Federal Court  Cour fédérale

Date: May 26, 2017

Docket: T-1844-07

Citation: 2017 FC 526

Ottawa, Ontario, May 26, 2017

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

PFIZER CANADA INC.

Defendant

JUDGMENT AND REASONS

[1] At trial, it was found that the Plaintiff had made its case for damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the *PMNOC Regulations*]: See *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 248 [the Trial Decision] and *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 634 [the Judgment].

[2] On appeal, the Federal Court of Appeal held that the Trial Decision relied, in part, on evidence that was not admissible for the truth of its content; it was hearsay.[1] The Federal Court of Appeal set aside the judgment and remitted the matter back to this Court to redetermine "the

issue whether Teva is entitled to damages and, if so, to what extent": *Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161 [the Appeal Decision]. At paragraph 164, it stated that:

> 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 the 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. [emphasis added]

Background

[3] The background to this claim for damages pursuant to section 8 of the *PMNOC Regulations* is set out in the Trial Decision at paragraphs 14 to 24 and in the Appeal Decision at paragraphs 6 to 12 and 19 to 27. For the purposes of this redetermination, the following are the relevant background facts.

[4] The Defendant is the corporate successor to Wyeth and Wyeth Canada [Wyeth]. The Plaintiff is the corporate successor to ratiopharm inc. [Ratiopharm].

[5] Wyeth marketed an extended release version of venlafaxine hydrochloride [Venlafaxine] under the trade name Effexor XR, under Canadian Patent 1,248,540 [the 540 Patent]. When Ratiopharm made the decision to market a generic form of Venlafaxine, the 540 Patent was the only patent listed against Effexor XR on the Patent Register and it was due to expire on January 10, 2006.

[6] Kent Major, then Ratiopharm's Vice-President for Development Management and Regulatory Affairs, testified that Ratiopharm (then named Altimed Pharma Inc.) became

interested in Venlafaxine around 2000.[2] The first step taken by Ratiopharm to be in a position to market a generic Venlafaxine, was to enter into an agreement with Karma Pharm, Ltd. [KarmaPharm] on April 18, 2002, to obtain the exclusive rights to KarmaPharm's formulation for generic Venlafaxine.[3]

[7] Ratiopharm then looked for a party to manufacture its generic Venlafaxine. Ratiopharm selected BioArc Research Solutions, a Division of Alembic Limited [Alembic] to manufacture both the generic Venlafaxine active pharmaceutical ingredient [API] and the Ratiopharm Venlafaxine capsules.

[8] Mr. Major testified that "Alembic is a pharmaceutical manufacturer of both active pharmaceutical ingredients and dosage form located in Gujarat, India." He also testified that "Alembic had a long relationship with [Ratiopharm] as an API supplier, and we were aware of their intentions to go into the dosage form business as well."[4] [emphasis added]

[9] On March 24, 2004, Ratiopharm and Alembic entered into the first of two agreements relating to generic Venlafaxine - a development contract [the Development Agreement].[5] Pursuant to the Development Agreement, Alembic manufactured bio-batches of the generic Venlafaxine which Ratiopharm used to demonstrate to Health Canada that its product was bio-equivalent, met purity and safety standards, and that the manufacturing process was robust. Mr. Major testified that its demonstration was contained in the Abbreviated New Drug Submission [ANDS] for Ratiopharm's generic Venlafaxine, which Ratiopharm filed with Health Canada on February 24, 2005.[6]

[10] As part of the Health Canada approval process, in 2004, when Alembic was manufacturing the bio-batches, Mr. Major spent two weeks at Alembic's facilities alongside a Health Canada Inspector who inspected and certified the facilities as meeting Good Manufacturing Practices. This visit provided Mr. Major with personal knowledge, based on his experience in the pharmaceutical business and his observations, of the capacity of Alembic's facilities at that time. The Federal Court of Appeal accepted that it was open to "admit the evidence of what Mr. Major saw and the conclusions he drew from his observations."[7]

[11] On December 7, 2005, Health Canada informed Ratiopharm that it had completed its review of the ANDS and that a notice of compliance [NOC] would issue after the requirements of the *PMNOC Regulations* had been met. Ratiopharm had planned for a launch date after the expiry of the 540 Patent on January 10, 2006, and at that date, but for subsequent actions by Wyeth, it would have met all of the requirements under the *PMNOC Regulations*.

[12] In order to have product to launch and meet market demand, on April 13, 2005, some nine months before its anticipated launch, Ratiopharm and Alembic entered into a second contract [the Licence and Supply Agreement], pursuant to which Alembic agreed to manufacture and supply Ratiopharm with generic Venlafaxine.[8] Article 3.1 of the Licence and Supply Agreement provided:

> Alembic shall supply exclusively to ratiopharm and ratiopharm shall purchase exclusively from Alembic, <u>all of ratiopharm's requirements of Product</u>. [emphasis added]

[13] Ratiopharm, through Alembic, was manufacturing the API, and encapsulating the generic Venlafaxine, and complying with all regulatory requirements in order to be on the market on

January 10, 2006. In the real world, Ratiopharm did not expect that it would be the sole generic on the market.[9] In fact, Ratiopharm had entered into a cross-licence agreement with Pharmascience Inc. [Pharmascience] pursuant to which Pharmascience was permitted to use Ratiopharm's generic formulation and sell generic Venlafaxine under its name. Of note, their agreement also provided that Pharmascience would inform Ratiopharm of the quantities needed, and Ratiopharm would place orders in those amounts with Alembic, which would manufacture and deliver to Pharmascience the Pharmascience Venlafaxine. Thus, Alembic would be supplying both Ratiopharm and Pharmascience with generic Venlafaxine for the Canadian market. It was found in the Trial Decision, that in the but-for world, Pharmascience did not enter the market in the Relevant Period; thus in the but-for world, Alembic was required only to meet the Canadian market requirements of Ratiopharm.

[14] While Ratiopharm expected other generic companies to enter the generic Venlafaxine market, only Novopharm entered the Canadian market in the Relevant Period and it did so on December 1, 2006, under licence from Wyeth and after obtaining its NOC. In the Trial Decision, it was found that had Wyeth not taken the actions described immediately below, Ratiopharm would have occupied the entire generic Venlafaxine market from January 10, 2006, to December 1, 2006, when Novopharm commenced selling its product, and that thereafter Ratiopharm's share of the generic market would have eroded at the same rate that Novopharm's did in the real world when Ratiopharm actually entered the market.

[15] In May 2005, Mr. Major and others at Ratiopharm were warned that there was a "very strong likelihood" that Wyeth would try to "evergreen" Effexor XR by listing a new patent

against it on the Patent Registry, and it was expected that it would likely take this action in October or November 2005.[10] Mr. Deneke, a witness at trial, advised Ratiopharm officials in September 2005, that Wyeth had received an NOC for a new indication on September 1, 2005, for Effexor XR, thus making the likelihood of Wyeth being able to evergreen its product a strong likelihood.[11]

[16] If Wyeth added a new patent on the Patent Register against Effexor XR, and did so prior to the expiry of the 540 Patent, then Ratiopharm would be required to wait until that patent expired or was delisted to market its generic Venlafaxine. Although no new patent had yet been added to the Patent Registry, as a precaution, on October 24, 2005, Ratiopharm directed Alembic to put a hold to converting API to the manufactured product but to "complete the present production cycle and transfer any finished bulk to bright stock."[12]

[17] In fact, Canadian Patent 2,199,778 [the 778 Patent] was listed by Wyeth on the Patent Register as against Effexor XR on December 23, 2005. As a consequence, Ratiopharm was prevented from entering the Venlafaxine market and it remained so prevented until August 1, 2007 when the Federal Court of Appeal held that the 778 Patent was not eligible for listing: See *Ratiopharm Inc v Wyeth Canada*, 2007 FCA 264. That judgment cleared the way for Ratiopharm to launch into the Canadian market with its generic Venlafaxine.[13] It did so on September 18, 2007, and on October 22, 2007, it commenced this action against Wyeth pursuant to section 8 of the *PMNOC Regulations*.

[18] There is no dispute that in these circumstances, having improperly kept Ratiopharm off the market, Wyeth is "liable to the second person [Ratiopharm] for any loss suffered during the period." The question requiring the Court's attention is what loss, if any, Ratiopharm has proven on the balance of probabilities that it suffered.

[19] The test to establish damages under section 8 of the *PMNOC Regulations* is the 'but-for' test. A plaintiff must show on a balance of probabilities that it suffered a loss that but-for the defendant's wrongful conduct, it would not have suffered. In this action, Ratiopharm claims that but-for the wrongful act of Wyeth, it would have entered the generic Venlafaxine market on January 10, 2006, and thus it suffered the loss of the sales it would have made from January 10, 2006, to August 1, 2007, when it was able to enter the market.

[20] The Federal Court of Appeal in *Apotex Inc v Merck & Co Inc*, 2015 FCA 171 at paragraph 45 [*Lovastatin FCA*], has instructed that "the 'but-for' test for causation is to be applied in a 'robust common sense fashion'." In doing so, the Federal Court of Appeal referenced the judgment of the Supreme Court of Canada in *Clements v Clements*, 2012 SCC 32, an action in negligence, wherein at paragraphs 8-9, the majority stated the following:

> The test for showing causation is the "but for" test. The plaintiff must show on a balance of probabilities that "but for" the defendant's negligent act, the injury would not have occurred. Inherent in the phrase "but for" is the requirement that the defendant's negligence was *necessary* to bring about the injury -- in other words that the injury would not have occurred without the defendant's negligence. This is a factual inquiry. If the plaintiff does not establish this on a balance of probabilities, having regard to all the evidence, her action against the defendant fails.
>
> The "but for" causation test must be applied in a robust common sense fashion. There is no need for scientific evidence of the precise contribution the defendant's negligence made to the injury.

> See *Wilsher v. Essex Area Health Authority*, [1988] A.C. 1074 (H.L.), at p. 1090, *per* Lord Bridge; *Snell v. Farrell*, [1990] 2 S.C.R. 311. [emphasis added]

[21] In the context of this redetermination, the Federal Court of Appeal has directed that it is incumbent on Ratiopharm to show, on the balance of probabilities, either by way of admissible evidence or inference from such evidence, that it would have entered the generic Venlafaxine market and that it could have done so in the January 10, 2006 to August 1, 2007 period [the Relevant Period]. The Federal Court of Appeal observed that "would have" and "could have" are different aspects of the test, both of which have to be satisfied by a section 8 plaintiff. At paragraph 72 of the Appeal Decision, it is stated that whether Ratiopharm wanted to supply the market and whether Alembic was willing to produce Venlafaxine addresses the "would have" aspect; whereas whether Ratiopharm, and Alembic as its manufacturer and supplier, was able to supply the generic Venlafaxine market (or part of it) addresses the "could have" aspect.

[22] The Federal Court of Appeal at paragraph 169 of the Appeal Decision, directed the attention of this Court and the parties to the decision of Justice Ducharme of the Ontario Superior Court in *R v Munoz* (2006), 86 OR (3d) 134, 38 CR (6th) 376 at paragraphs 23-31, concerning the "legal limits on what inferences can be drawn from evidence." The principles set out in that decision have recently been summarized by this Court in *K (K) v The Minister of Citizenship and Immigration*, 2014 FC 78 at paragraph 61, in the following manner:

> - An inference is a conclusion that follows logically and reasonably to a sufficient degree of probability from accepted facts by the application of an inductive reasoning process that utilizes the uniformity of prior human experience as its benchmark.

> ● The facts that are said to provide the basis for the inference must be established by the evidence and cannot be substituted for by speculation.
>
> ● Because there is no bright line, drawing a distinction in degrees of probability between permissible reasonable inferences and impermissible speculation is often a very difficult task.
>
> ● Drawing inferences is not about possibilities, nor is it a process of creating a hypothetical narrative, or applying subjective imagination even where the circumstances permit an educated guess.
>
> ● Inferences need not be the most obvious or the most easily drawn; all that is required is that the inference be reasonable and logical. [emphasis added]

[23] Ratiopharm submits, with respect to the fourth bullet above, that it must be kept in mind that the but-for world is entirely hypothetical as the Federal Court of Appeal noted at paragraph 46 in the Appeal Decision: "In effect, the court is examining a hypothetical world."

[24] At trial, it was found that the overall Venlafaxine market in the Relevant Period was 361,506,200 capsules, and that in the but-for world the generic share of that overall market would be 248,640,087 capsules.[14]

[25] It is relevant to recall that Ratiopharm would not have supplied all 248,640,087 capsules of generic Venlafaxine during the Relevant Period, because it was found at trial that "[f]rom December 1, 2006, onwards, Ratiopharm's market share would have eroded at the same rate as Novopharm's did in the real world as a result of Ratiopharm entering the market, with an adjustment for any differences in formulary listing dates between Novopharm and

Ratiopharm."[15] If Ratiopharm met the would-have-could-have test, then it would have sold slightly less than 248,640,087 capsules in the Relevant Period.

[26] It was also found at trial that every generic works to be the first to market. The reason is set out at paragraph 136 of the Trial Decision:

> It is not disputed that the goal of every generic is to be the first to market, but if not the first to be tied for first. Coming second or later is never the goal. The first generic to market has the advantage. It is the only generic alternative to the innovator product and given the provincial formulary and many private plan requirements that the generic product is to be used to fill a prescription, it will quickly occupy a large share of the market. Once established, the evidence is that it is difficult for another generic to displace the first generic's product on the pharmacy shelves.

[27] Mr. Major testified that "we were ambitious and we felt that we would have a shot at being the first into market space."[16] In the but-for world, Ratiopharm, unlike all of the other generic hopefuls, did not have to address the 778 Patent: See *Apotex Inc v Sanofi Aventis*, 2012 FC 553 at paragraphs 156-158; and *Apotex Inc v Takeda Canada Inc*, 2013 FC 1237 at paragraph 56. Consequently, in the but-for world, Ratiopharm would have known that while the 778 Patent would prevent its competitors from entering the generic Venlafaxine market on January 10, 2006, it had no such impediment. As a consequence, Ratiopharm would have known that it would be the first generic into the Venlafaxine market or, at the very least, have known that it was highly probable that would be the case. The actions that it would have and could have taken in the but-for world must be considered in light of that very important background.

[28] Mr. Major also testified that in 2006, Ratiopharm was the third largest generic pharmaceutical company in the Canadian market, after Apotex and Novopharm. The difference between Novopharm and Ratiopharm was "less than 3 per cent market share and around about $50 million" in gross sales, which he testified was "about one product launch."[17] In addition to its Canadian operation, Mr. Major testified that Ratiopharm at the relevant time was the third largest generic manufacturer in the world, and had the largest generic production facility in Europe.[18]

[29] Mr. Major testified that in the real world, it takes time for a generic to erode the market share held by the innovator, and there is no reason to think the same would not occur in the but-for world. The evidence of Mr. Major was that at the end of the first year, Ratiopharm could have expected to have occupied 50% of the market held by Wyeth. In other words, in the but-for world when Ratiopharm commenced selling in the market, it would have 0% of the market and Wyeth would have 100%, but at the end of the first year, each would occupy 50% of the market, more or less.[19]

[30] Before addressing the material issues on this redetermination, I wish to say a few words about admissible evidence.

Admissible Evidence

[31] Admissible evidence is evidence the trier of fact is legally permitted to consider. Justice Watt in *R v Candir*, 2009 ONCA 915[20] at paragraph 50 stated:

> Admissibility is wholly and exclusively a creature of the law. The rules of admissibility, for the most part negative, exclude evidence that is both relevant and material. A rule of admissibility need not

> be invoked when an item of evidence is either irrelevant or immaterial. Evidence is admissible if it satisfies all applicable exclusionary rules.

[32] An issue raised by the parties on this redetermination is whether the Court is permitted to consider the "evidence" in the record that was not previously objected to by Wyeth at trial or on appeal, or whether the Court is now required to review that trial record with a fresh eye and exclude all inadmissible evidence. This issue arises because Wyeth is now objecting to other evidence in the record on the basis that it is hearsay and inadmissible, when no such objection was previously made.

[33] There is Canadian jurisprudence that a trial judge has a duty to reject inadmissible evidence even though no objection was made to it at trial: See *Young v Denton*, [1927] 1 DLR 426 (Sask CA); *McLeod v Pearson et al*, [1931] 4 DLR 673 (Alta SC); *Stadel v Stadel*, [1959] MJ No 71 (Man QB). In *Young v Denton*, Justice Martin at 433-434 put it as follows:

> In Phipson on Evidence [6th ed], p. 688, the author says: --"If inadmissible evidence has been received (whether with or without objection), it is the duty of the Judge to reject it when giving judgment; and if he has not done so, it will be rejected on appeal, as it is the duty of Court to arrive at their decisions upon legal evidence only."
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> This statement of the law appears to me to answer the contention of counsel for the defendant that, inasmuch as the admission of the memorandum was not objected to, it is now too late to take the objection.

[34] Justice Martin cites only a part of the passage from *Phipson on Evidence*. The entire passage, which provides for a more nuanced approach than the Court's statement suggests, is this:

> If inadmissible evidence has been received (whether with or without objection), it is the duty of the Judge to reject it when giving judgment; and if he has not done so, it will be rejected on appeal, as it is the duty of Courts to arrive at their decisions upon legal evidence only; a party may however, by his conduct at the trial, be precluded from objecting to such evidence. [emphasis added and cited authorities omitted]

[35] On the other hand, there is authority that a failure to raise any objection at trial regarding the admissibility of evidence may be fatal if that party attempts to raise it on appeal: See Lederman, Bryant & Fuerst, *The Law of Evidence in Canada*, 4th ed (Markham: LexisNexis, 2014), §2.98:

> In a civil case, an objection on appeal will not usually succeed unless the objection is made at the trial. A failure to object may constitute the tacit waiver of a privilege that would otherwise apply to make the document inadmissible. [emphasis added]

[36] The Supreme Court of Canada has warned that when counsel has failed to challenge the admissibility of evidence, trial judges ought not to take it upon themselves to do so. Although stated in a criminal context, the following passage from *R v T (SG)*, 2010 SCC 20 at paragraphs 35-36, in my view, applies equally in the civil context:

> More importantly, in deciding whether there was clear evidence that ought to have triggered the need for the trial judge to raise the issue on his own motion, an appellate court must consider the question from the perspective of the trial judge at the time the decision was made.
>
> Here, the most significant circumstance is that the defence consented to the admission of the evidence. In an adversarial system of criminal trials, trial judges must, barring exceptional circumstances, defer to the tactical decisions of counsel: see generally *R. v. Lomage* (1991), 2 O.R. (3d) 621 (C.A.), at pp. 629-30. There is a "strong presumption" that defence counsel are competent in advancing the interests of their clients: see *R. v. G.D.B.*, 2000 SCC 22, [2000] 1 S.C.R. 520, at para. 27; *Hodgson*,

> at para. 99. Moreover, counsel will generally be in a better position to assess the wisdom, in light of their overall trial strategy, of a particular tactical decision than is the trial judge. By contrast, trial judges are expected to be impartial arbiters of the dispute before them; the more a trial judge second-guesses or overrides the decisions of counsel, the greater is the risk that the trial judge will, in either appearance or reality, cease being a neutral arbiter and instead become an advocate for one party. For these reasons, this Court has previously held that the burden to raise evidentiary issues properly rests on the shoulders of counsel: *Hodgson*, at para. 98. [emphasis added]

[37] In addition to this rationale, it is my view that on a redetermination of a fundamental issue at trial based on an existing trial record, the principle of fairness dictates that the Court deal with the record as it stands and not as one party might wish it to stand. This is so because there is now no possibility for Ratiopharm to cure any deficiency or to supplement its case by leading other evidence, whereas there would have been such an opportunity had the objection been raised by Wyeth at trial thus putting Ratiopharm on notice of its position. This is exactly what occurred with respect to the hearsay objections it raised regarding some of the tendered evidence. Ratiopharm knew that Wyeth had objections and, although the objection was overruled, it had the opportunity to consider its case, including the likelihood of an appeal, and an opportunity to supplement the evidence that had been put before the Court. No such opportunity now exists with these new objections.

[38] This is the position advanced and the rationale given by the British Columbia Court of Appeal in *Lam v Chiu*, 2014 BCCA 32, wherein at paragraphs 47-48, it stated:

> If a party objects to the admissibility of evidence, then that objection should be made in a timely manner, namely at the time the evidence is tendered. This is particularly so in civil cases. As Chief Justice Macdonald stated in *Hall v. Geiger*, [1930] 3 D.L.R. 644 at 644 (B.C.C.A.), "The Court assumes that where no

> objection is taken to evidence, it is not regarded as of any prejudice to the defendant, the person who might have taken the objection." See also: *McBryde v. Womack*, 2013 BCCA 260 at paras. 52 - 57, 44 B.C.L.R. (5th) 209; *Bransford v. Yilmazcan*, 2010 BCCA 271 at para. 24, 320 D.L.R. (4th) 535; *Mallet v. Alberta (Motor Vehicle Accident Claims Act, Administrator)*, 2002 ABCA 297 at paras. 62 - 65, 15 Alta. L.R. (4th) 231. …
>
> Another consideration is that had a timely objection been taken, Mr. Lam might have been able to establish a basis for admitting the notes. In his factum, Mr. Lam advances several such arguments to which Ms. Chiu has filed a reply. However, because of the position taken by Ms. Chiu at trial, this Court does not have available the record necessary to deal with all of those arguments. The following statement by Mr. Justice Doherty in *R. v. Bero* (2000), 151 C.C.C. (3d) 545 (Ont. C.A.), is equally apt in civil cases:
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> > [12] It would be wrong for this court to undertake the analysis required to decide whether the evidence was admissible based on a record in which none of the relevant considerations were explored because the defence chose not to litigate the admissibility of the evidence at trial. Absent any suggestion of ineffective representation at trial, or some other adequate explanation for the absence of any objection to admissibility at trial, I would not give effect to an argument that comes down to the contention that an accused should receive a new trial on the ground that had he chosen to challenge the admissibility of evidence at trial he might have been successful.

[39] Wigmore takes a similar approach to that stated in *Phipson on Evidence*: A failure to raise a timely objection at trial constitutes a waiver of the right to later raise an objection:

> A rule of evidence not invoked is waived. The authority gathered below and the various decisions, rules and codes gathered throughout this section show that this principle is well established.[21]

[40] The Federal Court of Appeal, in rejecting a late challenge to the admissibility of expert evidence in a section 8 claim for damages in *Pfizer Canada Inc v Apotex Inc*, 2014 FCA 54, offered a rationale similar to that expressed above. There, Justice Gauthier for the Court, at paragraphs 9-11 stated:

> The Supreme Court of Canada in [*R. v J.-L.J.*, 2000 SCC 51, [2000] 2 S.C.R. 600] at paragraph 28 observed that the admissibility of expert evidence should be scrutinized "at the time it is proffered". There is an important rationale behind the preclusion of objections to the admissibility of evidence on appeal: had the objection been made in a timely way before or at trial, the parties would have been able to conduct examinations of the person presented as an expert, the trial judge would have made all appropriate factual and credibility findings on the matter, after the ruling of the trial judge the parties might call other evidence or adjust their examinations of other witnesses accordingly, and the appellate court would have the reasons of the trial judge. [emphasis added]
>
> It is also material to consider that nowadays, complex civil cases like pharmaceutical patent cases are court managed from the start to ensure that there is full disclosure of all the evidence and of all the issues to be determined before the trial or at the trial in a manner that will ensure the most efficient prosecution of the case and use of court resources. In this context, trial judges should generally be allowed to rely on experienced counsel who have the assistance of their technical experts to raise admissibility issues, especially those regarding the reliability of scientific evidence. The court must be especially vigilant to prevent tactical conduct: *Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34 at paragraph 37.
>
> However, there are cases where appellate courts will use their discretion to consider admissibility issues despite the absence of an objection at first instance. Pfizer referred to a few such cases. But considering all the circumstances of this case, especially those set out in paragraph 8 above, this Court should refuse to consider the admissibility issue for the first time on this appeal.

[41] Like the Federal Court of Appeal, I am concerned that Wyeth's recent objection to admissibility is seriously prejudicial to Ratiopharm. It cannot advance other evidence or take

any of the steps it might have taken at trial had it known that admissibility of unchallenged evidence would be at issue, whether then or now. For this reason, I will not entertain any new objection to admissibility proffered by Wyeth.

[42] This approach is consistent with the direction provided in paragraph 109 of the Appeal Decision which draws a distinction between admissible evidence and evidence not objected to at trial: "Yet there is admissible evidence or evidence not objected to in the record that might conceivably bear on these matters … ." [emphasis added] In my assessment, the Federal Court of Appeal in so stating recognized that there may be evidence in the record that might be inadmissible had a timely objection been made, but it may be considered on this reconsideration because no objection was made at trial to that evidence being received.

[43] With this background and instruction, I turn to the issue on this redetermination, which I will address by responding to three questions:

1. Would Ratiopharm have wanted to supply the market with generic Venlafaxine in the but-for world during the Relevant Period and was Alembic willing to produce Venlafaxine? This is responsive to the "would have" requirement of the analysis.
2. Was Ratiopharm, through Alembic, able to supply the market with generic Venlafaxine during the Relevant Period? This is responsive to the "could have" requirement of the analysis.
3. If Ratiopharm, through Alembic, would have and could have supplied the market with generic Venlafaxine in the Relevant Period, then would it and could it have access to sufficient quantities to supply all or a part of the generic market?

The "Would Have" Analysis

[44] Leaving aside for the moment the question of the size of the generic Venlafaxine market, there is ample admissible evidence from which to conclude on the balance of probabilities that Ratiopharm wanted to supply the market with generic Venlafaxine and that Alembic wanted and was willing to produce it for Ratiopharm.

[45] When judging a claim made pursuant to section 8 of the *PMNOC Regulations*, and having to make findings as to what would have and could have happened had the innovator pharmaceutical company not acted in the manner that it did to prevent the generic from entering the market, a judge is constructing a hypothetical world. It has been often observed by this Court that the construct of that hypothetical world is often best informed by what happened in the real world: See e.g. *Apotex Inc v Takeda Canada Inc*, 2013 FC 1237 at paragraph 21.

[46] At trial, admissible evidence was lead through the testimony of John Kane Deneke and Kent Major, in addition to admissible exhibits entered during their testimony (discussed below), that Ratiopharm very much wished to supply the market with generic Venlafaxine in the Relevant Period. Aside from the evidence of Ratiopharm's witnesses as to the "wishes" of the company, this is evidenced by the fact that Ratiopharm had previously taken the required and appropriate steps to be in a position to do so commencing in January 2006.[22]

[47] As noted above, in 2002, Ratiopharm negotiated the rights to KarmaPharm's generic Venlafaxine product in anticipation of being able to enter the Canadian market upon the expiry of the 540 Patent. It also, in 2005, entered into two agreements with Alembic; the first for the

development of the product and the second for the manufacture of the product. No objection was taken to either of these agreements when tendered as evidence. There is evidence from Mr. Major, again made without objection, that pursuant to these agreements Alembic manufactured both the API and the generic Venlafaxine capsules that Ratiopharm intended to market. Moreover, as detailed immediately below, it did so in a manner satisfactory to Health Canada. In entering into these agreements, Ratiopharm had secured a willing and able supplier of the generic Venlafaxine product. In taking these steps, Ratiopharm had satisfied all of the practical requirements to be able to enter the generic Venlafaxine market in January 2006, had Wyeth not listed the 778 Patent when it did.

[48] Ratiopharm ensured that the Alembic plant was inspected and certified by Health Canada. In February 2005, Ratiopharm filed its ANDS with Health Canada for its generic Venlafaxine.[23] No objection was raised to the ANDS being entered as an exhibit. On February 24, 2005, Ratiopharm received a letter from Health Canada acknowledging the receipt of the ANDS.[24] By letter dated December 9, 2005 from Health Canada [the Patent Hold Letter], Ratiopharm was advised that the examination of its ANDS had been completed on December 7, 2005, and that an NOC would issue once the requirements of the *PMNOC Regulations* were met.[25] Again, there was no objection made to any of these letters being entered as exhibits. In taking these steps and receiving the approvals of Health Canada, Ratiopharm had satisfied all the legal requirements to be able to enter the generic Venlafaxine market in January 2006, had Wyeth not listed the 778 Patent when it did.

[49] In addition to the above, in the Licence and Supply Agreement, Alembic committed to "supply exclusively to ratiopharm … all of ratiopharm's requirements of Product."[26] It was acknowledged by counsel for Wyeth, that this agreement is admissible to show the intention of the parties at the time when it was entered into.[27] In short, it proves that Alembic was willing to produce the generic Venlafaxine, which goes to the "would have" aspect of the test. Moreover, Alembic actually did manufacture bio-batches and a full batch of the generic Venlafaxine prior to January 2006. There can be no better evidence of its willingness to supply Ratiopharm with generic Venlafaxine, than the fact that in the real world it did just that.

[50] The above evidence satisfies me, on the balance of probabilities, that Ratiopharm (through Alembic) would have entered the market with generic Venlafaxine at the commencement of the Relevant Period on January 10, 2006, but for the wrongful actions of Wyeth. The same evidence supports a finding that it would have continued in the market having entered it.

The "Could Have" Analysis

[51] Much of the admissible evidence relied on above for the "would have" analysis is also relevant to the "could have" analysis. In this section, the question to be addressed is whether Ratiopharm (and Alembic as its manufacturer and supplier) was able to supply the market with generic Venlafaxine at the relevant time. Again, the quantity of generic Venlafaxine it would be able to supply is left aside for the moment.

[52] In addition to having complied with all regulatory requirements in the but-for world, and having secured a manufacturer and supplier of its generic Venlafaxine, Ratiopharm had placed

orders with Alembic to manufacture the product so that it would be in a position to enter the market in January 2006. There is uncontroverted evidence from Mr. Major that Alembic had manufactured "quantities" of the generic Venlafaxine for the "purpose of the proposed January 2006 launch."[28] Alembic had manufactured and had in storage "saleable" bio-batches of the generic Venlafaxine produced for the purposes of the ANDS, and it also had the initial larger scale batch that had been manufactured prior to Ratiopharm directing Alembic to stand-down manufacturing due to the probable 778 Patent listing.[29] His uncontradicted evidence was that if Ratiopharm had not directed Alembic to cease production, then by January 2006, it would have had 6.6 million capsules in addition to the bio-batches, bringing the inventory to "probably around 7 million."[30]

[53] Mr. Major testified that the quantity of product at hand as described above would have permitted Ratiopharm to have launched its product in January 2006.[31] Although the product was in India, Mr. Major testified that Ratiopharm would have used air freight to move the product to Canada had it been necessary in order to have the product in Canada to launch in January 2006.[32]

[54] The question whether Alembic could have supplied product to Ratiopharm to launch in January 2006 is answered by this same evidence. It had in fact manufactured some product – bio-batches, one full production run, and additional API, before it was told by Ratiopharm to put a hold on production. It is a reasonable and logical inference from the evidence that but-for Ratiopharm stopping production because of the wrongful conduct of Wyeth, Alembic was in a

position to be able to produce sufficient quantities of the product to permit Ratiopharm to commence and continue marketing its generic Venlafaxine.

[55] The answer to the question whether Ratiopharm (and Alembic as its manufacturer and supplier) was able to supply the market with generic Venlafaxine at the relevant time is that it was. There is admissible evidence that but-for Wyeth's actions, Ratiopharm could have had sufficient product on hand from Alembic to launch its product. There is no evidence that would support any supposition (and none was advanced) that at any time during the Relevant Period Ratiopharm (through Alembic) would cease having generic Venlafaxine to market.

[56] Thus, the second part of the test has been satisfied on the balance of probabilities.

The Portion of the Market Analysis

[57] Having found that Ratiopharm and Alembic would have and could have supplied the market at the relevant time with its generic Venlafaxine, the final question to address 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 [emphasis added]."[33] This essentially turns on the extent of Alembic's ability to supply Ratiopharm with its generic Venlafaxine, as Ratiopharm would undoubtedly be willing to sell as much of it as the market demanded. At trial, it was found that Ratiopharm would have been the sole generic on the market from January 10, 2006 to December 1, 2006, and thereafter, when Novopharm entered the generic market, Ratiopharm's share would have eroded at the same rate as Novopharm's market share in the real world eroded to Ratiopharm's product.[34]

[58] I have already found that the evidence proves on the balance of probabilities that Ratiopharm (through Alembic) would have had and could have had access to a sufficient quantity of generic Venlafaxine to enter the market on January 2006. There is no evidence that but-for the listing of the 778 Patent, Alembic could have or would have ceased manufacturing the generic Venlafaxine during the Relevant Period, or that Ratiopharm would have directed it to do so.

[59] Wyeth submits at paragraphs 18 and 19 of its Written Argument on Redetermination that the question before the Court is as follows:

> The only issue on this redetermination is whether Ratiopharm, through Alembic, would have and could have supplied 100% of the Canadian venlafaxine market during the relevant period.
>
> There are only two possible outcomes on redetermination: (i) the Court can find that Ratiopharm would have and could have supplied 100% of the venlafaxine market during the relevant period; or (ii) the Court can find that Ratiopharm would not have and/or could not have supplied 100% of the venlafaxine market during the relevant period, such that Teva is not entitled to any damages. Teva has not pleaded or sought to establish any alternative scenario.

[60] One difficulty with this submission is that it was never found that Ratiopharm would or could supply "100% of the venlafaxine market." At paragraph 11 of its Written Argument, Wyeth states that the entire Venlafaxine market was 226 million capsules annually. However, in the but-for world this market would be supplied by both the innovator product and the generic products. As noted earlier, Mr. Major's evidence was that a generic would expect to erode 50% of the market from the innovator by the end of the first year on the market. Further,

it was found that Ratiopharm's share of the generic market in the but-for world was subject to erosion by Novopharm when it would have entered on December 1, 2006.

[61] This sort of erosion is confirmed by the finding at trial that while the total Venlafaxine market in the 18.5 month Relevant Period was 361,506,200 capsules, the generic products would consist of only 248,640,087 capsules, or 68.78% of the total market.[35]

[62] The total generic sales in the Relevant Period of 18.5 months averaged 161,280,056 capsules annually. The annual figure is misleading as Ratiopharm would have had to ramp up sales in the first 12 month period. Nonetheless, as an average, and while still a substantial number of capsules, it is significantly less than the 226,000,000 capsules annually that the Defendant references in its submissions.

[63] The second difficulty I have with Wyeth's submission is its assertion that this redetermination on the quantity of generic Venlafaxine Ratiopharm would and could have supplied in the Relevant Period is all-or-nothing. Ratiopharm's principal submission is that the former judgment ought to be reinstated; however, this redetermination is not necessarily an all-or-nothing case.

[64] I agree with the submissions of Ratiopharm that if I were to find that no reasonable and logical inference can be drawn from the evidence that it would and could have supplied the quantity found in the Trial Decision, then the alternative is not to find that it would and could have supplied none of it. That would be illogical on the evidence before this Court.

[65] Unlike many section 8 cases, where the generic company has no manufactured product on hand, here it has been found as a fact that Ratiopharm had a sufficient quantity of product to launch in January 2006. Moreover, we know from the evidence that had Ratiopharm not told Alembic to cease making API and converting existing API to capsules, additional product would have been produced and it too would and could have been marketed.

[66] Ratiopharm submits that if I am unable to find that it would and could have sold the quantities as found in the Trial Decision, then I should use the broad axe approach applied by Justice Hughes in *Janssen Inc v Teva Canada Limited*, 2016 FC 593. Had it been necessary I would have adopted that approach; but it is not necessary as I find that Ratiopharm would and could have supplied the generic Venlafaxine market in the quantities found in the Trial Decision.

[67] I make that finding as a reasonable and logical inference based on the following facts, each of which will be discussed below:

1. The contractual commitment made by Alembic to supply "all of ratiopharm's requirements" for generic Venlafaxine;
2. The existing relationship between Ratiopharm and Alembic;
3. The encapsulating capacity of Alembic;
4. The surplus capacity of Alembic in the Relevant Period; and
5. The steps to which Ratiopharm would go to occupy the entire Canadian generic market.

A. *The Contract*

[68] In the Licence and Supply Agreement, Alembic agreed to supply exclusively to Ratiopharm "all of ratiopharm's requirements" for generic Venlafaxine [emphasis added].

[69] Wyeth correctly points out that the "Preliminary forecast for Venlafaxine" attached to the Licence and Supply Agreement forecasted only 8,862,000 capsules in 2006 and 18,627,000 capsules in 2007 – a far cry from the 248,640,087 capsules that would be needed to supply the entire generic Venlafaxine market as found in the Trial Decision. However, the Licence and Supply Agreement does not restrict the amount Alembic would produce to any specific number of capsules, and it provided that Ratiopharm could adjust its estimates and orders at any time.

[70] Article 4.1 specified that "Prior to the Launch Date of the Product, ratiopharm shall provide Alembic with a written estimate as to the quantity of the Product that ratiopharm wishes to have delivered to it (by month) during the following twelve (12) months." Article 4.2 provided that firm written orders were to be provided to Alembic and it was to fill those orders within 120 days. Moreover, any doubt that Alembic was contracting to provide sufficient quantities of the generic Venlafaxine to meet whatever the market required is evidenced by the parties' statement of intent in the Development Agreement at section 3.1:

> The Parties will negotiate in good faith and may conclude a future agreement for BioArc/Alembic to manufacture and sell to ratiopharm quantities of the PRODUCT necessary to satisfy the Canadian market demand at the time of issuance of a Notice of Compliance (NOC) for the PRODUCT by the [Canadian Health Authority Therapeutic Products Directorate]; however, ratiopharm shall have no obligation to do so. [emphasis added]

[71] These contractual provisions show the intention of both Ratiopharm and Alembic. In the but-for world, knowing it was the sole generic on the market, it is reasonable and logical to infer that in mid-2005, when it became known that it was likely that Wyeth would evergreen its pharmaceutical, that Ratiopharm would have increased both its estimate of and its firm orders for generic Venlafaxine capsules to be produced for sale in the Relevant Period to a number close to the 248,640,087 capsules of generic Venlafaxine.

[72] In the real world, Ratiopharm learned of the likelihood of Wyeth evergreening Effexor XR in May 2005. It would also have known that at the same time in the but-for world. The difference, as discussed at paragraph 27 above, is that in the but-for world it would have known that the 778 Patent would not prevent its entry into the market but it would prevent others. Thus, Ratiopharm would have known then that it would most likely be the sole generic entering the market in January 2006, and it had eight months to revise its forecasts and orders and eight months for Alembic to provide the increased quantity Ratiopharm would need in the first months after entry into the market. In the but-for world, Ratiopharm would have had more than sufficient time to adjust its orders and Alembic to produce the product.

[73] I accept that the fact that parties have a contract is not in itself incontrovertible proof that each will fully comply with its terms. Unforeseen events occasionally occur that make performance or full performance impossible. Fire, natural disaster, labour disruptions, and machinery failures, for example, are all possible and may result in contractual breaches. However, as the Supreme Court of Canada has observed, each party to a commercial contract is

entitled to assume that the other is entering into it in good faith and is able to meet its contractual commitment.

> Commercial parties reasonably expect a basic level of honesty and good faith in contractual dealings. While they remain at arm's length and are not subject to the duties of a fiduciary, a basic level of honest conduct is necessary to the proper functioning of commerce. The growth of longer term, relational contracts that depend on an element of trust and cooperation clearly call for a basic element of honesty in performance, but, even in transactional exchanges, misleading or deceitful conduct will fly in the face of the expectations of the parties: see Swan and Adamski, at §1.24.[36]

[74] I am of the view that, absent evidence that performance of a contractual obligation in whole or in part was not possible at the relevant time, or that a party entered into the contract in bad faith never intending to honour its commitments, the parties are entitled to assume that all contractual obligations will be performed.

[75] There is a strong, albeit rebuttable, presumption that parties intend what they have expressed in a contract. Contracts are made to be performed, and the courts should imply an obligation on the part of both parties to do everything necessary to secure performance of the agreement between them. This principle was stated by the Supreme Court of Canada in *Dynamic Transport Ltd v OK Detailing Ltd*, [1978] 2 SCR 1072 at 1083-1084, as follows:

> This type of case is merely a specific instance of the general principle that "the court will readily imply a promise on the part of each party to do all that is necessary to secure performance of the contract": 9 *Hals.* (4th ed.), p. 234, para. 350: see also *Chitty on Contracts*, "General Principles", (23rd ed.) p. 316, para. 698, where it is said: "The court will also imply that each party is under an obligation to do all that is necessary on his part to secure performance of the contract."

[76] Accordingly, if a section 8 plaintiff can point to a supply agreement with a third party that provides for the supply of the pharmaceutical at issue in the amounts required to fill the generic market in the but-for world then, in the absence of any contrary evidence, it must be found that the plaintiff has proven its loss on the balance of probabilities. Faced with such an agreement, the evidentiary burden shifts to the defendant to lead evidence that the contract would not or could not have been fulfilled according to its terms.

[77] A court's ability to make this connection between the supply contract and proof that the plaintiff would and could have had sufficient quantities of the pharmaceutical is easier and stronger where, as here, there is evidence of the contracting supplier's ability to perform and no evidence that it has ever failed to meet a contractual commitment to produce pharmaceuticals of the quality and quantity it has contracted.[37]

B. *Relationship*

[78] The Trial Decision outlined Mr. Major's evidence as to the relationship between Alembic and Ratiopharm. In the Appeal Decision at paragraph 107, the Federal Court of Appeal accepted that this evidence was admissible:

> 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. [emphasis added]

[79] There were several instances during Mr. Major's testimony in which he referred to the relationship between Ratiopharm and Alembic as their API supplier[38] as being one of long-standing, and it being a trusted supplier.[39] Their relationship of trust becomes relevant when one considers what Alembic would and could have done for Ratiopharm in the but-for world. It

is a reasonable and logical inference that parties with a close and long relationship are more likely to accommodate and meet the needs of the other than would parties who have a recent or cool relationship. Indeed, as noted above, there is no evidence that Alembic had ever failed meet its contractual commitment to supply product.

[80] The nature of the relationship and the trust Ratiopharm placed in Alembic is evidenced by the fact that Ratiopharm contracted with Alembic to produce not just the API but also the Venlafaxine capsules. Mr. Major, who has first-hand knowledge of generic pharmaceutical companies, including Ratiopharm, testified that contracting with one external supplier to do both was "not that common."[40] In the present circumstances, it was all the more uncommon because, as Mr. Major testified, while Alembic had been a recognized API producer, it had only recently expanded its facility to include the ability to encapsulate product. In fact, when Ratiopharm first considered Alembic as its supplier, Mr. Major testified that at that time it was "aware of their intentions to go into the dosage form business as well" [emphasis added][41] suggesting that it had not yet entered the dosage form business prior to 2004, or thereabouts. It says much of the trust Ratiopharm placed in Alembic that it contracted with a company new to encapsulating to provide it with the generic Venlafaxine.

[81] Wyeth submits that particularly in light of their alleged relationship, the Court ought to draw an unfavourable inference from the fact that Ratiopharm failed to call a witness from Alembic to testify at trial. This submission is considered below in the following section.

[82] It was submitted by Wyeth that we do not know what contracts Alembic had with others to produce product in the Relevant Period and thus no evidence that it would not be over-booked. I reject as mere speculation the suggestion made that Alembic might have been overbooked. As discussed in the previous section, it is my view the burden was on Wyeth to lead evidence if it wished to establish that to be the case. Furthermore, as will be discussed below when examining capacity, there is every reason to find that it was not over-booked because after it contracted with Ratiopharm to supply the Canadian market, it agreed with Ratiopharm to supply the larger U.S.A. market. Acting in good faith, it could not have done so if it did not have room to supply both markets. In the but-for world, when Ratiopharm was looking to supply a much larger quantity of generic Venlafaxine in Canada, Alembic would not have entered into the agreement to supply the U.S.A. market if it would jeopardize supplying an existing contract.

[83] In any event, there was evidence that Ratiopharm would compensate Alembic should it have to cancel any existing contracts to meet the needs of the Canadian market.[42] Given their relationship, there is every reason to infer that absent extraordinary circumstances, such an offer would be accepted by Alembic in order to meet the needs of its long-standing and trusted customer.

C. *Capacity of Alembic*

[84] Mr. Major testified that Alembic had "constructed a dosage form facility on their campus that was specifically designed and intended for regulated markets [being] Canada, U.S., European Union."[43] He described this facility in many ways, including the following: "It is a large facility, very large API, very large dosage manufacturing;"[44] "[T]hey had enormous

capacity for encapsulating;" [45] and "They were initially an API facility, and they had enormous capacity in tonnages in order to produce the active pharmaceutical ingredient."[46] Although this information was based on his 2004 inspection, there is nothing in the record that would support any conclusion but that in the Relevant Period it remained as he saw it in 2004. In the absence of any such evidence, it is reasonable and logical to infer that the plant's capacity in the Relevant Period was as Mr. Major described it in 2004.

[85] In the context of Mr. Major's evidence regarding Alembic's ability to supply Ratiopharm's needs in the U.S.A. market, he was taken to an email of April 7, 2006, entered as Exhibit P-3 Tab 13, which speaks to the capacity of the Alembic facility. This email was held by the Federal Court of Appeal to be hearsay and not admissible for the truth of its content. When that email was put to Mr. Major in his direct examination, the following exchange occurred:[47]

> Q Now, the capacity numbers you're looking at here [one billion capsules annually], are those consistent with your understanding of the capacity of Alembic having inspected their plant?
>
> A Yeah, they would be. [emphasis added]

[86] He made a similar statement during his cross-examination when he was again directed to Exhibit P-3 Tab 13. The following exchange occurred:[48]

> Q That wasn't the question. The content, you certainly can't say standing here today the specific content in this e mail that you were aware of prior to in the context of this litigation.
>
> A I was aware in the content that they had their FDA inspection. That was a key point for us moving forward with them as partners for the U.S. I was aware that they had significant capacity. A billion is reasonable based on what I recall from

> having visited the plant, that they are operating at 40 per cent. That's common, and that they
>
> Q. Well, was it common or did you know that?
>
> A. That they were working at 40 per cent?
>
> Q. Yes.
>
> A. The precise number, perhaps not, but it's not unusual…
>
> Q. Thank you.
>
> A. …that they don't work at 100 per cent.
>
> Q. I didn't ask that. You're surmising now.
>
> A. Based on experience with the company, and our own experience as manufacturers. [emphasis added]

[87] Although the document was ruled to be inadmissible for the truth of its content, it is not being put to Mr. Major in this exchange for that purpose. Given the question asked, the document was put to Mr. Major in direct examination as an aide-mémoire, or trigger, and this is acceptable even if the document itself is hearsay and inadmissible. The Supreme Court of Canada in *R v Fliss*, 2002 SCC 16 at paragraph 45 makes this point:

> There is also no doubt that the officer was entitled to refresh his memory by any means that would rekindle his recollection, whether or not the stimulus itself constituted admissible evidence. This is because it is his recollection, not the stimulus, that becomes evidence. The stimulus may be hearsay, it may itself be largely inaccurate, it may be nothing more than the sight of someone who had been present or hearing some music that had played in the background. If the recollection here had been stimulated by hearing a tape of his conversation with the accused, even if the tape was made without valid authorization, the officer's recollection -- not the tape -- would be admissible. [emphasis added]

[88] As original testimony of a one billion annual capsule capacity, counsel on cross-examination was entitled to explore the extent to which Mr. Major's statement accurately reflected his memory and assessment in 2004, or whether it was dependant on the document for that information. That was not done.

[89] In the Appeal Decision, the Federal Court of Appeal states that the manner of proceeding here was acceptable:

> 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. [emphasis added][49]

[90] In a similar fashion, the Federal Court of Appeal in *Eli Lilly and Co v Apotex Inc*, 2010 FCA 240 at paragraphs 10-11, held that a witness's evidence based largely on personal knowledge is admissible even if the witness relies on inadmissible hearsay notes made by others to refresh his memory of some technical details:

> Lilly says that the Judge erred in law in admitting the oral evidence of Mr Satpute, Lupin's Vice President, Active Pharmaceutical Ingredient Manufacturing, and, at the relevant time, the senior manager of Lupin's factory in India where 7-ACCA was manufactured. Lilly argues that Mr Satpute's evidence respecting the process used to produce the intermediate was inadmissible

> hearsay because it was based on information given to him by Lupin scientists. The Judge did not address this issue in her reasons.
>
> We do not agree that the Judge erred by not excluding Mr Satpute's testimony as hearsay. It was based largely on his direct knowledge of the manufacturing process used to produce the 7-ACCA to fill Apotex' large order for bulk cefaclor. That he may have relied on others' notes to refresh his memory or for some of the technical detail of the process used does not warrant characterizing his evidence as hearsay. [emphasis added]

[91] In my view, Mr. Major's evidence about the numerical capacity of Alembic is based on his first-hand observation of what he saw when he inspected the facility. He was knowledgeable about pharmaceutical manufacturing facilities. He had already described Alembic's capacity in general terms to be "enormous." His evidence is that the one billion number is consistent with his understanding having viewed the facility, and it is also consistent with his more general evidence.

[92] In the Trial Decision at paragraph 156, I accepted that Alembic's one billion capsule capacity was evidenced by Mr. Major's first-hand knowledge of the facility. As noted by Ratiopharm in its submissions, this was not upset in the Appeal Decision. Moreover, the Federal Court of Appeal at paragraph 109 of the Appeal Decision held that such evidence was admissible and might form the basis for the inference as to Alembic's ability to fully supply Ratiopharm:

> 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. [emphasis added]

[93] Accordingly, I find that there is admissible evidence supporting a finding that the production capacity of the Alembic facility at the relevant time was about one billion capsules annually. Based on that number, Alembic would be using approximately 16% of its capacity to meet the generic Venlafaxine market in the Relevant Period in Canada in the but-for world.

[94] Wyeth submits that the Court ought to draw an unfavourable inference from the fact that Ratiopharm failed to call a witness from Alembic to testify at trial. It submits that "this Court ought to conclude that such a witness would not have supported [Ratiopharm's] position that Alembic would not have and could not have manufactured sufficient quantities of venlafaxine to supply the entire market during the relevant period [emphasis in original]."

[95] In my view, no such negative inference is warranted. One must keep in mind that had a witness from Alembic been called, that witness would have been offering evidence of what Alembic's intentions would have been in a hypothetical world. However, we know what its intentions were in the real world – it was to supply all of Ratiopharm's requirements for generic Venlafaxine. Its intentions in the but-for world were the same because that was what it had contracted with Ratiopharm to supply. Accordingly, this evidence was not necessary and, as outlined above, if Wyeth wished to offer contrary evidence, the burden was on it to do so.

[96] Wyeth advanced the position that even if Alembic had a billion capsule capacity, it may have had other contractual commitments that prevented it from meeting Ratiopharm's needs. In the absence of any evidence to support that proposition, I reject it for the following reason.

[97] In the but-for world, I have found that Ratiopharm in May 2005 would have known that it would be the sole generic in the Canadian market when it launched its product in January 2006. It would have taken steps then or very soon thereafter to revise the estimated product needs and its orders to be in a position to have sufficient product to satisfy its needs throughout the Relevant Period. This would provide Alembic with about 6 months to arrange its plant to meet those demands. Article 4.1 of the Licence and Supply Agreement specifically provided that estimates were "for the purpose of enabling Alembic to tentatively Schedule the use of its facilities to meet ratiopharm's estimated requirements of the Product." With that advanced time and the ability to schedule its plant, and given its contractual obligation to produce the increased amounts that would have been ordered by Ratiopharm, it is a reasonable and logical inference that other commitments, if there were any, would not prevent Alembic from meeting Ratiopharm's needs in the Relevant Period. The burden was on Wyeth to lead evidence to show otherwise.

D. *Surplus Capacity*

[98] I find that the evidence of Mr. Major at paragraph 86 above, that Alembic is operating at 40% capacity, is of no probative value as he has no personal knowledge of Alembic's surplus capacity in the 2005 - 2006 period. However, he does testify that it is not unusual for manufacturing facilities to operate at less than 100%. That evidence is worthy of some weight given his experience and knowledge of generic drug manufacturers. At a minimum, it

corroborates the inferences made above and it is supported by other evidence that Alembic had capacity in 2005 - 2006 to produce more generic Venlafaxine capsules than had originally been ordered by Ratiopharm for its Canadian market.

[99] There is evidence that the contract to produce Ratiopharm's generic Venlafaxine was one of, if not Alembic's first, for its encapsulating facility. The initial full-size batch was produced on a single machine and Alembic had many. In cross-examination, Mr. Major testified:

> [W]e were manufacturing on a single machine and there were multiple machines, so certainly the capacity at Alembic would have been brought into play in your but-for world if we woke up and discovered we were alone. So that would have certainly come into play.[50]

[100] I accept that there is no evidence as to how much of Alembic's capacity may have been otherwise contracted for by other parties prior to and during the Relevant Period, but I also note that this was a very new facility and there had only been a short period during which it could have entered into arrangements with others.

[101] There is strong evidence that in the latter part of 2005 and early 2006, Alembic had surplus capacity. This must be so because after Alembic entered into the Licence and Supply Agreement, it agreed to increase the manufacture of generic Venlafaxine to meet the requirements of Pharmascience in the Canadian market. Moreover, based on the evidence at trial, I infer that it had agreed to also supply Ratiopharm in the larger U.S.A. market and it could not have done so in good faith if it did not have additional capacity available.

[102] I make that inference based on the following. Mr. Major, whose role included "direct responsibility over the regulatory affairs function for Canada and also for U.S.", would have first-hand knowledge of Ratiopharm's U.S.A. pharmaceutical plans.[51] He confirmed that Ratiopharm asked Alembic if it could increase its capacity:

> Q. Perhaps we can just regroup a little, Mr. Major. I had asked you if ratiopharm had ever asked Alembic if it could increase its capacity, and you indicated that it had been asked to support a U.S. launch?
>
> A. Yes, we had asked them to confirm.
>
> Q. Perhaps you can just give us a recap of what the circumstances were at the time and what you were asking them to do.
>
> A. Mm-hm. What we were asking them was could they supply, did they have the capacity to meet the larger U.S. market space? We had licensed the Karma formulation for Canada, and we extended our license to include the territory U.S. using the Karma product as the basis for that Abbreviated New Drug application which was prepared for my group and filed. So we did file the ANDS in the U.S. The question in advance of that, of course, is you want to make sure that the party that you're going to be going forward into such a large market has the ability to manufacture the volumes that you're going to need, and that's really where the questioning came from. [emphasis added][52]

[103] Although subsequent answers given by Mr. Major recounting the statements made to him regarding Alembic's capacity were ruled hearsay and inadmissible for the truth of their content, the evidence above is not hearsay. What can be taken from this evidence is that Ratiopharm was looking to enter the "larger" U.S.A. market and approached Alembic to ascertain if it had the capacity to produce the volumes needed to be in that market. Mr. Major testified that one wants to ensure a source of supply in advance of filing an Abbreviated New Drug Application [ANDA] in the U.S.A. His evidence is that Ratiopharm did file an ANDA in the U.S.A., and

the only reasonable and logical inference one can draw from that is that Alembic did confirm that it had the capacity to produce the needed quantities of generic Venlafaxine for the larger market in the U.S.A., in addition to its production for Ratiopharm and Pharmascience in the Canadian market.

