Federal Court  Cour fédérale

Date: 20170404

Docket: T-1048-07

Citation: 2017 FC 88

Ottawa, Ontario, April 4, 2017

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, ELI LILLY AND COMPANY LIMITED, AND ELI LILLY SA

Plaintiffs

(Defendants by Counterclaim)

and

TEVA CANADA LIMITED

Defendant

(Plaintiff by Counterclaim)

AMENDED PUBLIC JUDGMENT AND REASONS

(Redacted from Confidential Judgment and Reasons issued January 30, 2017)

I. Overview

[1] Teva Canada Ltd (formerly Novopharm Ltd) seeks damages from Eli Lilly Canada, Inc as compensation for having been prevented from coming to market in 2006-2007 with a generic version of a medicine called olanzapine. Olanzapine is useful primarily in the treatment of

schizophrenia. Teva alleges that it suffered losses for having been kept out of the olanzapine market as a result of Lilly's application for an order prohibiting Teva from obtaining a Notice of Compliance (NOC) from the Minister of Health, and from the corresponding regulatory stay, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. Teva was kept out of the olanzapine market until the proceedings under the Regulations were completed on June 5, 2007, when Justice Roger Hughes ruled against Lilly (*Eli Lilly Canada Inc v Novopharm Ltd*, 2007 FC 596).

[2] Subsequently, Lilly commenced an action against Teva for infringement of its patent for olanzapine. I found that Lilly's patent for olanzapine was invalid (*Eli Lilly Canada Inc v Novopharm Ltd*, 2009 FC 1018). I also concluded that Teva was entitled to damages under s 8 of the Regulations in an amount which would be determined in a separate proceeding (see Annex II for all provisions cited). An appeal from my decision was allowed in part (*Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197). In a later decision, I again concluded that Lilly's patent was invalid (*Eli Lilly Canada Inc v Novopharm Ltd*, 2011 FC 1288). The latter decision was upheld by the Federal Court of Appeal; the Supreme Court of Canada denied leave to appeal.

[3] In effect, the dispute has come to me for a third time to decide a new question: What is the amount of the damages, if any, to which Teva is entitled under the Regulations for the time it was kept off the market? To answer that question, one must create a hypothetical world in which Lilly would not have brought an application whose effect was to deny Teva access to the olanzapine market. In that hypothetical world, Teva might have come to market on the strength of an NOC for generic olanzapine as early as March 3, 2006, when the Minister would have

granted an NOC to Teva but for the proceedings initiated by Lilly. Lilly disputes that start date on the basis that Teva had earlier abandoned its claim for damages, and that Teva was not actually in a position to bring its product to market until the spring of 2007, at the earliest.

[4] Lilly also raises a number of grounds on which Teva's damages should be discounted, including: Teva has included losses that are not attributable to the operation of the Regulations; Teva has failed to take account of the likely presence of another generic manufacturer, Apotex Inc, in the market at the same time; Teva has overstated the actual profits it would have realized in the various provinces; and Teva's claim fails to include the full amounts that Teva would have given to pharmacies to promote its product (so-called "trade-spend"). Each of these factors requires separate analysis.

[5] Accordingly, the main issue, the amount of damages owed to Teva, raises five distinct questions:

1. What is the period of liability?
2. What was the size of the olanzapine market?
3. What was the generics' share of the olanzapine market?
4. What was Teva's share of the generic olanzapine market?
5. What is the real amount of Teva's losses?

[6] The parties do not ask me to make any calculations. They ask me simply to make the factual findings necessary for those calculations to be made.

II. The Legal Framework

[7] Under the Regulations, a drug company holding a patent on a particular drug (the "first person") can commence proceedings to prohibit another company wishing to market a generic version of that drug (the "second person") from obtaining an NOC until the latter has addressed the former's patent or until the patent has expired. The second person can address the patent by alleging that its product will not infringe the patent or that the patent is invalid. Until the Court has ruled on those allegations, the second person cannot enter the market. The Regulations impose an automatic stay for 24 months or until the first person's prohibition application has been dismissed.

[8] If the first person fails to persuade the Court that the second person's allegations are unjustified, the first person will not obtain its prohibition order and the second person will be free to obtain its NOC. However, the Regulations recognize that the automatic stay will keep the second person off the market for the duration of the proceedings even where the second person's allegations are ultimately found to be justified. Accordingly, the Regulations state that where the Court dismisses a first person's application for a prohibition order, the first person is liable to the second person for any losses suffered during the relevant period. The relevant period begins on the date certified by the Minister as being the date the second person would have obtained its NOC but for the proceedings initiated by the first person, unless the Court finds that another date is more appropriate. The relevant period ends on the date the first person's application was dismissed.

[9] Teva shoulders the legal burden of establishing all of the elements of its claim for damages: this includes showing that its alleged losses were a product of the operation of the Regulations (*Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161 at para 64). To be recoverable, there must be a causal connection between the damages Teva seeks and the proceedings initiated by Lilly. The essential question is: What would have happened if Lilly had not applied for an order of prohibition against Teva?

[10] Lilly has an evidentiary burden to respond to Teva's evidence, and bears the legal burden in respect of its defences. For example, in its defence, Lilly maintains that Teva had earlier abandoned its claim for damages and that the start date for the period of liability is much later than the date certified by the Minister. Lilly bears the burden of proof on those issues (*Pfizer Canada Inc v Teva Canada Limited*, above, at para 65).

III. Evidentiary Issues

[11] The parties disputed two major evidentiary issues. The first was whether fact witnesses could testify about what they thought would or would not have happened in the but-for world. For the most part, this involved Lilly objecting to testimony proffered by Teva's fact witnesses on the basis that asking those witnesses hypothetical questions invited them to provide opinion evidence, an area that should be left to qualified experts. Teva argued repeatedly that it had no choice but to ask fact witnesses about the but-for world given its burden of proving what would have happened if Lilly had not initiated proceedings under the Regulations. Teva pointed me to previous cases where this kind of evidence had been allowed. During the trial, I allowed some

hypothetical questions to be put to fact witnesses, reserving on Lilly's objection until I had an opportunity to consider the objection further and review the authorities.

[12] The second evidentiary issue related to alleged hearsay evidence. Lilly objected to the admission of certain documents for the truth of their contents. Again, for the most part, I reserved on Lilly's objections until I had an opportunity to consider the admissibility of the documents in question, considering their necessity and reliability in the context of the case as a whole.

[13] With respect to the first issue, I agree with Lilly that the opinions of fact witnesses are not admissible. During the trial, I suggested to counsel that the best way to provide the relevant evidence to the Court would be to explore with fact witnesses what they did in the real world. The witnesses could then be asked whether they knew of any reason why they would have acted differently in the but-for world. This would confine fact witnesses to their own knowledge and experience, as opposed to asking them, in an open-ended fashion, what they would have done or what they thought would have happened in the but-for world. The latter involved inadmissible opinion evidence; the former related to admissible facts within the witness' knowledge.

[14] I note that the Federal Court of Appeal has ruled that fact witnesses can, in a limited way, give evidence about a company's "general intentions in the hypothetical world" and "the general steps it took to prepare itself for entry into the market" (*Pfizer Canada Inc v Teva Canada Limited*, above, at para 106). However, the evidence Teva sought from its fact witnesses went beyond general intentions or preparatory steps: the witnesses were sometimes asked what they

actually would have done or what would have actually happened in the but-for world. The witnesses were being improperly invited to provide opinion evidence.

[15] However, the approach I suggested was not possible for some witnesses. For example, Teva's witness Dr Brian Des Islet, Executive Director of Scientific Affairs at Teva, was invited to imagine a scenario in which Teva had obtained its NOC on March 3, 2006, and was asked whether Teva would have launched with material produced by a particular process (Process 1) or by another (Process 2). Counsel for Lilly objected to the question on the basis that it invited Dr Des Islet, a fact witness, to provide an opinion. Since only Process 2 material was used in the real world, asking Dr Des Islet whether Teva would have relied on Process 1 material in the but-for world would have invited him to offer a speculative opinion. The question of whether Teva could have and would have launched with Process 1 material can be answered only after considering all the relevant evidence; it is my responsibility to answer it based on the evidence before me. The fact that the burden falls on Teva to prove that it could have and would have launched in March 2006 with Process 1 API does not mean that it is entitled to ask a fact witness to answer that question.

