS