Federal Court of Appeal | Cour d'appel fédérale

Date: 20160531

Docket: A-422-14

Citation: 2016 FCA 161

CORAM: **STRATAS J.A.**
RYER J.A.
GLEASON J.A.

BETWEEN:

PFIZER CANADA INC.

Appellant

and

TEVA CANADA LIMITED

Respondent

Heard at Toronto, Ontario, on December 1, 2015.

Judgment delivered at Ottawa, Ontario, May 31, 2016.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: RYER J.A.
GLEASON J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

A. Introduction

[1] Pfizer appeals from the judgment dated June 30, 2014 of the Federal Court (*per* Zinn J.). The judgment is based on reasons dated April 3, 2014 (2014 FC 248) and subsequent reasons dated June 30, 2014 (2014 FC 634).

[2] Following fifteen days of trial, the Federal Court found Pfizer liable for damages under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R. 93-133 in the amount of $92,228,000.00, pre-judgment interest in the amount of $32,539,550.36, post-judgment interest at the rate of 3.0% on $124,766,550.36 (the sum of the damages and prejudgment interest) from the date of judgment until payment, and costs.

[3] Pfizer appeals. It alleges that the Federal Court committed reversible error in a number of ways.

[4] I agree with Pfizer on one of the issues it raises, namely the Federal Court's admission of and reliance upon hearsay evidence in the trial. While this Court has the power to consider the matter without the hearsay evidence and make the judgment the Federal Court should have made, I would not exercise that power in this factually-complex circumstance where the result is unclear. Rather, I would remit the matter to the Federal Court for redetermination.

[5] Therefore, for the reasons that follow, I would allow the appeal, set aside the judgment of the Federal Court, and remit the matter to the Federal Court for redetermination on this record, excluding the hearsay evidence. I would grant Pfizer its costs of the appeal.

B. Background facts

[6] In the Federal Court, Teva sued Pfizer for damages arising from Pfizer's conduct under the *PMNOC Regulations* that improperly kept one of its corporate predecessors from selling its

drug on the market. This suit was founded upon the legislative cause of action in section 8 of the *PMNOC Regulations*.

[7] In this summary of background facts, I shall describe the relevant drugs and the relevant parties and then review the portions of the *PMNOC Regulations* that relate to this appeal. Then I shall review what the parties did under those portions of the *PMNOC Regulations* that gave rise to Teva's action for damages under section 8 of the *PMNOC Regulations*. Finally, I shall review the Federal Court's reasons.

[8] Throughout these reasons, when I refer to a paragraph number in the Federal Court's reasons, the relevant reasons are the first set of reasons dated April 3, 2014 (2014 FC 248).

(1) The relevant drug and the relevant parties

[9] The innovative drug at issue in this matter is venlafaxine hydrochloride ("venlafaxine") marketed under the name Effexor XR.

[10] The appellant, Pfizer, is the corporate successor to Wyeth and Wyeth Canada. Wyeth was the innovative manufacturer of venlafaxine. In these reasons, for the purposes of describing Wyeth's conduct before it became part of Pfizer, I shall refer to Wyeth as "Wyeth (Pfizer)."

[11] The respondent, Teva, is the corporate successor to ratiopharm inc. During many of the events giving rise to its claim for damages under section 8 of the *PMNOC Regulations*,

Ratiopharm sought to be a generic manufacturer of venlafaxine. In these reasons, for the purposes of describing Ratiopharm's conduct before it became part of Teva, I shall refer to Ratiopharm as "Ratiopharm (Teva)."

[12] As the Federal Court noted in its reasons, Novopharm Limited and Pharmascience Inc. played a role as generic entrants into the market for venlafaxine. I shall refer to them as Novopharm and Pharmascience. Novopharm is now part of Teva. But in the interests of clarity and due to their less significant role in these reasons, it is not necessary to acknowledge their current status, as I have for Ratiopharm (Teva) and Wyeth (Pfizer).

(2) The *PMNOC Regulations* as they relate to this appeal

[13] In order to market a new drug in Canada, an innovative drug manufacturer must, among other things, file a new drug submission and receive approval in the form of a notice of compliance from the Minister of Health. As part of that process, the *PMNOC Regulations* permit the manufacturer to list in a patent register all of the relevant patents pertaining to the submission.

[14] Later, a generic drug manufacturer wishing to make and market a generic version of the innovator's drug may submit an abbreviated new drug submission demonstrating, among other things, that the generic formulation is bioequivalent to the innovator's drug by cross-referencing clinical trials regarding safety and effectiveness undertaken by the innovator. This dispenses with the need for the generic manufacturer to undertake its own clinical trials.

[15] The generic drug manufacturer must address any patent listed in the patent register concerning the innovator drug: *PMNOC Regulations*, s. 5. It does so either by stating that it is not seeking the issuance of a notice of compliance until the patent expires or by alleging that the patent is not valid or will not be infringed by the making, using or selling of the generic drug. In furtherance of the allegation, it must serve a notice of allegation which contains a detailed statement of the factual and legal bases for the allegation.

[16] An innovator who wishes to challenge the allegation of invalidity or non-infringement in the notice of allegation must apply to the Federal Court within 45 days for an order prohibiting the Minister of Health from issuing a notice of compliance for the generic product before the expiry of the patent(s) that are the subject of the notice of allegation. If the innovator does that, the Minister of Health is precluded from issuing a notice of compliance to the generic manufacturer in most cases for twenty-four months or until the prohibition application has been dismissed: *PMNOC Regulations*, s. 7(1).

[17] A generic manufacturer may seek an order dismissing all or part of the prohibition application concerning patents it says are not eligible for inclusion on the patent register: *PMNOC Regulations*, para. 6(5)(*a*). If the motion is successful, the prohibition application is dismissed as against any improperly listed patents.

[18] If a prohibition application is ultimately unsuccessful either at first instance or on appeal, or if it is discontinued or withdrawn, the innovator may be liable for damages for "any loss

suffered during the period": *PMNOC Regulations*, s. 8(1). In assessing damages, a court is to take into account "all matters that it considers relevant": *PMNOC Regulations*, s. 8(5).

(3) What happened under the *PMNOC Regulations* in this case

[19] In this case, Wyeth (Pfizer) marketed an extended release version of venlafaxine hydrochloride under the name Effexor XR. Related to it is Canadian Patent 1,248,540, a patent that was to expire on January 10, 2006. It was listed on the Patent Register against Effexor XR.

[20] In 2005, Ratiopharm (Teva) wanted to market its generic version of venlafaxine hydrochloride and filed an abbreviated new drug submission on February 24, 2005. On December 9, 2005, Health Canada informed Ratiopharm (Teva) that it had completed its review of its abbreviated new drug submission but that it would not issue a notice of compliance until the requirements under the *PMNOC Regulations* were met.

[21] On December 20, 2005, on the eve of the expiry of the '540 Patent, Canadian Patent 2,199,778, covering the extended release formulation of venlafaxine was issued. On December 23, 2005, Wyeth (Pfizer) listed it on the Patent Register against Effexor XR.

[22] In response, on the same day, Ratiopharm (Teva) served a notice of allegation. In its notice of allegation, Ratiopharm (Teva) accepted that its notice of compliance for its version of venlafaxine would not issue until the expiry of the '540 Patent, namely January 10, 2006. Ratiopharm (Teva) also alleged that the newly-listed '778 Patent was invalid or would not be

infringed by its version of venlafaxine. On February 10, 2006, Wyeth (Pfizer) applied for prohibition preventing the Minister from issuing a notice of compliance to Ratiopharm (Teva). This triggered the automatic twenty-four month stay of the Minister's ability to grant a notice of compliance to Ratiopharm (Teva) for its version of venlafaxine.

[23] Some time passed. Then, on December 18, 2006, Ratiopharm (Teva) filed a motion to dismiss Pfizer's prohibition application. It submitted that the '778 Patent was not eligible for listing on the Patent Register for Effexor XR.

[24] Following litigation of the motion in the Federal Court, the matter arrived in this Court. This Court agreed that the '778 Patent was not eligible for listing on the patent register for Effexor XR. So it granted Ratiopharm (Teva)'s motion and dismissed Wyeth (Pfizer)'s prohibition application: *Ratiopharm Inc. v. Wyeth*, 2007 FCA 264, [2008] 1 F.C.R. 447, rev'g 2007 FC 340, 58 C.P.R. (4th) 154. This Court released its judgment on August 1, 2007.

[25] This removed the obstacles that stood in the way of Ratiopharm (Teva) receiving a notice of compliance to launch its version of venlafaxine. On August 2, 2007, the Minister granted Ratiopharm (Teva) its notice of compliance for its version of venlafaxine. Ratiopharm (Teva) launched its product into the Canadian market on September 18, 2007.

[26] Looking at this history with the benefit of hindsight, it can be said Wyeth (Pfizer) should not have listed its '778 Patent on the patent register for Effexor XR and should not have brought a prohibition application. Put another way, Wyeth (Pfizer) improperly kept Ratiopharm (Teva)'s

version of venlafaxine off the market. Under section 8 of the *PMNOC Regulations*, Ratiopharm (Teva) could seek damages for that.

[27] So Ratiopharm (Teva) did just that and started an action for damages in the Federal Court. Wyeth (Pfizer) counterclaimed on the ground that Ratiopharm (Teva)'s venlafaxine product infringed the '778 Patent. Later, it discontinued that counterclaim.

(4) The Federal Court's consideration of the damages claim

[28] The Federal Court first considered the period of loss suffered that is compensable under section 8 of the *PMNOC Regulations*.

[29] The parties did not dispute the end date of that period of loss. Both agreed that under paragraph 8(1)(*b*) of the *PMNOC Regulations*, the end date is the date the prohibition application is withdrawn, discontinued, dismissed or reversed. Here, that date was August 1, 2007, the date this Court dismissed Wyeth (Pfizer)'s prohibition application.

[30] However, the parties disputed the start date of the period of loss. Teva submitted that the start date was January 10, 2006, the date the '540 Patent expired. Pfizer, on the other hand, submitted that the start date could not be earlier than February 13, 2006, the date the Minister would have issued a notice of compliance to Ratiopharm (Teva) if it had served Pfizer with a notice of allegation relating to the '778 Patent and Pfizer had not started a prohibition application.

[31] The Federal Court rejected Pfizer's submission based on the wording of paragraph 8(1)(*a*) of the *PMNOC Regulations*. In its view, that paragraph governed the start date. Paragraph 8(1)(*a*) provides that the period starts "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…a date other than the certified date is more appropriate." The Minister certified the date as December 7, 2005. That date, in *PMNOC Regulations* parlance, is the patent hold date.

[32] Paragraph 8(1)(*a*), quoted above, by default sets the start date as the date the Minister certifies a notice of compliance would have been issued in the absence of the Regulations "unless the court concludes that…a date other than the certified date is more appropriate." Here, the Federal Court found that there was a more appropriate date, namely the date of expiry of the '540 Patent, January 10, 2006. It will be recalled that in its notice of allegation, Ratiopharm (Teva) accepted that its notice of compliance for its version of venlafaxine would not issue until the expiry of the '540 Patent.

[33] On this point, the Federal Court concluded as follows (at paras. 64-65):

> [64] In short, based on the evidence, [Wyeth (Pfizer)] knew that [Ratiopharm (Teva)] or another generic would be entering the market in January 2006 or very shortly thereafter and it chose to list the '778 Patent in an attempt to evergreen its drug and prevent generic competition. It knew or ought to have known that a generic ready to enter the market in January 2006 would very likely serve it with a [notice of allegation], rather than wait many more years to gain entry into the venlafaxine market.
>
> [65] In this case, but for the improper listing of the '778 Patent on the Patent Register, all things being equal, [Ratiopharm (Teva)] would have received its [notice of compliance] and been in a position to launch its product on January 10, 2006. The earlier Patent Hold date [December 7, 2005] is an appropriate date to

> commence the [period of loss]; however, because no loss is claimed by [Ratiopharm (Teva)] prior to January 10, 2006, I accept [Ratiopharm (Teva)'s] submission that January 10, 2006, is a more appropriate commencement for the [period of loss] than the Patent Hold Date [December 7, 2005].

[34] Having determined the start date and the end date for the period of loss, the Federal Court then determined a number of issues: the size of the overall market for venlafaxine, the size of the generic venlafaxine market and Ratiopharm (Teva)'s market share, the time when Ratiopharm (Teva) and its competitors' generic products would have been listed on the provincial formularies and the entry of competitors into the generic market, the overall value of Ratiopharm (Teva)'s lost sales in the relevant period, and whether any deductions should be made under subsection 8(5) of the *PMNOC Regulations*. Below, in the context of submissions made by Pfizer in this Court, I shall review in more detail the Federal Court's reasons on the entry of Ratiopharm (Teva)'s competitors into the generic market.

[35] The Federal Court then considered the central issues in this appeal: the time when Ratiopharm (Teva) would have launched its venlafaxine product and the existence of any impediments to Ratiopharm (Teva) being able to supply the market. Teva submitted that it would have launched its product as soon as it could, on January 10, 2006, and there were no impediments to it obtaining the necessary product and supplying the full generic market. Pfizer disagreed.

[36] At the outset of its reasons on this point, the Federal Court held (at para. 148) that on the authorities Teva had to show "on a balance of probabilities that [Ratiopharm (Teva)] was able to supply the market." In this case, that meant that Teva had to identify a supplier of the active

pharmaceutical ingredient and show that that supplier had the capacity to supply the market over the relevant period. It noted (at paras. 149-152) that the only evidence offered on this point was that of Mr. Major, a witness called by Teva. Mr. Major was a former executive of Ratiopharm (Teva) and acted in that position at all material times.

[37] Mr. Major testified that Ratiopharm (Teva) relied upon a separate company, Alembic Pharmaceuticals, to manufacture its venlafaxine product. He testified that on a site visit over two weeks in 2004, he thoroughly inspected Alembic's facility. From that, he formed the view that Alembic had sufficient capacity to produce Ratiopharm (Teva)'s venlafaxine product in the necessary quantities. Ratiopharm (Teva) had worked with Alembic before and Alembic was an eager and enthusiastic business partner of Ratiopharm (Teva) in such matters.

[38] In support of his testimony that Alembic had sufficient capacity to produce Ratiopharm (Teva)'s venlafaxine product in sufficient quantities at the relevant time, Mr. Major also relied on emails between Ratiopharm (Teva) personnel and Alembic personnel, most of which he was not copied upon. He also relied on what some colleagues at Ratiopharm (Teva) told him about Alembic's ability to supply and on documents prepared by others. During my analysis, below, I shall review Mr. Major's testimony in more detail.

[39] During Mr. Major's testimony, Pfizer repeatedly objected on the ground that some of the evidence offered was inadmissible hearsay. In response to the objections, the Federal Court ruled that it would consider what weight to give to the evidence.

[40] Ultimately, the Federal Court released two reasons for judgment. In the first, on April 3, 2014 (reported at 2014 FC 248), the Federal Court found Pfizer liable and set out certain principles for the calculation of damages. In the second, on June 30, 2014 (reported at 2014 FC 634), the Federal Court quantified the damages award and calculated pre-judgment and post-judgment interest and costs. It then released its formal judgment.

[41] Overall, in its first set of reasons (2014 FC 248), the Federal Court found that Alembic would have been able to supply adequate quantities of Ratiopharm (Teva)'s venlafaxine product at the relevant time. It took into account all of the evidence offered by Mr. Major, holding (at para. 153) that "[a]lthough Mr. Major speaks as an observer rather than as an employee of Alembic, I find that his evidence is reliable." It found that Teva had established loss under section 8 of the *PMNOC Regulations* and, thus, was entitled to damages.

[42] In its second set of reasons (2014 FC 634), the Federal Court quantified Teva's damages and awarded pre-judgment and post-judgment interest and costs.

C. Issues on appeal

[43] Pfizer appeals to this Court. In light of the submissions the parties have advanced, these reasons address six issues:

(1) *Some basic issues concerning section 8 damages claims.* Before us, the parties disagree on what must be proven and who bears the burden of proof in a claim under section 8 of the *PMNOC Regulations*.

(2) *The hearsay issue.* Pfizer submits that the Federal Court wrongly admitted and relied upon hearsay evidence in determining whether Ratiopharm (Teva) could have supplied the market with its venlafaxine product at the relevant time in sufficient quantities.

(3) *The issue whether there was palpable and overriding error on a factual finding.* Pfizer attacks one of the key factual findings the Federal Court made in support of its conclusion that Ratiopharm (Teva) could have supplied the market with its venlafaxine product at the relevant time in sufficient quantities.

(4) *Other section 8 damages issues.* Here Pfizer raises a number of issues. It submits that the Federal Court chose the wrong starting date for the period of Ratiopharm (Teva)'s loss and another generic drug manufacturer, Pharmascience, would have entered the hypothetical market and competed with Ratiopharm (Teva). Also it says that the Federal Court failed to attribute Novopharm's rebates to Ratiopharm (Teva).

(5) *Pre-judgment interest*. Pfizer submits that the Federal Court calculated pre-judgment interest improperly.

(6) *The disposition of this appeal: what should happen now?* Pfizer primarily submits that if the Federal Court wrongly admitted and relied upon hearsay evidence, the remaining admissible evidence is insufficient to support a finding that Ratiopharm (Teva) could have supplied the market with venlafaxine. Thus, Ratiopharm (Teva) suffered no loss and so this Court, making the judgment the Federal Court should have made, should now allow the appeal and dismiss Teva's action. Teva primarily submits that Pfizer is just asking for a reweighing of the factually-suffused findings of the Federal Court and so its appeal should be dismissed.

D. Analysis

(1) Some basic issues concerning section 8 damages claims

(a) General principles

[44] A plaintiff suing for damages under section 8 of the *PMNOC Regulations* must show that it did in fact suffer a loss caused by the failed proceedings under the *PMNOC Regulations*. Section 8 provides that compensation is available for "any loss suffered" during the relevant period—usually starting from the date on which a notice of compliance would have been issued in the absence of the Regulations as certified by the Minister of Health and ending on the date of the termination of the prohibition application.

[45] If a plaintiff cannot prove a loss caused by the failed proceedings under the *PMNOC Regulations* during that period, it cannot recover section 8 damages. Typically most of the plaintiff's loss will be its inability to sell its version of a drug during that period, in other words, the financial impact of lost sales. To assess that, the court must examine what would have happened had the defendant's triggering conduct for section 8 damages not taken place.

[46] In effect, the court is examining a hypothetical world. What would have happened in that hypothetical world must be proven by admissible evidence and any permissible inferences from that evidence.

(b) Determining lost sales in the hypothetical world

[47] This Court offered much guidance on how to go about assessing the hypothetical world in *Apotex Inc. v. Merck & Co., Inc.*, 2015 FCA 171, 387 D.L.R. (4th) 552 (*Lovastatin*). I acknowledge that *Lovastatin* concerned a claim for compensatory damages for patent infringement, not a claim for damages under section 8 of the *PMNOC Regulations*. But in both types of claims the court's task is the same: to assess a hypothetical world where the defendant's impugned conduct did not take place. And in both the overriding principle is the same: a plaintiff is to be compensated, no more, no less: *AstraZeneca Canada Inc. v. Apotex Inc.*, 2013 FCA 77, 444 N.R. 254 at para. 7.

[48] In *Lovastatin*, the plaintiff claimed that the defendant, by making and selling infringing product, caused it to lose sales it could have made. The defendant submitted, among other things,

that in the hypothetical world it would have been able to make the product in a non-infringing way. The sales would still have happened, cutting into the defendant's sales just as actually happened.

[49] This Court held that to make out that argument, the defendant would have had to show, on the evidence, that in the hypothetical world it would have and could have had access to sufficient quantities of non-infringing product and would have and could have used it: *Lovastatin*, at paras. 32, 53, 55, 70, 77 and 78.

[50] Both "would have" and "could have" are key. Compensatory damages are to place plaintiffs in the position they would have been in had a wrong not been committed. Proof of that first requires demonstration that nothing made it impossible for them to be in that position—*i.e.*, they *could* have been in that position. And proof that plaintiffs would have been in a particular position also requires demonstration that events would transpire in such a way as to put them in that position—*i.e.*, they *would* have been in that position.

[51] Both elements have to be present. "Could have" does not prove "would have"; "would have" does not prove "could have":

- Evidence that a party would have done something does not prove that it could have done something. I might swear up and down that I would have run in a marathon in Toronto on April 1 aiming to complete it, but that says nothing about whether I could have completed it. Maybe I am not fit enough to complete it.

- Evidence that a party could have done something does not prove that it would have done something. A trainer might testify that I was fit enough to complete a marathon race in Toronto on April 1, but that says nothing about whether I would have completed it. Perhaps on April 1 I would have skipped the marathon and gone to a baseball game instead.

[52] There must be evidence that the parties "would have" and "could have" ordered and supplied material at the relevant time. Evidence that a manufacturing plant had capacity at some time other than the relevant time for the assessment of loss under section 8 does not necessarily mean that the plant could have and would have had capacity in the hypothetical world at the relevant time. In the words of *Lovastatin*, without more it is an error to "[jump] from a statement as to manufacturing capacity to conclusions as to what [a generic] could and would do in the 'but for' [hypothetical] world" (at para. 77).

(c) The burden of proof concerning the hypothetical world

[53] In the case at bar, Teva submits that it did not bear the burden of proof concerning what would and could have happened in the hypothetical world had its venlafaxine product not been kept off the market. It submits that Pfizer bore this burden of proof. It says that if evidence of what Alembic would have and could have done in the hypothetical world were needed from Alembic, Pfizer had to call that evidence.

[54] I disagree. Here too, *Lovastatin*, above, is instructive. In that case, this Court held that the plaintiffs bear the burden of proving the hypothetical world on the balance of probabilities as part of their damages claim (at para. 45).

[55] This is no surprise: in suits for breach of contract or for damages caused by a wrong, such as tort cases, the plaintiff usually bears the burden to prove what would have transpired had the breach or wrong not been committed, *i.e.*, the persuasive burden to show what would have transpired in the hypothetical world: *Red Deer College v. Michaels*, [1976] 2 S.C.R. 324 at p. 330, 57 D.L.R. (3d) 386; *Janiak v. Ippolito*, [1985] 1 S.C.R. 146, 16 D.L.R. (4th) 1 at para. 32. The task of constructing the hypothetical world for the purposes of assessing compensatory damages is a factual inquiry using "robust common sense": *Clements v. Clements*, 2012 SCC 32, [2012] 2 S.C.R. 181, at paras. 8 and 9.

[56] The analytical exercise of constructing a hypothetical world exists elsewhere in our law and the burden of proof remains upon the plaintiff/complainant. For example, in some competition cases, the decision-maker must examine the state of competition in a hypothetical world. There, the party alleging anti-competitive conduct bears the burden of proving on the basis of admissible evidence what would have transpired in the hypothetical world on the balance of probabilities. Mere possibilities short of probabilities do not suffice. See generally *Tervita Corp. v. Canada (Commissioner of Competition)*, 2015 SCC 3, [2015] 1 S.C.R. 161 at paras. 49-51 and 66, citing *F.H. v. McDougall*, 2008 SCC 53, [2008] 3 S.C.R. 41 at paras. 40 and 49.

[57] There is nothing in section 8 of the *PMNOC Regulations* that would suggest a different conclusion on the burden of proof.

[58] Teva also offers the Supreme Court's decision in *Rainbow Industrial Caterers Ltd. v. Canadian National Railway Co.*, [1991] 3 S.C.R. 3, 84 D.L.R. (4th) 291 in support of its submission on the burden of proof. *Rainbow Industrial Caterers* does not assist Teva.

[59] The plaintiff, Rainbow, was a caterer bidding on a catering contract for CN. The defendant, CN, advised Rainbow of the number of meals it would have to prepare. Rainbow set its bid based on that estimate. CN awarded Rainbow the contract. But CN's estimate was way too high and Rainbow lost money on the contract.

[60] Rainbow sued for damages caused by the estimate. Rainbow bore the burden of proving on the balance of probabilities what would have and could have happened in the hypothetical world where CN gave a proper estimate. See *Rainbow Industrial Caterers* at p. 14, citing D.W. McLauchlan, "Assessment of Damages for Misrepresentations Inducing Contracts" (1987), 6 Otago L.R. 370 at p. 388. In discharge of that burden, among other things, Rainbow presented evidence concerning what bid it would have made had the estimate not been faulty.

[61] In response, CN could have worked within the hypothetical world proposed by Rainbow and defended on the basis that Rainbow did not prove that certain events in that hypothetical world could have and would have happened. For example, CN could have argued that Rainbow

did not adduce sufficient evidence of what would have transpired in the hypothetical world to meet the balance of probabilities standard or to prove its quantum of damages.

[62] But CN did not do that. Rather, CN offered a different hypothetical world, one where Rainbow still would have made a low bid to win the contract and still would have lost money. In effect, CN's submission was that the real cause of Rainbow's loss was not its faulty estimate but Rainbow's strong desire to get the contract, even if it meant proposing terms favourable to CN.

[63] The Supreme Court held that Rainbow had proven what would have happened in the hypothetical world and its quantum of loss in that world. That discharged its burden. CN, by suggesting a different hypothetical world—in effect a different view of who caused the loss—set up, in the words of the Supreme Court, a "new issue" or what others might perhaps call a positive defence. In the Supreme Court's view, a defendant that sets up a new issue bears the burden of proving it. The plaintiff, having proved its version of the hypothetical world, does not have to disprove other speculative hypotheses. The key passage in the Supreme Court's decision in *Rainbow Industrial Caterers* is at p. 15:

> Once the loss occasioned by the transaction is established, the plaintiff has discharged the burden of proof with respect to damages. A defendant who alleges that a plaintiff would have entered into a transaction on different terms sets up a new issue. It is an issue that requires the court to speculate as to what would have happened in a hypothetical situation. It is an area in which it is usually impossible to adduce concrete evidence. In the absence of evidence to support a finding on this issue, should the plaintiff or defendant bear the risk of non-persuasion? Must the plaintiff negative all speculative hypotheses about his position if the defendant had not committed a tort or must the tortfeasor who sets up this hypothetical situation establish it?
>
> …

> … In my opinion, [the answer to these questions is no]. [T]here is good reason for such reversal [of burden] in this kind of case. The plaintiff is the innocent victim of a misrepresentation which has induced a change of position. It is just that the plaintiff should be entitled to say "but for the tortious conduct of the defendant, I would not have changed my position". A tortfeasor who says "Yes, but you would have assumed a position other than the *status quo ante*", and thereby asks a court to find a transaction whose terms are hypothetical and speculative, should bear the burden of displacing the plaintiff's assertion of the *status quo ante*.

[64] In the case at bar, Teva's position was that in the hypothetical world, Ratiopharm (Teva) could have and would have obtained venlafaxine in sufficient quantities from Alembic. As *Rainbow Industrial Caterers* tells us, Teva bore the burden of proving that as part of its general burden to prove its loss.

[65] Suppose Pfizer took the position that Ratiopharm (Teva) would not have tried to obtain venlafaxine from Alembic but instead would have given up and pursued another business objective, such as getting another generic drug to market. *Rainbow Industrial Caterers* instructs us that Pfizer, setting up a different hypothetical, would have borne the burden of proof on that point. Put a different way, Teva would not have borne the burden of proving that it would not have pursued a different business objective.

[66] But Pfizer did not do that. Rather, it contested the very hypothetical that Teva relied upon in support of its damages claim—that Ratiopharm (Teva) would have and could have obtained venlafaxine in sufficient quantities from Alembic—and it submitted that Teva failed to prove that on the balance of probabilities. It is as if, in *Rainbow Industrial Caterers*, CN took the position that Rainbow had failed to adduce enough evidence to prove its version of what could

have and would have happened in the hypothetical world. Under the reasoning in *Rainbow Industrial Caterers*, the burden of proof would have remained on the plaintiff, Rainbow.

(d) Did the Federal Court err on these matters of principle?

[67] Pfizer submits that the Federal Court was not mindful of the foregoing principles. It suggests that the Federal Court only had regard to Alembic's willingness and potential capacity—not actual capacity—to manufacture Ratiopharm (Teva)'s venlafaxine product at the relevant time. I disagree.

[68] Faced with an allegation that a first-instance court did not apply proper principles, an appellate court must assess what the first-instance court did by reviewing in a holistic, organic and fair way the reasons offered by the court against the record it was considering. Often first-instance courts do not describe the principles that bear upon a case in a perfectly precise or encyclopedic way. Yet, in many such cases, a holistic, organic and fair review of their reasons against the record shows they brought to bear all correct principles.

[69] It must be remembered that judges' reasons—particularly after long complex trials involving many issues—are often the product of synthesis and distillation. When it comes time to draft reasons in a complex case, trial judges "are not trying to draft an encyclopedia memorializing every last [relevant] morsel." Rather, they are trying to "distill and synthesize masses of information, separating the wheat from the chaff," in the end "expressing only the most

important…findings and justifications for them": *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286 at para. 50.

[70] It is true that the Federal Court did not offer a great deal on the proper principles to be applied concerning the availability of s. 8 damages. However, it was mindful of these principles.

[71] It proceeded on the basis that the hypothetical world that Teva had to prove was one where Wyeth (Pfizer) did not improperly list its '778 Patent and Ratiopharm (Teva) received its notice of compliance on December 7, 2005. In part for reasons set out later, the Federal Court committed neither legal error nor palpable and overriding error in proceeding on that basis.

[72] With that hypothetical world in mind, the Federal Court held that Teva had to "show on the balance of probabilities that [Ratiopharm (Teva)] was able to supply the market" (at para. 148). This is the "could have" portion of the analysis. And at a number of portions in its reasons, it showed it was alive to the issue whether Ratiopharm (Teva) wanted to supply the market and whether Alembic was willing to produce venlafaxine. This is the "would have" portion of the analysis.

[73] Overall, the Federal Court was very much alive to the need for a firm causal link between failed proceedings under the *PMNOC Regulations* and the claimed loss. At paragraph 57, it identified the damages as "those that the plaintiff generic suffered 'by reason of the delayed market entry of its drug' as stated in the Regulatory Impact Analysis Statement" for the *PMNOC Regulations*. And at paragraph 61, it identified "[t]he question for the Court" as "whether there is

a causal connection between the failed PMNOC proceedings and the loss claimed as damages," stressing again that the damages claimed must be "causally connected."

[74] Even if I am wrong in my conclusion that the Federal Court was mindful of proper principles, this is of no consequence. The redetermination I propose will take place upon the proper principles set out in these reasons.

(2) The hearsay issue

[75] Pfizer submits that even if the Federal Court appreciated that Teva had to prove it could have supplied its version of venlafaxine in the hypothetical world, it wrongly admitted hearsay evidence on this point.

[76] Pfizer submitted that the Federal Court wrongly adopted hearsay evidence from Mr. Major. Putting aside the first-hand evidence Mr. Major offered from his two week visit to Alembic's manufacturing facility, some of the rest of his evidence consisted of things told to him by Alembic's personnel or information from other Ratiopharm (Teva) employees who got that information from Alembic's personnel. The former is hearsay, the latter is double hearsay. Pfizer says that the Federal Court erred in not excluding this evidence. Teva maintained that none of this evidence was hearsay and so the Federal Court properly admitted all of the evidence.

[77] I agree with Pfizer. The Federal Court improperly admitted hearsay evidence.

(a) General evidentiary principles

[78] In considering evidentiary issues in complicated, high-stakes cases such as this, certain high-level principles are best kept front of mind.

[79] We start with a fundamental general principle: facts must be proven by admissible evidence: see *R. v. Schwartz*, [1988] 2 S.C.R. 443 at pp. 476-77, 55 D.L.R. (4th) 1; *Canadian Copyright Licensing Agency (Access Copyright) v. Alberta*, 2015 FCA 268, 392 D.L.R. (4th) 563 at para. 20; *Canada v. Kabul Farms Inc.*, 2016 FCA 143 at para. 38. Put another way, a court can act only on the basis of facts proven by admissible evidence or evidence whose admissibility has not been contested: *Kahkewistahaw First Nation v. Taypotat*, 2015 SCC 30, [2015] 2 S.C.R. 548 at paras. 26-27.

[80] There are rarely-occurring exceptions to this. These include circumstances where facts are subject to judicial notice (see, *e.g.*, *R. v. Spence*, 2005 SCC 71, [2005] 3 S.C.R. 458), facts are deemed or presumed by legislation to exist, facts have been found in previous proceedings in circumstances where they bind the court (see, *e.g.*, *Danyluk v. Ainsworth Technologies Inc.*, 2001 SCC 44, [2001] 2 S.C.R. 460), and facts have been stipulated or agreed to.

[81] In a civil case, absent one of those exceptions, admissibility must be the court's first inquiry where an objection has been made. If the evidence is not admissible, it is not before the court in any way and, thus, the court cannot deal with it in any way.

[82] Appellate courts may interfere with admissibility decisions vitiated by errors of law: *R. v. Fanjoy*, [1985] 2 S.C.R. 233 at p. 238, 21 D.L.R. (4th) 321; *R. v. Evans*, [1993] 3 S.C.R. 653 at p. 664, 108 D.L.R. (4th) 32; *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235; and in the case of hearsay evidence, see *R. v. Saddleback*, 2014 ABCA 166, 575 A.R. 203 at para. 8. Any factual findings that affect the application of a law of evidence are entitled to deference: *R. v. Youvarajah*, 2013 SCC 41, [2013] 2 S.C.R. 720 at para. 31.

[83] Recently, some rules of evidence have been liberalized, allowing for more flexibility. Seduced by this trend towards flexibility, some judges in various jurisdictions have been tempted to rule all relevant evidence as admissible, subject to their later assessment of weight. But according to our Supreme Court, this is heresy. The trend towards flexibility has not undermined the need for judges to take a rigorous approach to admissibility, separating that analytical step from others, such as determining the weight to be given to evidence: *R. v. Khelawon*, 2006 SCC 57, [2006] 2 S.C.R. 787 at para. 59.

[84] Sometimes courts—aiming to prevent trials from bogging down—provisionally receive evidence whose admissibility is challenged, reserving their rulings on admissibility until later. In some circumstances, there may be much to commend that approach; in other circumstances, the trial may be more orderly and fair if rulings are made immediately so the parties know where they stand. It is a matter of discretion. But, in the end, before a court can rely on the evidence and ascribe it any weight or draw any inferences from it, it first must determine its admissibility.

[85] Now to the task of determining admissibility. The starting point is that evidence logically tending to prove a point is admissible: *The Queen v. Wray*, [1971] S.C.R. 272 at p. 297, 11 D.L.R. (3d) 673. If evidence does not logically tend to prove a point, it is irrelevant and inadmissible at the outset.

[86] But there are exceptions to that general principle, stated in the form of exclusionary rules. One such rule is that hearsay evidence shall not be admitted.

[87] In courts—civil, criminal or military—the hearsay rule remains in full force. Indeed, recently the Supreme Court has emphasized that hearsay evidence is presumptively inadmissible in court proceedings: *Khelawon*, above at paras. 3, 34, 42 and 59; *Youvarajah*, above at para. 18.

[88] It is true that some administrative decision-makers can ignore the hearsay rule: see, *e.g.*, the Supreme Court's discussion in *Quebec (Commission des droits de la personne et des droits de la jeunesse) v. Bombardier Inc. (Bombardier Aerospace Training Center)*, 2015 SCC 39, [2015] 2 S.C.R. 789 at para. 68. But that is only because legislative provisions have explicitly or implicitly given them the power to do that. Absent a specific legislative provision speaking to the matter, all courts must apply the rules of evidence, including the hearsay rule.

[89] The status of a particular piece of evidence as hearsay depends on its use. Hearsay is an oral or written statement that was made by someone other than the person testifying at the proceeding, out of court, that the witness repeats or produces in court in an effort to prove that what was said or written is true: see, *e.g.*, *Khelawon*, above at paras. 35-36; *R. v. Smith*, [1992] 2

S.C.R. 915 at pp. 924-925, 94 D.L.R. (4th) 590; *R. v. Starr*, 2000 SCC 40, [2000] 2 S.C.R. 144 at para. 162.

[90] This is to be distinguished from a non-hearsay use, where a witness repeats or produces a statement to prove merely that it was made. The classic expression of this distinction is as follows:

> Evidence of a statement made to a witness by a person who is not himself called as a witness may or may not be hearsay. It is hearsay and inadmissible when the object of the evidence is to establish the truth of what is contained in the statement. It is not hearsay and is admissible when it is proposed to establish by the evidence not the truth of the statement but the fact that it was made.

(*Subramanian v. Public Prosecutor*, [1956] 1 W.L.R. 965 at p. 969 (P.C.).)

[91] So if a witness says that a supplier told her that it would be able to deliver supplies on date X, and if the witness' evidence is offered to prove that the supplier would be able to deliver supplies at that time, the evidence is hearsay and falls within the rule against admission of hearsay evidence.

[92] In some cases, the fact that the supplier told the witness it would supply by date X, regardless of whether or not the supplier's statement is true, might be relevant to an issue in the proceeding and be admissible for that purpose. For example, suppose that the witness, in reliance on what the supplier told her, set aside time to work with the promised supplies. The witness may use the supplier's statement to explain why she set aside the time she did. In that case, the statement is not being used to prove that the supplier would supply by date X—a hearsay

purpose—but is being used for a non-hearsay purpose—it was the triggering event that caused the witness to do something.

[93] The same is true for documents, with an additional wrinkle, the requirement of authentication. Suppose a witness produces a printout of an email from the supplier to her stating that the supplier would supply. Absent the parties' agreement or a specific legislative provision speaking to the matter, the document must by authenticated by the witness or someone else: *Schwartz*, above at p. 476; *Evans*, above at pp. 664-65; *R. v. Schertzer*, 2011 ONSC 579 at para. 7; David M. Paciocco and Lee Stuesser, *The Law of Evidence*, 4th ed. (Toronto: Irwin Law, 2005) at p. 419; and in the case of electronic documents, see Graham Underwood and Jonathan Penner, *Electronic Evidence in Canada*, loose-leaf (Toronto: Carswell, July 2015) at 13-18.2 to 13-18.4 and the *Canada Evidence Act*, R.S.C. 1985, c. C-5, s. 31.1. For example, to authenticate the document, the witness could testify that she received the email and the printout is an exact copy of what she received. But after the document is authenticated, the communication is still hearsay if it is tendered to show that the supplier would supply.

[94] There can be multiple layers of hearsay. If a witness has a printout of an email on which she was not copied sent by the supplier to one of her colleagues assuring that colleague that supplies would be delivered by date X, the document is double hearsay if tendered to prove that the supplier would supply by date X. Someone other than the witness is reporting to the witness that the supplier told him that it would deliver by date X.

[95] When faced with hearsay objections, courts must not only appreciate the terms of the hearsay rule but should keep in mind the rationales underlying it: the need for trials to be effective in discovering the truth while ensuring procedural fairness to all parties.

[96] On this, the right of parties in a civil action to confront evidence presented against their positions is paramount. Their main instrument is cross-examination—what Wigmore has called "beyond any doubt the greatest legal engine ever invented for the discovery of truth" and what the Supreme Court has called "a vital element of the adversarial system applied and followed in our legal system…since the earliest times," of "essential importance in determining whether a witness is credible": *Wigmore on Evidence* (Chadbourne rev. 1974) vol. 5, p. 32, para. 1367; *Innisfil Township v. Vespra Township*, [1981] 2 S.C.R. 145 at p. 167, 123 D.L.R. (3d) 530; *R. v. Osolin*, [1993] 4 S.C.R. 595 at p. 663, 109 D.L.R. (4th) 478. For this reason, counsel are given the greatest latitude in cross-examination and restrictions are rare: see, *e.g.*, *C.H.D v. C.R.H.*, 2007 NSCA 1, 250 N.S.R. (2d) 138 at para. 41.

[97] To be effective, cross-examination must be able to test many aspects of witnesses' testimony—their observation, perception, memory and narration of events or facts, their accuracy in recounting or perceiving them, and their sincerity and honesty as witnesses.

[98] All of these vital objectives are lost when witnesses testify second-hand about an event. When that happens, only their sincerity and honesty about what they were told can be tested. The person who actually knows first-hand about the event or fact is out of court, shielded from any testing of their observation, memory, accuracy, sincerity or honesty.

[99] The Supreme Court recently expressed this idea as follows:

> Our adversary system puts a premium on the calling of witnesses, who testify under oath or solemn affirmation, whose demeanour can be observed by the trier of fact, and whose testimony can be tested by cross-examination. We regard this process as the optimal way of testing testimonial evidence. Because hearsay evidence comes in a different form, it raises particular concerns. The general exclusionary rule is a recognition of the difficulty for a trier of fact to assess what weight, if any, is to be given to a statement made by a person who has not been seen or heard, and who has not been subject to the test of cross-examination. The fear is that untested hearsay evidence may be afforded more weight than it deserves.

(*Khelawon*, above, at para. 35.)

[100] Even more recently, the Supreme Court confirmed that those who try to test hearsay evidence face "difficulties inherent in testing the reliability of the declarant's assertion": *R. v. Baldree*, 2013 SCC 35, [2013] 2 S.C.R. 520 at para. 31. An out of court declarant may have supplied inaccurate information but, unless in court as a witness, that possibility can never be tested:

> First, the declarant may have *misperceived* the facts to which the hearsay statement relates; second, even if correctly perceived, the relevant facts may have been *wrongly remembered*; third, the declarant may have narrated the relevant facts in an *unintentionally misleading manner*; and finally, the declarant may have *knowingly made a false assertion*. The opportunity to fully probe these potential sources of error arises only if the declarant is present in court and subject to cross-examination.

(*Baldree*, above at para. 32. [emphasis in original])

[101] The exclusionary rule against the admission of hearsay, however, does not stand alone.

[102] Over time, the law has recognized that, in certain circumstances, it is safe for courts to rely on out-of-court statements for the truth of their contents even though a party is unable to test the evidence by way of cross-examination. So certain exceptions to the hearsay rule have developed. For example, a witness could report another person's statement made against interest because of the unlikelihood of that person falsely saying something against interest.

[103] Aside from those exceptions, the Supreme Court has recently developed a more general, principled exception to the exclusionary hearsay rule. Under that broader exception, courts can admit hearsay evidence if it is necessary and reliable. See, *e.g.*, *R. v. Khan*, [1990] 2 S.C.R. 531, 59 C.C.C. (3d) 92; *Smith*, above; *R. v. B. (K.G.)*, [1993] 1 S.C.R. 740, 79 C.C.C. (3d) 257; *R. v. U. (F.J.)*, [1995] 3 S.C.R. 764, 128 D.L.R. (4th) 121; *R. v. Blackman*, 2008 SCC 37, [2008] 2 S.C.R. 298.

(b) Applying the evidentiary principles to this case

[104] No current or former Alembic employees testified at trial. Teva did not adduce any direct evidence from Alembic. Instead, Teva relied upon the testimony of Mr. Major.

[105] At all material times, Mr. Major was the vice-president for development management and regulatory affairs and a member of the executive management committee with Ratiopharm (Teva). A fair reading of the Federal Court's reasons is that the Federal Court was satisfied that Mr. Major, acting in that capacity, would have had first-hand knowledge of the corporate wishes and objectives of Ratiopharm (Teva), the steps it took to achieve those objectives, commercial

arrangements Ratiopharm (Teva) had made, and the state of the market (*i.e.*, evidence of the sort described in the transcript at pages 475-478 of the Appeal Book). As part of this, a venlafaxine supply agreement between Ratiopharm (Teva) and Alembic and another related agreement were placed before the Court: see Appeal Book at pp. 462-463. No objection was taken to this.

[106] The Federal Court took some of Mr. Major's testimony as showing that Ratiopharm (Teva) had the corporate objective of securing adequate supply of venlafaxine from Alembic, manifested that objective by making inquiries and sending documents to Alembic regarding the supply of venlafaxine should the need arise, and assured Alembic that it would redirect equipment to Alembic should the need arise at a particular time. The Federal Court considered that sort of evidence admissible on the issue of Ratiopharm (Teva)'s general intentions in the hypothetical world and evidence of the general steps it took to prepare itself for entry into the market. In this respect, the Federal Court did not err. In the words of the Federal Court during the hearing, "He does have the expertise having been employed there for a number of years to say, this is what we [Ratiopharm (Teva)] would have done [in the hypothetical world] or this is what I believe we would have done": see Appeal Book, p. 487.

[107] Similarly, by virtue of his position, Mr. Major had first-hand knowledge of the general relationship between Ratiopharm (Teva) and Alembic. He testified that the relationship was a warm, long-trusted one: see Appeal Book, p. 479.

[108] The Federal Court also properly admitted another category of evidence from Mr. Major. In 2004, over a year before the relevant supply times in the hypothetical world, Mr. Major visited

Alembic's manufacturing facility in Gujarat, India for two weeks. From this visit, he developed the view that Alembic was eager to please Ratiopharm (Teva) and was keen to do what it could to satisfy Ratiopharm (Teva)'s need for venlafaxine as it arose. Based on his visit, Mr. Major testified at trial about the capacity of Alembic's manufacturing facility and Alembic's desire to supply venlafaxine to Canada. It was open to the Federal Court judge on this record to admit the evidence of what Mr. Major saw and the conclusions he drew from his observations; however, any reports made to Mr. Major by Alembic personnel during his visit could not be used as evidence of the truth of those reports, as that would be a hearsay use.

[109] In his testimony, Mr. Major could not supply evidence based on direct, first-hand knowledge or observation of at least the following: the operating capacity of Alembic's facility during the relevant time, Alembic's actual ability and willingness to redirect or add equipment at the relevant time, and how long production at Alembic would have taken at the relevant time. Yet there is admissible evidence or evidence that was not objected to in the record that might conceivably bear on these matters, such as the venlafaxine supply agreement, Alembic's production of venlafaxine at other times, and Mr. Major's impressions, observations and conclusions he drew from his visit to Alembic's manufacturing facility. The inferences that could permissibly be drawn from the admissible evidence, in conjunction with other admissible evidence about Alembic's ability to supply venlafaxine at the relevant time, is a question I shall return to later in these reasons.

[110] During the course of his testimony, Mr. Major was presented with emails and documents, such as a spreadsheet setting out Teva's marketing forecast and associated documents, and was

asked to comment on them: see Appeal Book, pp. 466-467. Many spoke to Alembic's capacity to produce in the abstract. He neither authored nor received many of the emails and documents. In fact, out of all of the emails, he authored only one—a meeting request—that the Federal Court did not cite in its reasons. The other emails contained particular statements made by various employees of Alembic and Ratiopharm (Teva) and the documents were prepared by others or by persons unknown. Mr. Major was not in a position to authenticate emails or documents that he neither received nor sent.

[111] At the outset, counsel for Pfizer raised an objection stating that "[w]e haven't admitted these documents" and added, in the case of the first document, that "I haven't heard my friend properly identify it through this witness, other than through hearsay." He warned that he would be "standing up for a few of these documents." See Appeal Book, p. 465. I construe the objection as a warning that if Teva sought to have the documents admitted as evidence, it would have to authenticate them.

[112] Teva submits that Mr. Major could use the emails and documents to refresh his memory. I accept that if Mr. Major had some first-hand memory of matters responsive to questions posed to him, he could use unauthenticated emails and documents to refresh his memory, even if those emails and documents were themselves inadmissible: *R. v. Fliss*, 2002 SCC 16, [2002] 1 S.C.R. 535 at paras. 60-68. For example, the spreadsheet setting out Teva's marketing forecast, prepared by persons other than Mr. Major and an unauthenticated document, is not admissible through Mr. Major. But Mr. Major's knowledge of Ratiopharm (Teva)'s marketing expectations, if first-hand, is something to which Mr. Major can testify given his role (see paras. 105-108, above) and he

was free to refresh his memory using this spreadsheet. But on the issue of Alembic's production capacity, his first-hand knowledge was limited to what he saw on his visit to Alembic's manufacturing facility in 2004.

[113] At one point, Mr. Major was asked whether Mr. Woloschuk, Ratiopharm (Teva)'s Vice-President for Business Development, reported to him about Alembic's capacity to supply venlafaxine: see Appeal Book, p. 495. Pfizer objected to the question on the basis Teva was seeking to elicit hearsay evidence. If the evidence were offered as truth of Alembic's actual capacity to supply, it was. Pfizer registered similarly meritorious hearsay objections to Tabs 12-15 and 21 in the book of documents put before Mr. Major, some of which the Federal Court relied upon: Appeal Book, p. 496.

[114] Teva submits that it was not using some of the emails for the truth of their contents. It said that at best they were just corroboration of Mr. Major's testimony as to his personal knowledge of the production capacity of Alembic. But hearsay they were: whether being used as primary evidence or corroborative evidence, these emails recounting the statements of others—sometimes recounting the recounting of statements of others—were tendered for the purpose of proving what Alembic would and could have done in the hypothetical world, not just to prove the fact that they were made. And corroborative evidence must itself be evidence that is admissible: *Khelawon*, above at para. 100. There is no "corroborative evidence" exception to hearsay.

[115] Teva also suggests that statements in emails written to and from personnel in Mr. Major's department or area could be admitted as truth of their contents through Mr. Major. As discussed above, Mr. Major, by virtue of his position, could be found—as the Federal Court found— to have first-hand knowledge of the corporate wishes and objectives of Ratiopharm (Teva), how it went about achieving those objectives, and Ratiopharm (Teva)'s willingness to redirect equipment to Alembic. But he does not have first-hand knowledge of the truth of particular statements made by employees in emails they write to each other. Tendering particular statements in emails between employees in Ratiopharm (Teva) through a separate witness, such as Mr. Major, to prove the truth of the statements is a hearsay use. There is no "department head" exception to hearsay whereby specific statements in emails passing between underlings in the department can be admitted through the department head for the truth of their contents.

[116] In this case, the Federal Court explicitly relied upon some of these inadmissible emails to support its conclusions about what would have transpired in the hypothetical world: an email from Kavit Tyagi of Alembic, to Jim Mihail, a product manager with Ratiopharm (Teva)'s marketing group (at para. 154), an email exchange between Alembic and Bob Woloschuk, Ratiopharm (Teva)'s Vice-President for Business Development that reported that Alembic was only operating at 40 per cent capacity and that it was planning to expand its manufacturing plant to "double its capacity to handle at least 2 billion capsules" (at para. 156), and an email exchange between Ratiopharm (Teva) representatives and Alembic that said that had Ratiopharm (Teva) not called off production in October 2005, Alembic would have produced 6.6 million capsules by December 2005 (at para. 157). In each case, the emails are unauthenticated and are statements of others, not Mr. Major, reporting on statements made by others at Alembic. They are at least

double hearsay on the issue of what Alembic could have or would have done. And depending on whether the people at Alembic had first-hand knowledge of the matters they were describing, they might be triple hearsay or even more.

[117] Teva also invokes the state of mind exception to hearsay in support of the admissibility of emails where Alembic employees expressed a willingness or optimism about the supply of venlafaxine in the required quantities when required. It is true that an out-of-court declarant's statement tendered to show the declarant's state of mind or intention is admissible: *Brisco Estate v. Canadian Premier Life Insurance Company*, 2012 ONCA 854, 113 OR (3d) 161, citing *Smith* and *Starr*, both above. However, the emails Mr. Major referred to in his testimony—communications from colleagues about what Alembic employees said—are double hearsay: even if the state of mind exception applies, the emails remain a hearsay report by an out-of-court declarant and the emails remain unauthenticated. A further problem is that the state of mind of an Alembic employee is not necessarily the state of mind of Alembic, the corporate entity: *Canadian Dredge & Dock Co. v. The Queen*, [1985] 1 S.C.R. 662, 19 D.L.R. (4th) 314; *Rhône (The) v. Peter A.B. Widener (The)*, [1993] 1 S.C.R. 497, 101 D.L.R. (4th) 188. So proof of the employee's state of mind may be irrelevant to the issue of Alembic's state of mind and inadmissible on that basis. Finally, as *Brisco Estate* shows, the evidence goes no higher than what the employee believed or wished at that time: an inference must be drawn to extend that belief into a different time and that may not be possible. On this, again, the issue of when inferences are permissible from evidence is discussed below.

[118] In both this Court and the Federal Court, Teva did not provide evidence or submissions to the effect that the hearsay evidence nevertheless was admissible because it was reliable or necessary. Nor could it:

- *Necessity*. Many of the emails Mr. Major testified about disclose the names of many Alembic employees who might have been able to give direct testimony on Alembic's ability to supply during the relevant time. Those emails also disclose the names of personnel at Ratiopharm (Teva) who also could have been called. Teva offered no evidence or submissions as to why these individuals or others could not be called to testify. Instead, Teva called Mr. Major, who had no direct, first-hand knowledge of Alembic or its operations at the relevant time.

- *Reliability*. The hearsay evidence tendered by Mr. Major did not possess circumstantial guarantees of trustworthiness. Quite the contrary. Ratiopharm (Teva) was Alembic's client and one may presume that Alembic had an incentive to say whatever needed to be said to keep its customer pleased and give it the impression that it could satisfy its customer's needs at any time it asked.

[119] All of the mischief associated with admitting hearsay evidence is present in this case. Confronted with the hearsay evidence, all that Pfizer could do was test Mr. Major's sincerity and honesty about what he was reading from documents he did not author, what he had heard from Alembic personnel, and what colleagues were saying Alembic personnel were saying. In a high-stakes case such as this, that was hardly any sort of meaningful or fair test.

[120] Those who actually knew first-hand about whether Alembic could supply the desired quantities of venlafaxine at the relevant times in the hypothetical world—personnel at Alembic—were out of court, shielded from any testing of their observation, memory, accuracy, sincerity or honesty, but their say-so on that issue—recounted or recorded by others—was admitted into these proceedings. This worked great unfairness to Pfizer.

[121] Pfizer frequently objected to the admissibility of hearsay evidence. It was largely right to do so: in my view, every hearsay objection it made during Mr. Major's testimony was correct, except on the subject-matters discussed at paras. 105-108 and 112, above. But on a number of occasions, the Federal Court said that it would consider the weight of the evidence or it said that Pfizer's objection was one of weight, not admissibility. On one occasion, it said that because Mr. Major's name did not appear on a document, the document would "probably just go to weight." The Federal Court admitted this evidence when it should have been excluded. This was an error that might have affected the outcome of the case. Therefore, the Federal Court's judgment must be set aside.

(3) The issue whether there was palpable and overriding error on a factual finding

[122] Pfizer attacks one of the bases upon which the Federal Court found that Ratiopharm (Teva) could have supplied its product in the hypothetical world.

[123] At one point in its reasons, the Federal Court considered (at para. 152) whether any "bottleneck" in Alembic's manufacture of Ratiopharm (Teva)'s venlafaxine product in the

hypothetical world would have come at the stage of encapsulation. In finding that no bottleneck would have taken place at that stage, the Federal Court relied in part on the fact that Alembic had many fluid bed processors. But, as Pfizer notes, fluid bed processors are not used for encapsulation. Teva does not disagree.

[124] However, Teva suggests that any error by the Federal Court here was inconsequential, not overriding, and so it does not vitiate the Federal Court's judgment. Based on this Court's decision in *South Yukon*, above at paragraph 46, I agree:

> "Overriding" means an error that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall.

[125] In the course of its reasons on this point (at para. 152), the Federal Court also accepted and relied upon Mr. Major's non-hearsay testimony that if necessary, his then-employer, Ratiopharm (Teva), would have "bought equipment, put equipment in place" to avoid any bottleneck. Thus, to the extent the Federal Court misunderstood the use of fluid bed processors, I am not persuaded that its overall finding was vitiated by palpable and overriding error.

(4) Other section 8 damages issues

[126] Pfizer submits that the Federal Court erred in selecting January 10, 2006 as the start of the period of loss, or, in other words, the time when Ratiopharm (Teva) would have been legally able to start selling its venlafaxine product in the market.

[127] It submits that in the hypothetical world, Ratiopharm (Teva) would not have received a notice of compliance allowing it to sell its venlafaxine product before February 13, 2006. It says that when the '778 Patent was listed on the patent register, Ratiopharm (Teva) would have had to serve a notice of allegation addressing it and the Minister would then be prohibited from issuing a notice of compliance until 45 days had passed: see *PMNOC Regulations*, para. 7(1)(*d*).

[128] The Federal Court selected January 10, 2006, the expiry of the '540 Patent as the start date. This was the soonest Ratiopharm (Teva) could have marketed its venlafaxine product given that the Minister had certified that, but for the *PMNOC Regulations*, it would have given Ratiopharm (Teva) its notice of compliance on December 7, 2005.

[129] In my view, the Federal Court committed no error in principle in setting January 10, 2006 as the start date.

[130] In essence, Pfizer's submission is that in the hypothetical world the *PMNOC Regulations* should not be disregarded for the purpose of determining the start of Ratiopharm (Teva)'s period of loss.

[131] This submission runs counter to the express wording of paragraph 8(1)(*a*) of the *PMNOC Regulations*. That paragraph provides that the section 8 liability period begins "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 [under subparagraph 8(1)(*a*)(ii)] that … a date other than the certified date is more appropriate" [my emphasis]. Thus, it is only in circumstances

where, under subparagraph 8(1)(*a*)(ii), the Court deems that another date is more appropriate that this default date can be set aside.

[132] Pfizer's submission is also precisely the opposite of what a majority of this Court held in *Apotex Inc. v. Sanofi-Aventis*, 2014 FCA 68, 125 C.P.R. (4th) 403 at paragraph 170 (*Apotex Ramipril s. 8 FCA*): "the [*PMNOC Regulations*] are to be disregarded in determining the beginning of the section 8 liability period." On appeal, the Supreme Court of Canada affirmed those reasons: *Sanofi-Aventis v. Apotex Inc.*, 2015 SCC 20, [2015] 2 S.C.R. 136.

[133] Pfizer's submission is also contrary to the holding of a majority of this Court in *Teva Canada Limited v. Sanofi-Aventis Canada Inc.*, 2014 FCA 67, 126 C.P.R. (4th) 1 at paragraph 145 (*Teva Ramipril s. 8 FCA*):

> [145] My view, in summary, is that in the hypothetical world constructed for the purposes of determining section 8 damages, the *NOC Regulations* should not be assumed away except to the extent required by paragraph 8(1)(*a*), that is, for the purpose of determining the beginning of the section 8 liability period. For all other purposes, the *NOC Regulations* should be assumed to exist in the hypothetical world, and all steps that were actually taken under the *NOC Regulations* should be assumed to have been taken in the hypothetical world unless there is evidence upon which the trier of fact may reasonably conclude that different steps would have been taken. [my emphasis]

[134] Pfizer also takes issue with the Federal Court's conclusions concerning the entry and participation of Ratiopharm (Teva)'s generic competitors in the venlafaxine market in the hypothetical world.

[135] In the Federal Court, Pfizer submitted that Teva's damages claim would be reduced because in the hypothetical world Novopharm and Pharmascience would have entered into the market, cutting down Ratiopharm (Teva)'s market share.

[136] In dealing with this submission, the Federal Court did not have the benefit of *Apotex Ramipril s. 8 FCA*. In that case, this Court held that the regulatory barriers to entry, including the *PMNOC Regulations*, which all generic manufacturers face in the real world, also affect all generic manufacturers in the hypothetical world. Thus, in order to assess whether and when other generic manufacturers could have and would have entered the market in the hypothetical world, the Federal Court had to assess, among other things, whether regulatory barriers stood in their way.

[137] Although the Federal Court did not have the benefit of *Apotex Ramipril s. 8 FCA*, it applied principles consistent with it and committed no error in principle. It proceeded on the basis that other generic manufacturers entering the market would have had to follow the *PMNOC Regulations*. It considered all of the evidence, in part guided by real world events and based on the evidence before it, to determine whether "any other generics would have entered the market during the Relevant Period" and, if so, when (at para. 89).

[138] This was precisely in accordance with *Apotex Ramipril s. 8 FCA*. At paragraph 159 of *Apotex Ramipril s. 8 FCA*, the majority of this Court (whose reasons were adopted on appeal by the Supreme Court) agreed with the methodology the Federal Court adopted in that case. It described the methodology as follows (at para. 158):

> [I]n the hypothetical world, the competitors of a section 8 damages claimant are bound by the [*PMNOC*] *Regulations*, and…[they must be taken to] act as they did in the real world in relation to the [*PMNOC*] *Regulations* except to the extent that there is evidence upon which the trier of fact can reasonably conclude that they would have acted differently.

And a few paragraphs later, the majority confirmed the state of the law on this point (at para. 162):

> It follows that in the hypothetical market, the behaviour of competing generic drug manufacturers must be determined on the basis that the [*PMNOC*] *Regulations* exist, and each generic drug manufacturer will conduct itself accordingly.

[139] On the evidence, the Federal Court found (at para. 94) that in the hypothetical world Novopharm would have received a notice of compliance shortly after Ratiopharm (Teva). Novopharm had entered into an agreement with Wyeth (Pfizer). Under this agreement, Novopharm could obtain a notice of compliance and take steps to obtain listing on formularies soon after Ratiopharm (Teva) could. But it noted (at para. 111) that Novopharm faced problems in manufacturing venlafaxine. Considering the evidence before it, it found (at para. 129) that "Novopharm would have entered the market with Novo-Venlafaxine on December 1, 2006 in the [hypothetical] world, as it did in the real world."

[140] In the case of Pharmascience, the main question for the Federal Court was whether it would have served a notice of allegation in the hypothetical world. The Federal Court answered this in the negative (at para. 132). Pharmascience intended to time the launch of its product to coincide with a decision on the '778 Patent in favour of Ratiopharm (Teva). It was adverse to

litigation and would not act sooner (at para. 141). Therefore, the Federal Court concluded that Pharmascience would not have been ready to launch earlier than it did in the real world.

[141] Pfizer submits that in assessing what Pharmascience would have done in the hypothetical world, the Federal Court failed to sufficiently take into account real world events. In my view, this is a complaint about how the Federal Court weighed the evidence. But appellate courts are not entitled to interfere based on their own weighing of the evidence short of palpable and overriding error: *Housen*, above. In my view, the record shows real world evidence of an intention on the part of Pharmascience to delay or avoid litigation concerning the ’778 Patent.

[142] Overall, in its analysis on this point, the Federal Court did not err in principle. And, in applying the principles to the evidence before it, it did not commit any palpable and overriding error.

[143] Pfizer also says that the Federal Court erred during its calculation of damages by attributing Novopharm’s market share to Ratiopharm (Teva) without also attributing Novopharm’s rebates to Ratiopharm (Teva). Pfizer also advanced this submission below. The Federal Court dealt with it (at various places in paras. 209-227) by considering and weighing the evidence of a number of witnesses and considering what weight should be given to Novopharm’s sole-source and multi-source trade spend rates in determining Ratiopharm (Teva)’s sole-source and multi-source trade spend rates in the hypothetical world. On this issue it also preferred the testimony of Teva’s expert and made an adverse credibility finding against Pfizer’s expert (at

para. 38). Pfizer has not persuaded me that there is any palpable and overriding error in the Federal Court's analysis on this point.

(5) Pre-judgment interest

[144] On the issue of pre-judgment interest, the parties dispute the date the cause of action arose. Pfizer submits that the cause of action arose on August 1, 2007 when this Court dismissed Wyeth (Pfizer)'s prohibition application. At that point, the requirements for a claim under section 8 of the *PMNOC Regulations* were met.

[145] The Federal Court disagreed with Pfizer. In its view, the cause of action arises on the date that the damages that are the basis for the claim actually begin to be suffered. Here that was January 10, 2006. It rejected Pfizer's submission that the dismissal of the prohibition application is the relevant start date. It offered the following basis (at para. 258), with which I agree:

> The disposition of a Prohibition Application does not ground liability, it simply confirms that liability exists. The cause of action arises on the date that damages that are the basis for the claim begin to be suffered. Typically, this will coincide with when the Relevant Period begins, as it did in *Pantoprazole FC 2012* [*Apotex Inc v. Takeda Canada Inc.*, 2013 FC 1237, 123 C.P.R. (4th) 261] and as it does in this case. However, because the Relevant Period may begin before damage is actually suffered, this need not always be the case. For that reason, prejudgment interest must be tied to when the loss actually begins to be suffered irrespective of whether that date is the same as the start of the Relevant Period.

[146] On two occasions, the Federal Court has found that the cause of action under section 8 arises on the patent hold date because that is when the period of liability commences: *Apotex Inc.*

v. *Takeda Canada Inc.*, 2013 FC 1237, 123 C.P.R. (4th) 261 at paras. 173-174; *Sanofi-Aventis Canada v*. *Teva Canada*, 2012 FC 552, 410 F.T.R. 1 at paras. 297-299.

[147] Section 8 damages—damages suffered during the period when a notice of compliance could have been issued but was not by reason of the automatic stay—are analogous to an undertaking to the court to pay damages in the event a successful applicant for an interlocutory injunction should ultimately fail at trial: *Apotex Inc. v*. *AstraZeneca Canada Inc.*, 2012 FC 559, 410 F.T.R. 168 at para. 58, aff'd 2013 FCA 77, 444 N.R. 254; *Apotex Inc. v*. *Merck & Co. Inc.*, 2009 FCA 187, [2010] 2 F.C.R. 389 at para. 48. This Court has held that pre-judgment interest on an undertaking in damages runs from the date an interlocutory injunction is granted, not from the day it is set aside, because that is when the damages start to arise: *Algonquin Mercantile Corp. v*. *Dart Industries Canada Ltd.*, [1988] 2 F.C. 305, 16 C.P.R. (3d) 193 at para. 27 (C.A.).

[148] Pfizer also challenges the Federal Court's decision to calculate pre-judgment interest from the beginning of each month on the entire amount of Teva's lost profits in that month, rather than at the end of each month.

[149] In this case, the Federal Court followed the calculation of pre-judgment interest in subsection 128(3) of the *Courts of Justice Act*, R.S.O. 1990, c. C.43 as it was bound to do: *Federal Courts Act*, R.S.C. 1985, c. F-7, ss. 36(1). It applied the principles set out by the Court of Appeal for Ontario in *Celanese Canada Inc. v*. *Canadian National Railway Co.* (2005), 196 O.A.C. 60, 138 A.C.W.S. (3d) 23 at para. 17:

> The purpose of s. 128(3) is to achieve fairness in the payment of the prejudgment interest on pecuniary damages by ensuring that a plaintiff will not recover a windfall that would otherwise result were s. 128(1) to be applied. It does so by providing a formula for the accrual of interest on pecuniary damages as they are incurred, in lieu of requiring the court to conduct a series of individual calculations. Section 128(3) accords with the underlying compensatory principle for awarding prejudgment interest, which is to compensate a party for the loss of the use of its money.

[150] The Federal Court also noted that an award of interest is meant to compensate rather than punish: *Bank of America Canada v. Mutual Trust Co*, 2002 SCC 43, [2002] 2 S.C.R. 601.