[16] Accordingly, I have not considered the testimony of fact witnesses in which they offered opinions about what would or would not have happened in the but-for world. I rely solely on the opinions of experts and my own inferences drawn from the evidence.

[17] With respect to Lilly's hearsay objections, I again agree with Lilly that hearsay evidence cannot be admitted unless it falls within a recognized exception (*eg*, business records) or it meets

the criteria of necessity and reliability. This basic proposition has been firmly underscored by the Federal Court of Appeal (*Pfizer Canada Inc v Teva Canada Limited*, above, at paras 95-103). Lilly's principal objection relates to a report prepared by Deloitte that, among other things, contains information about Teva's trade-spend rate on its venlafaxine product. The author of the report was not called as a witness.

[18] In my view, the Deloitte report does not meet the test for the business records exception. That exception requires that the author of the record have a duty to create it, and did so contemporaneously and based on personal knowledge (*Ares v Venner*, [1970] SCR 608 at p 626; see also *Canada Evidence Act*, RSC 1985, c C-5, s 30). Since the author of the Deloitte report is unknown and the details surrounding the report's preparation were not in evidence, the report cannot meet these criteria.

[19] Lilly also challenges on hearsay grounds documents purporting to contain information about the rebates and other incentives ("trade-spend") that Teva would have paid to pharmacies and other retailers of another one of its products, venlafaxine. The documents in question were not prepared contemporaneously with the financial transactions they allegedly record. Those who authored the documents were not called as witnesses. These, too, amount to inadmissible hearsay not falling within the business records exception.

[20] Even though there are some indications that these impugned documents are reliable, they are not admissible under the principled exception to the hearsay rule because the criterion of necessity is not met. Evidence relating to trade-spend was provided by way of direct evidence

from Teva's fact witnesses – Ms Oksana Tressel, Mr Doug Sommerville, and Mr Barry Fishman. It is not necessary to look to the Deloitte report or the other impugned documents to determine what Teva's trade-spend rate was for venlafaxine.

[21] Therefore, I have confined myself to the evidence that is properly before me. I have not considered opinions offered by fact witnesses or inadmissible hearsay.

A. *Issue One – What is the period of liability?*

[22] Teva maintains that the period of Lilly's liability commences on the date certified by the Minister as being the day on which Teva would have obtained its NOC if Lilly had not initiated proceedings under the Regulations: March 3, 2006. The parties agree that the period ends on the date on which Justice Hughes rendered his decision dismissing Lilly's application: June 5, 2007.

[23] Lilly's main position is that, because Teva abandoned its claim to damages, there is no period of liability. Alternatively, Lilly disputes Teva's reliance on the Minister's certified date of March 3, 2006, and suggests that the appropriate start date is March 22, 2007 because Teva could not actually have put its product on the market any sooner. In effect, Lilly would reduce the period of liability from the approximately 15 months asserted by Teva, to either zero or a maximum of 3.5 months.

[24] I am not persuaded by Lilly's arguments relating to abandonment or an alternate start date. Read in context, the evidence does not show that Teva abandoned its claim to damages in this proceeding. Further, the evidence demonstrates that but for the prohibition proceedings,

Teva would have been able to put its product on the market upon receiving its NOC on March 3, 2006. Therefore, the period of liability is from March 3, 2006 to June 5, 2007.

(1) Abandonment

[25] Lilly relies on the sequence of events relating to Teva's first Notice of Allegation (NOA) in which Teva alleged that Lilly's olanzapine patent, Canadian Patent No 2,041,113 (the '113 patent), was invalid. Teva served that NOA on August 5, 2004. Lilly responded to the NOA by invoking the Regulations and applying for a prohibition order against Teva (T-1734-04). Lilly filed its evidence, but Teva later withdrew its NOA and served a new one. Lilly sought its costs in the first proceeding; in response to Lilly, Teva submitted that it had been prejudiced by the delay resulting from the withdrawal, in part, because it had "abandoned its claim to s 8 damages".

[26] Lilly points to Teva's submissions on costs filed in that earlier proceeding and contends that Teva made an unequivocal undertaking, both to the Court and to Lilly, that it had unequivocally abandoned any claim to s 8 damages. According to Lilly, Teva's claim is blocked by the doctrines of abandonment and estoppel. Further, Lilly says, the Court should take account of Teva's submission in the earlier proceeding when assessing damages under s 8(5) of the Regulations here. Lilly also notes that the proceeding relating to Teva's second NOA had already been initiated at the time Teva made its submissions on costs. Therefore, says Lilly, Teva's earlier position on abandonment should carry over from the earlier proceeding and apply here, and should prevent Teva from advancing any damages claim against Lilly.

[27] I disagree with Lilly on this point. Reading Teva's submission on abandonment in context, I find that it related solely to the first proceeding. Teva's submission responded to Lilly's request for costs. As I read it, Teva was simply pointing out that one of the consequences of the withdrawal of its first NOA was a relinquishment of a claim to damages within that proceeding. Teva did not agree that it would not to seek s 8 damages in the second proceeding or, indeed, in this action.

[28] Further, in my first decision in this action, I concluded that Teva's claim to s 8 damages would be decided in a separate proceeding. While that decision was appealed successfully in part, the Federal Court of Appeal made clear that its ruling did not affect the issue of s 8 damages (2010 FCA 219 at para 13). It left the issue to be decided in a subsequent proceeding.

[29] I disagree with Teva's position, though, that my earlier decision in this case and the subsequent response of the Federal Court of Appeal renders the issue of abandonment *res judicata*. I specifically stated that the start and end date of the period of liability could be decided in the separate proceeding on damages, apart from the trial on liability and infringement (see my Order of December 16, 2009). As I read the bifurcation order, I was free, but not bound, to address all the issues relating to liability for damages in the first phase. The bifurcation order relieved the parties from adducing evidence on the quantum of damages during that phase, but it did not specify what would be decided in the second phase. I preferred to leave the issue of liability for damages to the second phase as I believed it was closely connected to the question of quantum. While I disagree with Lilly on the issue of abandonment, I do not fault it for raising the issue here. The issue of abandonment is not *res judicata*.

(2) The Start Date

[30] Lilly contends that the start date of the period of liability should be March 22, 2007. Lilly's position is based on the following:

1. Teva had to seek and obtain a notifiable change for the process it planned to use for its product before it entered the market. Its notifiable change was approved by Health Canada on March 22, 2007.
2. The bulk Active Pharmaceutical Ingredient (API) Teva received during the relevant period was provided by its supplier, Dr Reddy's Laboratory, [redacted].
3. Dr Reddy's supply of API was unreliable until late 2006.
4. Teva had not completed its validation tests until March 22, 2007.

[31] I disagree with Lilly. The evidence does not support its claim that Teva would have had difficulty entering the market once it obtained its NOC on March 3, 2006.

[32] Regarding the notifiable change, the evidence shows that Teva used one process (Process 1) for manufacturing API for regulatory purposes. [redacted]. Dr Reddy's then created Process 2 and Teva sought a notifiable change for the new process. Teva submitted its request on September 14, 2006. Health Canada agreed to review the request on November 9, 2006, and completed its review on March 22, 2007. From that date, Teva was able to sell its product with Process 2 API.

[33] Lilly's expert, Dr Gordon Munro, concludes from this evidence that Teva could not have implemented the change from Process 1 to Process 2 until March 22, 2007, and that no Process 2 product could have been marketed until after that date (see Annex I for a summary of experts' qualifications).

[34] Based on this evidence, Lilly submits that Teva's product could not have been marketed commercially until March 22, 2007.

[35] I disagree with Lilly's position. While the evidence shows that Teva could not have marketed its product with Process 2 API prior to March 22, 2007, it equally demonstrates that Teva could have sold olanzapine tablets containing Process 1 API as of March 3, 2006. Dr Reddy's was in a position to supply it. Mr Rajesh Sadanandan, an employee of Dr Reddy's who was responsible for European sales of Dr Reddy's API products at the relevant time, explained that Process 1 was developed [redacted]. During the 2005 to 2007 period, Dr Reddy's was capable of producing about 1800 kg a year. In 2007, Dr Reddy's started selling Process 2 material, in addition to Process 1 API.

[36] Dr Brian Des Islet, Executive Director of Scientific Affairs at Teva, testified that Dr Reddy's had supplied Teva with Process 1 material for the batches that were submitted to Health Canada for regulatory purposes and, in fact, has continuously supplied Teva with API for its olanzapine product. He explained that Teva asked Dr Reddy's to develop a different process for producing the API, which resulted in Teva's seeking a notifiable change to switch from Process

1 to Process 2. [redacted].

[37] Dr Des Islet was invited to imagine a scenario in which Teva had obtained its NOC on March 3, 2006, and was asked whether it would have launched with Process 1 or Process 2 API. I have discussed the inadmissibility of this evidence above. However, Dr Des Islet was able to state that the only material with which Teva had regulatory approval to launch on March 3, 2006 was Process 1 API. Further, he was aware that Dr Reddy's was able to supply the US market with Process 1 material, suggesting that Dr Reddy's could likely have met Teva's needs, as well.

[38] Lilly argues that Teva could not have come to market with Process 1 API [redacted]. However, there is little or no evidence that [redacted]. Lilly's expert, Dr Munro, stated in a supplemental report that he "would consider" [redacted]. However, on cross-examination, Dr Munro stated that he was merely making an observation, one which did not affect his overall opinion about when Teva might have been in a position to launch its product. He conceded that it was not a matter within his main area of expertise and that he could not render an opinion on infringement. Therefore, I cannot conclude that Teva would have been legally prevented from entering the market with tablets containing Process 1 API on March 3, 2006. [redacted].

[39] Regarding the US injunction, Lilly points to packing slips and invoices showing that Teva received bulk API from Dr Reddy's Laboratories in the US prior to June 2007. Any such shipments, says Lilly, would have violated a US court order. However, it is unclear whether the evidence on which Lilly relies shows the actual provenance of shipments of API to Teva in Canada, or whether they simply show where the documents originated or where the billing occurred. On this evidence, I cannot conclude that the shipments of API were illegal.

[40] Regarding supply of API, Lilly relies on Dr Munro's opinion that shipments from Dr Reddy's from India were slow and unpredictable, at least until June 2007. Dr Munro noted that early orders from Teva to Dr Reddy's took approximately six months to arrive. Prior to June 5, 2007, Teva had received only 61 kg of API. Delays thereafter were reduced to about six weeks. Still, Dr Munro concludes that Teva's access to API did not stabilize until June 2007. These problems related to Process 2 material. Dr Munro was asked whether Teva, given that it had successfully launched to a sole source market in June 2007, could have done the same in March 2006. Dr Munro characterized the question as hypothetical and refused to answer it. He based his opinion solely on the documents he had reviewed, which related to the events in the real world in 2006-2007: he was unwilling to consider what might have happened in the but-for world.

[41] Dr Munro also points out that Teva's validation batches, essential for regulatory approval, were not completed until March 2007. Based on that information, he concluded that Teva would not have been in a position to launch its product in March 2006. He was asked whether Teva would have carried out its validation process earlier if it knew it could come to

market in March 2006, but Dr Munro dismissed that as a hypothetical scenario for which he had no evidence on which to base an expert opinion.

[42] The data for these batches showed that the yields varied from 86% to 97%, a range that Dr Munro considered unusually low. Dr Munro also noted that the lot numbers appeared to be out of sequence, suggesting that Teva might not have tested its batches consecutively, as required. Again, Dr Munro expressed concern that the documentation revealed variability in the manufacture of Teva's product that would have impaired its commercial launch. However, he could not say that this variability would have actually affected the reliability of Teva's validations or interfered with its entry into the market.

(3) Conclusion on the Liability Period

[43] The liability period begins on March 3, 2006 and ends on June 5, 2007, the date on which Justice Hughes rendered his decision dismissing Lilly's application for an order prohibiting the Minister from issuing an NOC to Teva.

B. *Issue Two – What was the size of the olanzapine market?*

[44] The parties agree that the size of the olanzapine market in the but-for world would have been the same as it was in the real world. Entry of a generic manufacturer into the market would not have affected the overall olanzapine market. Since Teva launched its product only in certain dosage forms (2.5, 5, 7.5, 10 and 15 mg), it is the overall market for those particular products that should be considered.

C. *Issue Three – What was the generics' share of the olanzapine market?*

[45] The parties agree generally on the methodology for determining the generic portion of the olanzapine market. However, they dispute the speed with which a generic company could have entered the olanzapine market in each province. This depends on the date the generic could have obtained approval and listing on the provincial formularies. In each jurisdiction, one must consider what happened in the real world – the delay between Teva's obtaining its NOC and its entry on the market in each province – and then assess whether something different would have occurred in the but-for world.

[46] The parties' principal disputes relate to the provinces of British Columbia, Alberta, Saskatchewan, and Manitoba. However, the circumstances in those provinces can be understood only after considering the situation in Ontario in 2007. Therefore, even though the parties largely agree on the appropriate listing date in Ontario, I will review the Ontario scenario first.

(1) Ontario

[47] Assuming that Teva obtained its NOC on March 3, 2006, the parties agree that Teva's generic olanzapine would have been listed on the Ontario formulary on May 19, 2006. The more challenging question is the price at which it would have been listed, and what effect certain events in Ontario would have on the prices in other provinces.

[48] Generally speaking, Teva would have sought to list its product in all provinces, including Ontario, at 70% of Lilly's brand price. For Ontario, however, in the real world, the situation was

complicated by the introduction of new legislation, known as Bill 102, in October 2006. Teva's expert on this subject, Mr Ian Hilley, explained that under Bill 102, generic prices were generally set at 50% of brand prices. However, some exceptions were permitted. The Executive Officer of the Ontario formulary commonly allowed exceptions for sole-source generic products in which the manufacturers had invested heavily. For example, Teva achieved an exception for its sole-source venlafaxine product, which was listed at 70% of brand price instead of 50%.

[49] However, Teva sought, but was denied, an exception for its olanzapine product. Teva was unable to justify a listing at [redacted] of the brand price. [redacted] Teva obtained a published listing at 75% of brand price, [redacted]. Accordingly, the [redacted] under the agreement was [redacted] of Lilly's price.

[50] [redacted] Once Bill 102 came into effect, Teva would have sought, but would likely not have received, an

exception to the rule. Therefore, as of January 1, 2007, Teva would have had to [redacted]. In the but-for world, as in the real world, Teva would have had to set its effective price in Ontario at no more than [redacted] of Lilly's price.

[51] On the strength of its published 75% listing price in Ontario, Teva looked to increase its pricing in other provinces to an equivalent level. As will be seen below, this was a confounding factor in Teva's efforts to obtain listings in those provinces. Since the Ontario [redacted] agreement would not have been in place in the but-for world, one must consider what would have transpired in its absence. In addition, the landscape was changing in 2007, largely as a result of developments in Ontario. One must be mindful, therefore, in reconstructing the but-for world of 2006-2007, that certain real world events had not yet transpired.

[52] In my view, some real-world events in 2007 and thereafter – the impact of Bill 102, Lilly's competitive offer to Ontario, Teva's corresponding [redacted] agreement, and the ongoing litigation between the parties – do not reflect the situation in the 2006-2007 but-for world.

(2) British Columbia

[53] In the real world, Teva's product was not listed in British Columbia until May 2011, almost four years after Teva obtained its NOC. Lilly argues that Teva would have experienced the same difficulties getting its BC listing even if it had obtained its NOC in 2006 instead of 2007. Accordingly, says Lilly, Teva did not experience lost sales in BC during the relevant time frame.

[54] I disagree. There were particular circumstances in 2007 that delayed Teva's listing on the BC formulary. I am satisfied that those circumstances would not have prevailed in 2006 and, therefore, that Teva would have obtained its listing on the BC formulary fairly promptly had it obtained its NOC on March 3, 2006.

[55] Teva's expert, Ms Jane Costaris, estimated that Teva would likely have obtained its BC listing for generic olanzapine on March 17, 2006. By contrast, Lilly's expert, Mr Ghislain Gauthier, concluded that Teva would not have obtained its listing in BC until sometime after the liability period. On many points relating to formulary listings, I prefer the evidence of Ms Costaris who has substantial real-world experience making submissions to provincial formularies.