[104] In the but-for world it is reasonable and logical to infer that Alembic's surplus capacity in the Relevant Period was at least equal to the amount of Venlafaxine it contracted to supply to Ratiopharm for its U.S.A. market in the real world. While there is no evidence as to the quantity to be produced in the U.S.A. market, that market is about 10 times the population of the Canadian market. If it would and could supply the "larger" market in the U.S.A., then it is a reasonable and logical inference that it would and could supply the needs of Ratiopharm in the generic market as found in the Trial Decision.

E. *Steps Ratiopharm Would Take*

[105] This has already been explored. There is evidence from Mr. Major who testified as to what Ratiopharm would have done, that it would have used air freight if necessary to move product from India to Canada to sell in the Relevant Period. It would also have been prepared to compensate Alembic for any losses it might suffer if it had to breach or cancel other contracts to meet Ratiopharm's demands. Additionally, Ratiopharm would have "bought equipment, put equipment in place" to avoid any bottleneck.[53]

[106] These are not insignificant accommodations and they illustrate how important it was to Ratiopharm to be the first and sole generic in the market. They are also the basis from which

one can reasonably and logically infer that had it been necessary, Ratiopharm would have done all in its power to be in a position to fully supply the Canadian generic market.

Conclusion

[107] Based on the evidence recited above, and reasonable and logical inferences from that evidence, I conclude that Ratiopharm (through Alembic) would have and could have had sufficient quantities of the generic Venlafaxine product to supply the Canadian generic market in the Relevant Period, in the amounts found in the Trial Decision.

[108] The sums awarded in the initial Trial Decision and Judgment have been paid by the Defendant to the Plaintiff. Accordingly, there is no need to issue any further Judgment save to reaffirm the initial one, and to deal with the costs of the trial and this redetermination. Accordingly, I find that the determination made at trial must be reaffirmed.

Costs

[109] The Plaintiff is entitled to its costs of the trial (in accordance with the Trial Decision and Judgment) and of the redetermination. The Defendant is entitled to its reasonable costs thrown away as a consequence of the cancellation of the initial hearing of this redetermination which was scheduled, after consultation with the parties, to be held on September 1, 2016. That date was cancelled on very short notice as a consequence of Ratiopharm filing an application to the Supreme Court of Canada on August 30, 2016, for leave to appeal the Appeal Decision. If the parties are unable to agree on the costs on this redetermination, they may so advise the Court and provide written submissions of not more than 10 pages, within 14 days of the issuance of this judgment.

JUDGMENT in T-1844-07

THIS COURT'S JUDGMENT is that the Court's Judgment in this action dated April 3, 2014 (2014 FC 248) and June 30, 2014 (2014 FC 634) is reaffirmed and reissued; and costs of this redetermination are to the Plaintiff, save and except for the reasonable costs thrown away, as discussed in the Reasons, in an amount to be determined by the parties or the Court, as set out in the Reasons.

"Russel W. Zinn"
Judge

[1] Specifically, it was found that Exhibits P-3, Tabs 4, 11-15, were inadmissible for the truth of their content.
[2] Major Direct, Trial Transcript Vol 2, p 5, lines 5-18.
[3] Exhibit P-3, Tab 1.
[4] Major Direct, Trial Transcript Vol 2, p 9, lines 5-8 and 11-14.
[5] Exhibit P-3, Tab 2.
[6] Exhibit P-4, Tab 23.
[7] Appeal Decision at para 108.
[8] Exhibit P-3, Tab 3 and Exhibit D-8, Tab 6.
[9] Major Direct, Trial Transcript Vol 2, p 15, lines 15-28.
[10] Exhibit P-3, Tab 5.
[11] Exhibit P-1, Tab 4.
[12] Exhibit P-3, Tab 6.
[13] Ratiopharm had been planning for a launch in October 2007, based on its estimate that the decision would only issue close to that date: See Major Direct, Trial Transcript Vol 2, p 93, lines 10-23, and Exhibit P-3, Tab 26.
[14] Trial Decision at paras 81, 88.
[15] An illustration of the degree of the erosion of Ratiopharm's generic market share can be found in the evidence of Dr. Hollis. His exhibit P-29, Tab 26 shows that in the but-for world Ratiopharm held 100% of the generic market in the months preceding Novopharm's entry, but in Ontario, for example, Ratiopharm's share dropped to 82.5% by the end of the Relevant Period.
[16] Major Direct, Trial Transcript Vol 2, p 8, lines 17-19.
[17] Major Direct, Trial Transcript Vol 2, p 24, lines 5-8, and p 25, lines 8-28.
[18] Major Direct, Trial Transcript Vol 2, p 29, lines 14-16.
[19] Major Direct, Trial Transcript Vol 2, p 80, line 5 to p 82, line 15.
[20] Application for leave dismissed 2012 CanLii 22174 (SCC)
[21] John Henry Wigmore, *Wigmore on Evidence*, revised by Peter Tillers (Toronto: Little, Brown and Company, 1983), §18 at p 790 and footnote 1.
[22] The Appeal Decision at para 106 accepted that Mr. Major could speak to what Ratiopharm would have done in the but-for world.
[23] Deneke Direct, Trial Transcript Vol 1, p 81, line 7 to p 82, line 27.
[24] Exhibit P-1, Tab 1.
[25] Exhibit P-1, Tab 2.

[26] Exhibit P-3, Tab 3, Article 3.1.
[27] Transcript of Proceedings April 5, 2017, Submissions of Pfizer, p 79, line 3 to p 80, line 15.
[28] Major Direct, Trial Transcript Vol 2, p 18, lines 4-15.
[29] Major Direct, Trial Transcript Vol 2, p 45, line 9 to p 46, line 26.
[30] Major Direct, Trial Transcript Vol 2, p 49, line 22 to p 50, line12.
[31] Major Direct, Trial Transcript Vol 2, p 50, lines 13-17.
[32] Major Cross, Trial Transcript Vol 2, p 130 lines 11 – 18.
[33] Appeal Decision at para 164.
[34] Trial Decision at para 263 (4)(iv).
[35] Trial Decision at para 263.
[36] *Bhasin v Hrynew*, 2014 SCC 71 at para 60.
[37] Wyeth drew the Court's attention to *DRX Corporation v Alembic Limited*, 2010 ONSC 3242, where Alembic was sued for failure to pay the plaintiff some $25,000 in commissions. This decision is not authority for the bald proposition stated by Wyeth at paragraph 80 of its written submission that "Alembic has a history of breaching its contractual obligations." Moreover, it had nothing to do with Alembic failing to fulfill a supply contract.
[38] Major Direct, Trial Transcript Vol 2, p 9, lines 11-14.
[39] Major Direct, Trial Transcript Vol 2, p 26, lines 9-18.
[40] Major Direct, Trial Transcript Vol 2, p 30, line 18 to p 31, line 4.
[41] Major Direct, Trial Transcript Vol 2, p 9, lines 11-14.
[42] Major Cross, Trial Transcript Vol 2, p 149, line 15 to p 150, line 19.
[43] Major Direct, Trial Transcript Vol 2, p 26, lines 13-17.
[44] Major Direct, Trial Transcript Vol 2, p 28, lines 7-8.
[45] Major Direct, Trial Transcript Vol 2, p 29, lines 8-9.
[46] Major Direct, Trial Transcript Vol 2, p 30, lines 3-6.
[47] Major Direct, Trial Transcript Vol 2, p 45 lines 4-8.
[48] Major Cross, Trial Transcript Vol 3, p 8, line 12 to p 9, line 7.
[49] Appeal Decision, para 112. I do not read the final sentence of this passage to mean that Mr. Major cannot use inadmissible documents to trigger his memory as to his perception of the capacity of Alembic's plant as that would be inconsistent with the immediately preceding statement from the Appeal Court.
[50] Major Cross, Trial Transcript Vol 2 page 144, lines 12-17.
[51] Major Direct, Trial Transcript Vol 2, page 4, lines 2-4.
[52] Major Direct, Trial Transcript Vol 2, page 41, lines 4-23.
[53] Trial Decision at para 152, and see Appeal Decision at para 125.

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	TORONTO, ONTARIO
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