[151] It also adopted the statement in *Chandran v. National Bank*, 2011 ONSC 4369, 95 C.C.E.L. (3d) 322 at para. 8, aff'd 2012 ONCA 205, 99 C.C.E.L. (3d) 277 on a different point, that "[i]nterest is due for a month as soon as the payment is owed, not after the payment has been outstanding for a month": see also *Lowndes v. Summit Ford Sales Ltd.* (2006), 206 O.A.C. 55, 47 C.C.E.L. (3d) 198.

[152] In the circumstances of this case, I see no legal error in the Federal Court's approach, nor any palpable and overriding error that would vitiate its decision. The award of interest is a discretionary matter: *Courts of Justice Act*, above, s. 130. There is no principle of law requiring that pre-judgment interest be calculated at some other date in the month.

(6) The disposition of this appeal: what should happen now?

[153] After this Court finds that a trial court erred in admitting evidence, this Court may make the judgment the trial court should have made on the basis of the remaining admissible evidence

in the record: *Federal Courts Act*, above, para. 52(b)(*i*). In other words, this Court itself can redetermine the matter.

[154] Both parties made submissions, albeit rather brief, on the redetermination. Pfizer has asked this Court to exercise its power under paragraph 52(b)(*i*) of the *Federal Courts Act* and decide that the section 8 damages claim must fail on the basis of the evidentiary record left after the hearsay evidence has been excluded. It says the remaining evidence is insufficient to support a claim for damages under section 8 of the *PMNOC Regulations*. Teva disagrees.

[155] Complicating matters is the presence in the record of some conflicting evidence that may not have been adjudicated upon before but, if admissible in accordance with the principles set out in these reasons, now may have to be adjudicated upon: see, *e.g.*, the evidence cited at Pfizer's memorandum of fact and law at para. 90.

[156] I note that on occasion this Court has declined to conduct the redetermination itself and instead has remitted it to the Federal Court: see, *e.g.*, *Kelly v. Canada*, 2013 FCA 171, 446 N.R. 339 at paras. 66-72; *Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FCA 212, 75 C.P.R. (4th) 411 at para. 80; *Zero Spill Systems (Int'l) Inc. v. 614248 Alberta Ltd.*, 2015 FCA 115, 130 C.P.R. (4th) 291 at para. 107. Redetermination by the Federal Court is a further "process" that this Court may "award" within the meaning of paragraph 52(b)(*i*) of the *Federal Courts Act*.

[157] The Federal Court is more experienced and adept in fact-finding than is this Court. Allowing it to redetermine the matter makes sense where the case is factually complex and

factually voluminous, the Federal Court has seen the witnesses and has developed views on their credibility, and the result is uncertain and factually suffused: *Turberfield v. Canada*, 2012 FCA 170, 433 N.R. 236; *Canada v. Brokenhead First Nation*, 2011 FCA 148, 419 N.R. 289; *Kelly*, above. This is often true for damages issues: *Wells v. Newfoundland*, [1999] 3 S.C.R. 199, 177 D.L.R. (4th) 73 at para. 67. As *Kelly* shows, this option has even more merit where the parties have not offered substantial or meaningful submissions to the appellate court on the redetermination.

[158] In the case at bar, all of these factors are present. In particular, to conduct the redetermination ourselves and to make the judgment the Federal Court should have made, the parties would have had to provide far more detailed submissions to us concerning the specific admissible evidence remaining in the record after the hearsay evidence is disregarded, the inferences we can permissibly draw from that evidence, and the facts that we should find based on that evidence. Even then, we might still have deferred to the Federal Court's role as a fact-finder.

[159] Thus, as a matter of discretion, in this case I would remit the redetermination to the Federal Court.

[160] Neither party has asked for the opportunity to adduce further evidence in that redetermination, *i.e.*, something akin to a retrial under paragraph 52(b)(*ii*) of the *Federal Courts Act*. The parties were right not to ask. As paragraph 52(b)(*ii*) suggests, that remedy is granted as a matter of discretion only when required by the interests of justice. One possible circumstance is

where the trial court's error has undercut the integrity, viability or fairness of much if not all of the trial. Another possible circumstance is where a legal test has been materially changed since the trial, with the result that the parties did not have a chance at trial to adduce evidence responsive to it: see, *e.g.*, *Kelly*, above.

[161] Neither circumstance is here. In particular, the issue whether Ratiopharm (Teva) could have had and would have had sufficient quantities of its version of venlafaxine to supply the market at the relevant time was a live issue in the Federal Court; indeed, as I have held, the Federal Court understood that was the operative principle. The parties made legal, practical and tactical choices regarding the evidence they should adduce or not adduce concerning that point. The interests of justice do not support relieving them of the choices they made. This Court has never done so in circumstances like this.

[162] Of course, before redetermining the matter, the Federal Court will need to receive submissions from the parties.

[163] I wish to offer some further comments to guide the Federal Court in its redetermination.

[164] The redetermination is to decide upon whether and to what extent Ratiopharm (Teva) is entitled to section 8 damages and is to be conducted by applying proper legal principles to the admissible evidence in the record. Without limiting the foregoing, the key issue for redetermination is whether in the hypothetical world Ratiopharm (Teva) would have had and could have had access to sufficient quantities of venlafaxine at the relevant time.

[165] In my view, it is not enough to establish this on the balance of probabilities by pointing *only* to sufficient manufacturing capacity a long time (here over a year) before the relevant time and Alembic's general willingness to keep its customer, Ratiopharm (Teva), happy. Perhaps as part of the totality of the admissible evidence and permissible inferences therefrom, Teva can establish its case on the balance of probabilities. That will be for the Federal Court to determine.

[166] The inadmissible hearsay evidence, identified above, of course is to be excluded. These reasons have dealt with specific pieces of evidence used by the trial judge. But it has described some other evidence generically because, for the most part, the parties spoke of the evidence in that way. As a result, disputes might arise during the redetermination concerning the admissibility of specific pieces of evidence. The Federal Court may rule on those disputes using the principles set out in these reasons.

[167] Further, viewing the remaining evidentiary record, I note that there does not appear to be direct evidence from Alembic on a number of matters, including whether it had other commitments that would have restricted or prevented its ability to supply product, whether it could have acquired sufficient quantities of raw material to manufacture the product, and whether the length of the manufacturing process would have affected Alembic's ability to supply product at the relevant time. Despite these gaps, the redetermination should examine whether other evidence in the record, taken together, along with any permissible inferences, proves that in the hypothetical world Ratiopharm (Teva) would have and could have had access to sufficient quantities of venlafaxine at the relevant time. As mentioned above, Teva bears the persuasive burden on this. And also as mentioned above, the standard of proof on this is the balance of

probabilities, not just mere possibilities: *Tervita*, above at paras. 49-51 and 66; *F.H. v. McDougall*, above at paras. 40 and 49.

[168] Excluding the inadmissible hearsay evidence from the evidentiary record leaves a smaller body of admissible evidence for the Federal Court to bring to bear in its redetermination. The Federal Court will want to identify the admissible evidence that forms that body, and then assess it in accordance with the principles set out in these reasons. In assessing it, the Federal Court may consider, with the benefit of submissions, whether it can and should draw any positive or negative inferences about what Alembic could have and would have done at the relevant time. In doing so, it should ensure that any inferences it draws are legally permissible, and offer clear reasons for why it did or did not draw a positive or negative inference.

[169] To assist the redetermination, by way of non-exhaustive guidance concerning legal limits on what inferences can be drawn from evidence, the parties and the Federal Court might wish to consider *R. v. Munoz* (2006), 86 O.R. (3d) 134, 38 C.R. (6th) 376 at paragraphs 23-31 (and authorities cited therein)—an authority now applied approvingly by several appellate courts (*District of West Vancouver (Corporation of) v. Liu*, 2016 BCCA 96, 47 M.P.L.R. (5th) 1; *United States v. Viscomi*, 2015 ONCA 484, 126 O.R. (3d) 427; *R. v. G.S.*, 2013 NUCA 5, 100 C.R. (6th) 397), the Federal Court (*K.K. v. Canada (Citizenship and Immigration)*, 2014 FC 78, 446 F.T.R. 209), and virtually every other Canadian trial court.

[170] And by way of non-exhaustive guidance on when the Court might draw adverse inferences, the parties might have regard to *Lévesque v. Comeau*, [1970] S.C.R. 1010, 16 D.L.R.

(3d) 425; *R. v. Jolivet*, 2000 SCC 29, [2000] 1 S.C.R. 751 at paragraphs 22-30; and, in this Court, authorities that apply *Lévesque* and *Jolivet* such as *Merck & Co., Inc. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 45.

E. Proposed judgment

[171] For the foregoing reasons, I would set aside the judgment of the Federal Court and remit to the Federal Court for redetermination the issue whether Teva is entitled to damages and, if so, to what extent.

[172] Pfizer has been substantially successful on appeal. I would grant it its costs of the appeal.

[173] As I propose to set aside the Federal Court's judgment, the Federal Court's award of trial costs in favour of Teva would also fall away. But I would decline to make any award of trial costs in its place. Rather, at the end of its redetermination, after it has decided who has prevailed on the merits, the Federal Court should make that award.

[174] Therefore, I would allow the appeal, set aside the judgment of the Federal Court, and remit the matter to the Federal Court for redetermination in accordance with these reasons. I would grant Pfizer its costs of the appeal.

"David Stratas"

J.A.

"I agree
C. Michael Ryer J.A."

"I agree
Mary J.L. Gleason J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-422-14
APPEAL FROM THE JUDGMENT OF THE HONOURABLE MR. JUSTICE ZINN DATED JUNE 30, 2014, NO. T-1844-07	
STYLE OF CAUSE:	PFIZER CANADA INC. v. TEVA CANADA LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 1, 2015
REASONS FOR JUDGMENT BY:	STRATAS J.A.
CONCURRED IN BY:	RYER J.A. GLEASON J.A.
DATED:	MAY 31, 2016

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