[56] In Ms Costaris' opinion, in 2006, BC officials would have been keen to list Teva's generic olanzapine quickly because doing so would have saved the province over $8 million each year given that Teva's generic product would have been listed at 70% of the cost of Lilly's product. In reality, as pointed out above, it actually took nearly four years to list Teva's product. However, as Ms Costaris explained, that delay was the result of a series of special circumstances in 2007 that would not have existed in 2006.

[57] In August 2007, after Teva had obtained its NOC and while Lilly's appeal of Justice Hughes' decision was pending, Lilly entered into an agreement with BC to provide olanzapine at a price lower than Teva's in order to preserve its listing. After Lilly's appeal was dismissed, BC issued a request for proposal (RFP) in respect of olanzapine. It was the first time BC had invoked

this type of procedure. Lilly succeeded on the RFP and entered into further agreements with BC. Teva did not participate in the RFP; rather, it chose to challenge the process. It did not succeed. However, on May 5, 2011, Teva's product was ultimately listed in BC, just 16 days after it resubmitted its application.

[58] In the but-for world, Lilly would not have initiated its application to prevent Teva from obtaining its NOC. It follows that Lilly would have had no right to appeal Justice Hughes' decision in respect of that application. Therefore, to the extent that BC officials' concerns about the ongoing litigation between the parties under the Regulations impaired Teva's ability to get its product listed, I must disregard them. In fact, numerous documents in evidence cited Lilly's appeal as a significant factor standing in the way of Teva's listing. While he had not mentioned that factor in his report, Mr Gauthier conceded its significance on cross-examination.

[59] Lilly suggests that even in the absence of proceedings under the Regulations, its infringement action, commenced immediately after Justice Hughes' decision, would also have stood in the way of Teva's obtaining its listing in BC. However, I see no evidence of concern on the part of BC officials about patent infringement; rather, their concerns, as expressed in correspondence with Teva, related solely to the proceedings under the Regulations – that is, whether Teva's NOC was valid.

[60] In relation to the August 2007 agreement between BC and Lilly, Mr Gauthier stated that a similar agreement would likely have been entered into had Teva obtained its NOC in 2006. However, Mr Gauthier's opinion was based on the precedent of a 2005 product-listing agreement

(PLA) between BC and Lilly in respect of a drug called "Actos". On cross-examination, Mr Gauthier conceded that the 2005 PLA was not an exclusive listing agreement and was therefore unlike the 2007 agreement between BC and Lilly. He also failed to consider a 2006 BC report that stated that the province had historically "not actively negotiated drug prices with manufacturers", but would begin to do so in 2007.

[61] With respect to the RFP process, the evidence shows that this was likely a result of the introduction of Bill 102 in Ontario, which came into force on January 1, 2007. Dr Aidan Hollis, Teva's economics expert, described the BC tender process as an unprecedented event that responded to contemporaneous developments in Ontario. BC did not invoke a RFP process in 2006 in respect of risperidone, a drug with similar uses to olanzapine, and did not rely on that type of process again until 2015. In 2007, the Competition Bureau published a report recommending alternative drug plan approaches that would save costs, and BC's Deputy Minister of Health established a Pharmaceutical Task Force to explore various drug procurement and delivery options. These actions, according to Dr Hollis, were responsive to circumstances particular to the 2007 environment.

[62] In contrast, Dr Iain Cockburn, for Lilly, believed that the only reason Teva's product was not listed in BC in 2007 was because of the listing agreement between Lilly and the BC government entered into in August 2007. Given that a similar agreement would likely have been achieved in the but-for world, Dr Cockburn concluded that Teva's product would not have been listed in BC during the liability period. However, Dr Cockburn conceded that BC's concern

about the outstanding litigation between the parties was another possible, perhaps even more dominant, reason why Teva's product was not listed promptly in that province.

[63] Looking at this evidence as a whole, I am satisfied that the real-world events that unfolded in BC in late 2007 cannot be relied on to determine what would have happened in the liability period of March 2006 to June 2007. During the relevant time-frame, BC would probably not have entered into a PLA with Lilly, had a stay placed on Teva's listing pending the outcome of litigation, or established an RFP process for supplying olanzapine. In my view, in March 2006, BC would likely have listed Teva's product promptly. I agree with Ms Costaris that BC would likely have listed Teva's product on or about March 17, 2006. Mr Gauthier conceded that Ms Costaris' estimated date was reasonable, assuming that BC and Lilly had not entered into a PLA.

(3) Alberta

[64] In the real world, Teva's generic olanzapine product was listed in Alberta on September 1, 2007, nearly three months after Teva obtained its NOC.

[65] Mr Gauthier concluded that Teva would likely have received its listing on July 1, 2006, had it obtained its NOC on March 3, 2006, a delay of about four months.

[66] According to Ms Costaris, if Teva had obtained its NOC on March 3, 2006, it would have obtained its Alberta listing about two months later, on May 1, 2006. In her opinion, generic olanzapine would have received a fast-track listing given the quantity of annual savings that the

province would realize, about $5.5 million. Ms Costaris stated that generic olanzapine's listing in the real world was probably delayed somewhat because of issues about price. However, she notes, those issues arose out of the regulatory environment in Ontario in 2007 in which Teva negotiated [redacted] agreement with Ontario. In turn, Teva requested a price in Alberta of 75% of brand instead of 70%. That would not have happened, according to Ms Costaris, in the 2006-2007 but-for world.

[67] I agree with Ms Costaris' opinion. In his analysis, Mr Gauthier relied on listing dates for products that were not analogous to olanzapine, used a methodology based on average dates for listing that tended to overstate the delay for individual products, did not account for the delay caused by a requested change in price, and could not plausibly explain why his estimated listing dates were longer than those that occurred in the real world.

[68] The listing date for Teva's olanzapine product would likely have been May 1, 2006, at 70% of brand price.

(4) Saskatchewan

[69] In the real world, olanzapine was listed in Saskatchewan on November 1, 2009, nearly thirty months after Teva obtained its NOC.

[70] Ms Costaris and Mr Gauthier agree that the delay in Saskatchewan was at least partly the result of Teva's request for a price increase after it had made its submission for listing. As in Alberta, Teva's revised pricing was a product of the situation in Ontario in 2007. Accordingly,

Ms Costaris estimates that Teva's generic olanzapine would have been listed no later than October 1, 2006 if Teva had obtained its NOC on March 3, 2006. Ms Costaris compared olanzapine with another drug (Apo-Feno-Super) which was the subject of a NOC on April 1, 2006. The (negative) decision regarding listing of Apo-Feno-Super was issued six months later, on October 1, 2006. It is likely, therefore, according to Ms Costaris, that the decision to list Teva's olanzapine product would have been made at the same time.

[71] Mr Gauthier points to the discussions and the eventual agreement between Lilly and Saskatchewan according to which Lilly offered rebates in return for a commitment to continue to list its olanzapine product. The agreement was signed on December 12, 2008. Mr Gauthier believes that Lilly would have sought the same kind of arrangement with Saskatchewan if Teva had obtained its NOC earlier. Since the rebate Lilly was offering would have resulted in a lower price for Saskatchewan than Teva was seeking, Mr Gauthier concludes that there would been a significant delay in listing Teva's product in the but-for world to the point that it would not have been listed in Saskatchewan within the relevant time frame.

[72] Again, I find Ms Costaris' opinion more persuasive. First, the issue about pricing would not have arisen until after Bill 102 came into effect in Ontario in 2007: it would not have affected Teva's position in Saskatchewan in March 2006 when Teva would have obtained its NOC. Therefore, in the but-for world, Teva would probably not have experienced the delays that it encountered in the real world.

[73] Second, Lilly's agreement with Saskatchewan was not signed until eighteen months after Teva acquired its NOC. Assuming that Lilly would have sought a similar arrangement in the but-for world, Lilly would likely not have achieved it until after the expiry of the liability period; it would not have been a factor affecting Teva's listing in Saskatchewan.

[74] Therefore, I find that the appropriate listing date for Saskatchewan is October 1, 2006, and that Teva's product would have been listed at 70% of brand price.

(5) Manitoba

[75] In the real world, Teva's product was listed in Manitoba on October 14, 2010, more than three years after Teva obtained its NOC.

[76] In Ms Costaris' opinion, Teva's product would have been listed in Manitoba on September 14, 2006 in the but-for world, about six months after Teva obtained its NOC. In arriving at that date, she assumed that Teva would not have sought a price increase as it did in the real world and, therefore, that Teva's listing would not have been delayed. In addition, she assumed that Teva would have applied for its listing prior to Manitoba's introduction in 2007 of a new process called a utilization management agreement (UMA).

[77] Mr Gauthier stated that, in his view, Teva would not have obtained a listing in Manitoba in the but-for world any earlier than it did in the real world. He assumed that Teva would have sought a higher price in Manitoba compared to other provinces, just as it did in the real world. He also concludes that the discussions that led to the UMA that was ultimately reached between

Manitoba and Lilly in 2009 would also have occurred in the but-for world and delayed Teva's listing. Mr Gauthier did agree, however, that Manitoba was not actively seeking UMAs in 2006.

[78] I agree with Ms Costaris that the UMA process would not have existed in 2006. Therefore, I accept her projected listing date of September 14, 2006 at a price of 70% of brand.

(6) The Other Provinces

(a) *Quebec*

[79] The experts agree that Teva's product would have been listed in Quebec on October 11, 2006 at a price of 70% of brand. While Mr Gauthier believes that Teva would have been obliged to disclose to Quebec its subsequent [redacted] arrangement in Ontario and to give Quebec the equivalent net price of [redacted] of brand, the evidence shows that in the real world that did not happen. Prices in Quebec did not [redacted] until February 2008, well outside the liability period.

(b) *New Brunswick*

[80] The experts agree that Teva's olanzapine product would have been listed in New Brunswick on June 9, 2006. The product would have been listed at 70% of brand price.

(c) *Nova Scotia*

[81] Ms Costaris testified that Teva's listing date in Nova Scotia would have been June 1, 2006. She based her opinion on the treatment of other products submitted for listing around the same time. Mr Gauthier sets the date a month later, July 1, 2006, based on average listing delays in late 2005 to late 2006. As mentioned, I find that Mr Gauthier's approach tends to overstate delays to listing. Accordingly, I think Ms Costaris' date is more accurate. The listing price would have been 70% of brand price.

(d) *Prince Edward Island*

[82] Ms Costaris testified that Teva's product would have been listed on October 16, 2006 at the latest. Mr Gauthier agreed with her that an earlier date of July 1, 2006 was quite possible. Based on these opinions, my view is that the safer date is October 16, 2006, and that the price would have been 70% of brand.

(e) *Newfoundland and Labrador*

[83] Ms Costaris opined that Teva could have obtained a listing in Newfoundland and Labrador by January 1, 2007 or earlier. Mr Gauthier chose the earlier date of September 1, 2006. I am satisfied that Mr Gauthier's date is sound. Again, the listing price would have been 70% of brand.

D. *Issue Four – What was Teva's share of the generic olanzapine market?*

[84] Lilly maintains that Teva would have had to share the generic olanzapine market with another generic company, Apotex Inc. Lilly says that Apotex would likely have entered the

market on June 23, 2006, the date on which Apotex would have received its NOC for olanzapine if Lilly had discontinued its prohibition proceedings against Apotex. In the real world, Apotex entered the olanzapine market in October 2009 after Lilly's patent had been found to be invalid. Lilly was successful in its prohibition application against Apotex, which prevented Apotex from marketing its product any sooner.

[85] I have no basis for finding that in the but-for world in which Teva obtained its NOC on March 3, 2006, Lilly would have discontinued its proceeding against Apotex. Lilly commenced prohibition proceedings against numerous other generic companies in respect of olanzapine, and most of them were initiated after Lilly's application against Teva was dismissed on June 5, 2007. In respect of Apotex specifically, Lilly entered into discussions with that company, but the discussions did not result in any agreement to allow Apotex onto the market. In fact, the evidence indicates that Lilly rarely enters into agreements to authorize generic companies to participate in a market alongside Lilly. The last time Lilly signed an authorized generic agreement was in 1995.

[86] Lilly's actions in the real world do not suggest to me that it would have acted differently in the but-for world. In the but-for world, the Regulations would still have existed (*Apotex Inc v Sanofi-Aventis*, 2014 FCA 68 at paras 171, 186). Therefore, Apotex would have had to address the Regulations before it could have entered the market. Lilly would have had the remedies available to it under those Regulations in relation to olanzapine and, in my view, would have invoked those remedies against other generic companies wishing to market olanzapine, including Apotex.

[87] Further, there is no evidence that Apotex was even in a position to come to market in 2006. Mr Gordon Fahner, Apotex's Vice President of Global Finance, was called as a witness by Lilly, but he was unable to provide evidence about his company's access to bulk olanzapine API during the relevant period.

[88] Therefore, the evidence shows that Teva would have been the sole generic company on the market during the liability period.

E. *Issue Five – What is the amount of Teva's damages?*

[89] I have already dealt with the pricing of Teva's product in the various provinces. There remain two additional issues relating to the quantification of Teva's losses. First, should the calculation of Teva's losses include compensation for so-called "pipefill"? Second, how much should Teva's losses be reduced to account for the monies it would have paid to pharmacies and other retailers of its product (*ie*, trade-spend)?

(1) Pipefill

[90] Teva claims that its losses should include an amount for pipefill – that is, the quantity of sales Teva would have made to distributors in the but-for world, an amount that would not be captured by retail sales figures (from IMS Health Canada, referred to as IMS data). Teva contends that losses attributable to pipefill sales have been compensated in other s 8 cases.

[91] The concept of pipefill is that a manufacturer must first get its product into the channels of trade before any sales to customers can take place. There is a delay, therefore, between the shipment of a product from the factory and retail sales. Teva maintains that its losses should include a pipefill adjustment to include the shipments it would have made during the liability period.

[92] I disagree. As I understand it, pipefill does not represent lost sales during the liability period. Rather, pipefill represents the differential between retail sales and the quantity of product leaving the factory. That differential represents sales that would have been made outside the liability period. It is true that pipefill may represent some lost sales in the sense that in the but-for world Teva would have moved a certain amount of inventory into the distribution stream which, in due course, would be sold to customers. In the but-for world, those sales would have been made, but they would have been made outside the liability period. Accordingly, for present purposes, they should not be included in Teva's losses.

[93] I concur with Dr Iain Cockburn's opinion on pipefill. He explained that an adjustment to retail data would be appropriate to deal with the issue of timing – the delay between manufacture and retail sales. He stated:

> The drug is manufactured. It may sit in inventory at the factory for a while. Then it is shipped by the manufacturer to the wholesalers. That is what we are calling ex-factory sales. It may sit at the wholesaler for some time until it is ordered by the retailer. Having arrived [at] that retailer, it may then sit on the pharmacy shelf for some time until it is finally dispensed to an individual. I think the challenge that was being addressed here is, if you look at the IMS prescriptions data, you need to try to understand what would have been sold or moved through the distribution chain at an earlier point in time. You need to make an adjustment for timing.

[94] The economic loss associated with that delay, according to Dr Cockburn, is confined to the "time value of money" or the "opportunity cost" based on the fact that those sales would have been made earlier in the but-for world. The appropriate adjustment, in effect, would be to award Teva an amount representing interest on the money involved.

[95] Dr Cockburn distinguished this issue of timing from a pipefill adjustment in the sense described above. The latter, proposed by Dr Hollis, represents accumulation of inventory in the hands of wholesalers and not captured by the retail data. In Dr Cockburn's analysis, if Teva were able to recover for the amount of product that was held in inventory, it would be credited with market entry at a steady state of sales; that is, each tablet leaving the factory would be counted as a sale. In Dr Cockburn's view, with which I concur, such an approach would over-compensate Teva because it would not correspond with the amount of Teva's lost sales in the but-for world. As he explained, the accumulation of product in wholesalers' warehouses will eventually be sold. Since it will be sold, it cannot constitute lost sales.

[96] As mentioned, Teva maintains that compensation for pipefill has been awarded in other s 8 cases. In my view, unlike here, the issue of pipefill in those cases was not strenuously contested. Teva points to *Apotex Inc v Sanofi-Aventis*, 2012 FC 553 at paras 221-226, aff'd 2014 FCA 68; *Teva Canada Limited v Pfizer Canada Inc*, 2014 FC 248 at paras 186-190; and *Apotex Inc v Takeda Canada Inc*, 2013 FC 1237 at paras 119-120. I will address each of these cases, in turn.

[97] In *Apotex v Sanofi*, the experts before Justice Judith Snider agreed that the calculation of lost sales should include some measurement for the time-lag between sales to distributors and sales to individual customers. After considering the three experts' methodologies, she concluded that a simple adjustment of two months of sales should be added to the calculation of Apotex's losses. That figure represented the difference between Apotex's sales in the real world as compared to the data captured in IMS records. It is not clear whether the adjustment Justice Snider made was intended to include pipefill or simply to address the issue of timing. On the appeal of Justice Snider's decision, the Federal Court of Appeal did not address the issue of pipefill.

[98] Dr Cockburn reviewed Justice Snider's decision and could not tell whether the adjustment she awarded was for timing or for pipefill.

[99] In *Teva v Pfizer*, Justice Russell Zinn pointed out the difference between IMS data showing the number of sales made to individual customers, and the measurement of sales based on the amount of product leaving the manufacturer's factory, so-called ex-factory data. Justice Zinn concluded that IMS data underreports actual sales and, therefore, that ex-factory data should be used to calculate sales. In his view, using ex-factory data eliminated the need to calculate pipefill separately. A calculation of an amount specifically reflecting pipefill was not made.

[100] In *Apotex v Takeda*, the parties agreed that an adjustment had to be made for pipefill because IMS data would not capture it. As Justice Michael Phelan described it, the question

involved a “reporting system delay” and required a decision on when sales would reach a steady state in each jurisdiction (at para 110). The two experts before him suggested adjustments of 0.9 months and 1.5 months respectively. It is not clear to me that this adjustment represented pipefill in the sense in which the parties have used that term in the case before me.

[101] I find the preceding authorities to be somewhat ambiguous on the issue of pipefill. In none of them was the issue seriously contested or a quantum specifically calculated.

[102] Within the liability period, where there is a differential between data on retail sales and figures on the amount of product leaving the manufacturer’s factories, that difference represents future sales of the product, sales that will take place outside the liability period. Do those constitute lost sales for purposes of s 8 of the Regulations?

[103] It is clear that it is only losses suffered during the liability period that are compensable under the Regulations. It follows, in my view, that where a generic company lost sales that would have been made after the end of the liability period, those losses are not compensable. Accordingly, with the greatest respect for the learned judges of this Court who may have acceded to representations to the contrary, I find that a figure representing pipefill should not be added to Teva’s losses.

(2) Trade-spend

[104] Trade-spend represents the after-sales amount paid by generic drug manufacturers to their purchasers, mainly pharmacies and other retailers. Trade-spend can take various forms: rebates,

trade allowances, educational subsidies, purchasing incentives, etc. Generic companies use trade-spend to encourage trade with, and foster loyalty from, those who actually put pharmaceutical products on their shelves. In a multi-source market, generics often compete with one another through the amount of trade-spend they are willing to provide. The higher the trade-spend, the greater the incentive for a retailer to sell the generic product from a particular manufacturer.

[105] Lilly argues that in the but-for world Teva's trade-spend for its generic olanzapine product would have been in the range of [redacted], and that Teva's losses should be discounted accordingly. Lilly's position is that Teva's trade-spend should be set at the average rate across all products in the real world ([redacted]), or even higher ([redacted]) due to the circumstances that would have prevailed in the but-for world.

[106] I disagree with Lilly's submission. I am satisfied that in the 2006-2007 time frame, Teva's trade-spend would have been lower for generic olanzapine than it would have been than for its other products. In particular, given that Teva would have been the sole generic on the market during the relevant period, I am satisfied that its trade-spend rate would have been relatively low. Teva says it should be no higher than 30%. I agree.

[107] Lilly's expert, Ms Ann Woods, testified that a single-source trade-spend rate is a fiction. In reality, she says, retailers expected an overall rebate from manufacturers regardless of the molecule they were being asked to sell. In her experience, manufacturers did not set trade-spend rates molecule by molecule.

[108] Ms Woods opinion, while genuine, does not accord with the evidence before me. Further, it does not correspond with findings in other s 8 damages cases where this Court has concluded that single-source trade-spend rates are very low, much lower even than percentage put forward by Teva in this case. For example, Justice Phelan found that the trade-spend rate on a single-source molecule in circumstances where there was a risk of an infringement action was 8.9% (*Apotex v Takeda*, above, at paras 161-162). Justice Zinn found that the trade-spend rate on venlafaxine in a single-source market would have been 15% (*Pfizer Canada Inc v Teva Canada Limited*, above, at para 217).

[109] Teva's witnesses, both factual and expert, suggest that the trade-spend for olanzapine in the real world in late 2007 was higher than it would have been in the but-for world because Teva was trying to use its sole-source market position with olanzapine to leverage another Teva product, venlafaxine, which was facing competition from other generic entrants at the time. Teva claims it boosted its trade-spend on olanzapine, even though it was a sole-source product, in order to secure long-term commitments from retailers in respect of both olanzapine and venlafaxine. That was a circumstance peculiar to the late 2007 time-frame; it would not have existed, says Teva, during the liability period of March 2006 to June 2007.

[110] Rather, says Teva, it would have been the sole generic on the market with an olanzapine product during the liability period. To determine its likely trade-spend on olanzapine, Teva maintains one should look to the trade-spend rate for venlafaxine during the period when Teva was the sole-source supplier of that molecule – a rate close to [redacted].

[111] Lilly disputes the relevance of evidence relating to the trade-spend on venlafaxine. It points out that Teva sold venlafaxine under a license from Wyeth, which means that it was not at risk of being sued for infringement (unlike the situation with olanzapine) and could be reasonably certain of its exclusive position on the market. Further, Teva's agreement with Wyeth limited Teva only to reasonable expenses; in other words, Teva was not free to set trade-spend as high as it might have wished. Finally, Lilly notes that Teva was splitting its profits with Wyeth, which might have inclined Teva to maximize its own profits by reducing trade-spend. Accordingly, says Lilly, these circumstances would have led Teva to set a low trade-spend rate for venlafaxine.

[112] These circumstances, according to Lilly, would have caused Teva to set a lower trade-spend rate for venlafaxine than for olanzapine. In particular, since Teva would have been at risk of being found liable for infringing Lilly's patent, Teva would likely have reduced its exposure to damages (calculated according to profits) by increasing its trade-spend. In addition, since Teva would likely have faced imminent competition from other generics, Lilly maintains that Teva would have set elevated trade-spend rates for olanzapine, just as it did when competition in the venlafaxine market was on the horizon.

[113] In a different vein, Lilly also contends that the evidence relating to trade-spend for venlafaxine is inadmissible or, at best, unreliable. The evidence takes the form of a report prepared by Deloitte, which I have discussed above and found to be inadmissible hearsay. However, there is additional documentary evidence in the form of a summary of financial data relating to venlafaxine prepared by Ms Tressel, a former financial officer at Teva (2002 to 2011),

who also testified about her knowledge of venlafaxine trade-spend rates as reflected in her summary. Other Teva witnesses, Mr Doug Sommerville and Mr Barry Fishman, also gave direct testimony about trade-spend rates for venlafaxine and olanzapine.

[114] Ms Tressel confirmed that the trade-spend rate in her summary ([redacted]) reflected the underlying data captured in Teva's financial records for venlafaxine and reported to Deloitte pursuant to Teva's arrangement with Wyeth. It was Ms Tressel's responsibility to assemble the relevant data. She personally prepared the summary based on prior reports on sales and trade-spend prepared by members of her team, and personally verified the accuracy of the information contained in it. It was prepared in the ordinary course of business for purposes of tracking trade-spend on venlafaxine. I am satisfied that the summary meets the criteria for the business records exception to the hearsay rule and is therefore admissible as proof of its contents.

[115] Ms Tressel stated that the trade-spend policy for venlafaxine was set by Mr Sommerville and Mr Fishman, both of whom also testified.

[116] Mr Sommerville, Senior Vice-President and General Manager at Teva, was responsible for setting trade-spend rates in 2006-2007. He testified that while trade-spend rates varied with the product and the customer, rates for single-source products were typically much lower ([redacted]) than for multi-source products ([redacted]), especially those produced at a low cost. On some occasions, trade-spend rates for particular customers might be set relatively high in order to convince those customers to list other products or to gain their long-term loyalty. Contrary to

Lilly's argument, Mr Sommerville stated that when Teva was at risk of being sued for infringement, it kept its trade-spend rates low.

[117] Mr Fishman, former President of Teva Canada, concurred. He testified that the trade-spend on a single-source product would normally be less than [redacted]. Mr Gordon Fahner, from Apotex, agreed that trade-spend on single-source products was comparatively low. In effect, he said, the more competition the higher the trade-spend.

[118] I am satisfied that Teva's trade-spend on olanzapine in the but-for world would have been at the low end of the scale – I am prepared to accept Teva's proposed rate of 29.4%.

[119] Teva would have been the sole source for a generic version of olanzapine during the liability period. There were no competitors in a position to enter the market.

[120] As mentioned, trade-spend on sole-source products is usually low. I am persuaded that venlafaxine, a sole-source product in the same therapeutic class that was marketed during the relevant time frame, is a good model for calculating the trade-spend on olanzapine in the but-for world. I accept the opinion of Mr Errol Soriano, who calculated the venlafaxine trade-spend rate based on Ms Tressel's summary, that the trade-spend for venlafaxine was 29.4%. In his analysis, he adjusted his calculation to take account of a large sum paid to Loblaws in respect of venlafaxine, and the rising rate of trade-spend in the three months just before Teva faced competition in the venlafaxine market.

[121] In my view, Mr Soriano's adjustments were appropriate. Regarding the former, Mr Sommerville explained that the payment to Loblaws was attributed to venlafaxine for accounting purposes, but was actually meant to secure a long-term commitment from Loblaws across Teva's product line. Prior to that payment, Teva's trade-spend for venlafaxine at Loblaws was [redacted]. With respect to the latter, Mr Sommerville explained that Teva learned in the summer of 2007 that Ratiopharm was close to launching its own venlafaxine product. Accordingly, Teva raised it trade-spend in August 2007. I accept that the trade-spend on olanzapine would have remained low throughout the liability period because competition was not expected during that time frame. Accordingly, I agree with Mr Soriano's calculation.

[122] By contrast, actual trade-spend rates for olanzapine in the real world are not indicative of rates in the but-for world. As Mr Somerville explained, in the real world, olanzapine was used to leverage commitments to Teva's venlafaxine product, a circumstance that would not have arisen in the but-for world.

[123] Further, I do not accept that the possibility of a patent infringement action by Lilly would have raised Teva's trade-spend rate. I am not persuaded that a generic company with a sole-source product would have deliberately increased its trade-spend rate in order to lower its profits in an effort to limit its potential liability for damages in the event that it might be sued for infringement, and might lose.

F. *Other Costs*

[124] There are a few comparatively minor factors that should also be recognized in the calculation of Teva's losses:

- The provision of free goods;
- Distribution allowances, prompt payment discounts, and distribution expenses; and
- Costs of sales.

[125] Ms Woods calculated a discount for free goods based on actual data relating to olanzapine ([redacted]). Mr Soriano used an average figure across products ([redacted]); I accept that Ms Wood's calculation is more precise and better represents the quantity of free goods that would have been provided in the but-for world.

[126] The parties' experts agree on the issues of distribution allowances, discounts, and expenses. I need not make any finding on those questions.

[127] With respect to other costs of sales, the only amounts really in issue relate to employee bonuses, yield losses, and processing costs.

[128] Both Mr Sommerville and Ms Tressel testified that no bonuses would have been paid to sales personnel or other employees if Teva's olanzapine product had been launched in 2006. The budget had already been fixed and the unanticipated launch of a new product would not have given rise to new bonuses. However, Mr Sommerville conceded that in the absence of litigation,

a budget would have been put in place to provide for employee bonuses. I accept the evidence of Lilly's expert, Mr Greg McEvoy, that the proper amount is [redacted] of incremental gross sales.

[129] Lilly relies on the yield loss data from Teva's validation batches, while Teva contends that the figures from its commercial production are more accurate. I agree with Teva on this point and accept Mr Soriano's calculation based on yield loss data from 2007-2008.

[130] Similarly, I accept Mr. Soriano's estimate of the processing costs of goods sold. He relied on figures from 2008 based on actual production in 2007.

G. *Interest*

(1) Pre-judgment Interest

[131] Teva seeks pre-judgment interest beginning on March 3, 2006, calculated according to the Ontario *Courts of Justice Act*, RSO 1990, c C43, s 127, which would provide a rate of 4.5%. Lilly agrees that the presumptive rate is 4.5%, but urges the Court to set a lower percentage given the decline in interest rates in recent years, relying on the discretion set out in s 130(1) of the Ontario statute.

[132] I agree with Lilly that the rate of 4.5% sought by Teva is too high. I find that a variable rate interest rate over the relevant period would be more appropriate. This approach was proposed by Lilly's expert, Mr McEvoy, and accepted by this Court in *Apotex Inc v Sanofi-Aventis*¸ 2012 FC 553 at para 298.

(2) Post-judgment Interest

[133] Post-judgment interest should be calculated from the date this judgment is issued.

IV. Conclusion and Disposition

[134] I find the following:

1. The period of liability is from March 3, 2006 to June 5, 2007.

2. The size of the olanzapine market in that time frame would have been the same as it was in the real world.

3. The generic portion of the olanzapine market would have been the same as it was in the real world. Teva's olanzapine product would have been listed at 70% of brand price on the various formularies, as follows:

    - Ontario – May 19, 2006
    - British Columbia – March 17, 2006
    - Alberta – May 1, 2006
    - Saskatchewan – October 1, 2006
    - Manitoba – September 14, 2006
    - Quebec – October 11, 2006
    - New Brunswick – June 9, 2006

- Nova Scotia – June 1, 2006
- Prince Edward Island – October 16, 2006
- Newfoundland and Labrador – September 1, 2006

4. Teva was in a position to supply the entire generic market during the liability period, and no other generics would have been present. No allowance for pipefill should be included in lost sales.

5. Teva's trade-spend rate for olanzapine would have been 29.4%.

6. Other expenses include free goods, distribution allowances, prompt payment discounts, distribution expenses, and costs of sales, to be calculated in accordance with paras 124-130 above.

7. Teva is entitled to pre-judgment interest calculated at a variable rate from March 3, 2006, and post-judgment interest as of the date this judgment is issued.

JUDGMENT in T-1048-07

THIS COURT'S JUDGMENT is that:

1. Teva is entitled to damages calculated according to the factual findings set out in paragraph 134 above, with costs.
2. The parties may make submissions within 10 days regarding any redactions that are required before releasing a public version of this decision.

"James W. O'Reilly"
Judge

Annex I

Summary of Experts

Eli Lilly

Dr Iain M. Cockburn, B.Sc. (Hons.) (Econ.), M.A. (Econ.), Ph.D. (Econ.)

Dr Cockburn is an economist and professor in Management at the Boston University Questrom School of Business. He has also been a professor at the University of British Columbia in the Faculty of Commerce, as well as a visiting scholar at both the Department of Economics at Harvard University and in various departments at MIT. He has been a co-editor or referee for several academic journals, and published various peer-reviewed journal articles. He has been retained in the past as a consultant on pharmaceutical pricing and related issues by government agencies like the Patented Medicine Prices Review Board, as well as by international governments.

Mr Ghislain Gauthier, B.Comm. (Marketing)

Mr Gauthier has over 30 years' experience in sales and marketing/communication for the pharmaceutical and biotech sectors. He has worked for companies such as Pangaea Consultants, ICN Canada, Allard Pharma Communications, and Ortho Pharmaceuticals. His work at these companies has encompassed positions such as sales representatives, product manager, account manager, advertising manager, and director of marketing.

Mr Greg McEvoy, B.Comm., CA, CBV, CPA

Mr McEvoy has been an accountant for over 25 years, with a speciality in forensic accounting, damages quantification, and business valuation. He has authored accounting reports on damages quantification and investigative accounting, and has conducted criminal investigations for both the private sector and government agencies. His work has focused on the quantification of economic damages resulting from various legal disputes, including intellectual property matters.

Dr Gordon Munro, B.Sc. (Hons.) (Pharma.), M.Sc. (Pharma.), Ph.D. (Chem.), M.R.Pharm.S., C.Chem.MRSC, F.R.Pharm.S., F.R.S.C.

Dr Munro is a pharmacist and a chemist, and is currently employed as a consultant. His previous roles have involved being accountable for quality control and assurance, health and safety, as well as environmental matters at companies such as Watson Pharmaceuticals and Glaxo Wellcome Operations. He has also worked for the United Kingdom Medicines Control Agency, and has represented the European Regulators on a range of international committees. He has published a number of scientific papers, and lectured nationally and internationally.

Ms Ann Woods, B.Sc. (Biol.), M.A., C.F.A.

Ms Woods is a Chartered Financial Analyst and is currently the director of The Pangea Group. Prior to this position, she worked for Novartis Pharma in a role involving helping pharmacies, long-term care stakeholders, and industry associates, and has also worked at Sandoz, a generic drug manufacturer. She has held director roles involving providing consulting solutions for pharmacy, private companies, and government institutions.

Teva

Ms Jane Costaris, B.Sc. (Hons.) (Microbiol.)

Ms Costaris has over 20 years' experience in pharmaceutical Regulatory Affairs and Quality Assurance. She is the President of Regulatory Solutions Inc, which is a pharmaceutical regulatory approval and compliance consulting company. She has taught courses on Regulatory Submissions and Regulations & Guidelines at Humber College. She has also held positions that involved the preparation and filing of Health Canada new drug approval submissions and provincinal drug submissions for innovative drugs.

Mr Ian Hilley, B.Pharm. (Hons.)

Mr Hilly is a pharmacist who has held positions pertaining to the regulation of pharmaceutical products. He has been involved in directing market access planning and implementation, including provincial formulary filings and strategies.

Dr Aidan Hollis, M.A. (Eng.), M.A. (Econ.), Ph.D. (Econ.)

Dr Hollis is currently a Professor of Economics at the University of Calgary whose research focuses mainly on pharmaceutical markets. He was previously the Academic Director of the Centre for Regulatory Affairs of the Van Horne Institute, and has been the TD MacDonald Chair in Industrial Economics at the Competition Bureau at Industry Canada. His expertise includes both theoretical and empirical analysis of competitive markets. He has published articles on the pharmaceutical markets in various peer-reviewed journals.

Mr Errol Soriano, HBA, CA, CBV

Mr Soriano is a chartered business valuator, a chartered professional accountant, and a certified fraud examiner. He has experience in business valuation and financial loss quantification. He has authored books, articles, and teaching materials concerning accounting and financial loss.

Annex II

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
8 (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period	**8** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :
(a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that	a) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :
(i) the certified date was, by the operation of An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or	(i) soit que la date attestée est devancée en raison de l'application de la Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique), chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,
(ii) a date other than the	(ii) soit qu'une date autre

certified date is more appropriate; and

(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

que la date attestée est plus appropriée;

b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

…

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

[…]

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

Ontario Court of Justice Act, RSO 1990, c C43

Loi sur les tribunaux judiciaires, LRO 1990, c C.43

Prejudgment and postjudgment interest rates

Taux d'intérêt antérieur et postérieur au jugement

Definitions

Définitions

127. (1) In this section and in sections 128 and 129

127. (1) Les définitions qui suivent s'appliquent au présent article et aux articles 128 et 129

"postjudgment interest rate" means the bank rate at the end of the first day of the last month of the quarter preceding the quarter in which the date of the order falls, rounded to the next higher whole number where the bank rate includes a fraction, plus 1 per cent;

«taux d'intérêt postérieur au jugement» Le taux d'escompte à la fin du premier jour du dernier mois du trimestre précédant le trimestre au cours duquel se situe la date de l'ordonnance, arrondi au nombre entier supérieur si le taux comprend une fraction, plus 1 pour cent.

[…]

…

Discretion of court

Pouvoir discrétionnaire du tribunal

130. (1) The court may, where it considers it just to do so, in respect of the whole or any part of the amount on which interest is payable under section 128 or 129,

130. (1) Le tribunal peut, à l'égard de la totalité ou d'une partie de la somme qui porte intérêt aux termes de l'article 128 ou 129, s'il l'estime juste :

(a) disallow interest under either section;

a) refuser les intérêts prévus à l'un ou l'autre article;

(b) allow interest at a rate higher or lower than that provided in either section;

b) accorder des intérêts à un taux supérieur ou inférieur à celui qui est prévu à l'un ou l'autre article;

(c) allow interest for a period other than that provided in either section.

c) accorder des intérêts pour une période différente de celle qui est prévue à l'un ou l'autre article.

Same

Idem

(2) For the purpose of subsection (1), the court shall take into account,

(2) Pour l'application du paragraphe (1), le tribunal tient compte :

(a) changes in market interest rates;

a) de la fluctuation des taux d'intérêt du marché;

(b) the circumstances of the case;

b) des circonstances de l'espèce;

(c) the fact that an advance payment was made;

c) du fait qu'un paiement anticipé a été effectué;

(d) the circumstances of medical disclosure by the plaintiff;

d) des faits relatifs à la divulgation de renseignements médicaux par le demandeur;

(e) the amount claimed and the amount recovered in the proceeding;

e) du montant demandé et du montant recouvré dans le cadre de l'instance;

(f) the conduct of any party that tended to shorten or to lengthen unnecessarily the duration of the proceeding; and

f) du comportement de l'une ou l'autre partie, qui aurait eu pour effet d'abréger ou de prolonger indûment la durée de l'instance;

(g) any other relevant consideration. R.S.O. 1990, c. C.43, s. 130.

g) de tout autre facteur pertinent. L.R.O. 1990, chap. C.43, art. 130.

Federal Courts Act, RSC 1985, c F-7

Loi sur les Cours fédérales, LRC (1985), ch F-7

Judgment interest — causes of action within province

Intérêt sur les jugements — Fait survenu dans une seule province

37 (1) Except as otherwise provided in any other Act of Parliament and subject to subsection (2), the laws relating to interest on judgments in causes of action between subject and subject that are in force in a province apply to judgments of the Federal Court of Appeal or the Federal Court in respect of any cause of action arising in that province.

37 (1) Sauf disposition contraire de toute autre loi fédérale et sous réserve du paragraphe (2), les règles de droit en matière d'intérêt pour les jugements qui, dans une province, régissent les rapports entre particuliers s'appliquent à toute instance devant la Cour d'appel fédérale ou la Cour fédérale et dont le fait générateur est survenu dans cette province.

Judgment interest — causes of action outside or in more than one province

Intérêt sur les jugements — Fait non survenu dans une seule province

(2) A judgment of the Federal Court of Appeal or the Federal Court in respect of a cause of action arising outside a province or in respect of causes of action arising in more than one province bears

(2) Dans le cas où le fait générateur n'est pas survenu dans une province ou dans celui où les faits générateurs sont survenus dans plusieurs provinces, le jugement porte intérêt, à compter de son

interest at the rate that court considers reasonable in the circumstances, calculated from the time of the giving of the judgment.

prononcé, au taux que la Cour d’appel fédérale ou la Cour fédérale, selon le cas, estime raisonnable dans les circonstances.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1048-07
STYLE OF CAUSE:	ELI LILLY CANADA INC., ELI LILLY AND COMPANY, ELI LILLY AND COMPANY LIMITED, AND ELI LILLY SA v TEVA CANADA LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MAY 2 - 5, 2016; MAY 9 - 12, 2016; MAY 16-20, 2016 AND MAY 24-27, 2016
CONFIDENTIAL JUDGMENT AND REASONS:	O'REILLY J.
DATED:	JANUARY 30, 2017
AMENDED PUBLIC JUDGMENT AND REASONS:	O'REILLY J.
DATED:	APRIL 4, 2017

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