CITATION: Apotex v. Eli Lilly, 2023 ONSC 1968
COURT FILE NO.: CV-11-420115
DATE: 20230330

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
APOTEX INC.	)	*Harry Radomski, Jerry Topolski, Nando De Luca, Sarah Stothart, Ben Hackett, Daniel Cappe*, for the Plaintiff
Plaintiff	)	
– and –	)	
ELI LILLY AND COMPANY, ELI LILLY S.A., LILLY DEL CARIBE, INC., LILLY S.A., ELI LILLY EXPORT S.A. and ELI LILLY CANADA INC.	)	*Marc Richard, Alex Gloor, Frederic Lussier, Rebecca Johnston, Richard Dearden, Karl Racine*, for the Defendants
Defendants	)	
	)	**HEARD:** January 17 – 21, 24 – 28, 31, February 1, 3, 4, June 16, 17, 2022

KOEHNEN J.

PUBLIC REASONS FOR JUDGMENT

[1] The plaintiff, Apotex Inc., is a manufacturer of generic drugs. It brings this action for damages against the defendants (collectively "Eli Lilly") for damages that allegedly resulted from delays that Apotex encountered in bringing a drug known as Apo-Atomoxetine to market. Apo-Atomoxetine is a generic copy of Eli Lilly's branded and patented drug Strattera the active ingredient of which is atomoxetine. Both Strattera and Apo-Atomoxetine are used in the treatment of attention deficit disorder.

[2] The claim for damages arises out of s. 8 of the *Patented Medicines (Notice of Compliance) Regulations,*[1] (the "*Regulations*") which allows a generic manufacturer to claim damages in certain circumstances where a patent holder has taken steps to delay the generic manufacturer's entry into the market. If those circumstances are found to exist, then the generic manufacturer has a right to claim for losses it sustained during the period of delay. Those losses are determined by reference to a hypothetical world. Hypothetical because the court is being asked to calculate what the generic manufacturer's losses would have been had it been allowed to enter the market without the delay that gives rise to the claim for damages.

[3] For the reasons set out below I dismiss Apotex's claim. In my view, the circumstances out of which Apotex's claim arises are not such that they trigger a right to compensation under the *Regulations*. As a result, there is no liability on the part of the defendants. Further, even if the circumstances of the case did give rise to a right to compensation, I find that Apotex has not sustained any damages because it would not have entered into the market any sooner in the hypothetical world than it did in the real world.

PART ONE: LIABILITY

I. The Statutory Scheme

[4] An understanding of this action requires a brief background to the statutory scheme that governs patented medications in Canada.[2] The summary below does not purport to be a summary of the complete statutory scheme but summarizes only those elements that are relevant to this action.

[5] Under the patent regime that governs in Canada, patented drugs receive a monopoly for 20 years. However, to encourage the entry of generic drugs into the market immediately on the expiration of a patent, the *Patent Act*[3] allows generic manufacturers to prepare and stockpile their own competitive products during the life of the patent. The regime that governs this is found in the *Patented Medicines (Notice of Compliance) Regulations,*[4] (the "*Regulations*"). The Regulations refer to the innovator as the "first person" and to the generic manufacturer as the "second person."

[6] The sale of a patented or generic medicine in Canada requires a Notice of Compliance ("NOC") from the Federal Department of Health. An initial NOC in respect of a patented medicine generally obtained by a first person submitting a New Drug Submission ("NDS"). The NDS, among other things, sets out a description of the drug and provides data about testing, manufacturing, and safety. After an initial NOC has been granted, further NOCs in respect of that drug can be obtained by way of the submission of an Abbreviated New

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[1] *Patented Medicines (Notice of Compliance) Regulations*, SOR/99-133
[2] The Supreme Court of Canada helpfully summarized that scheme in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at paras. 6-24 which I further summarize in paras. 6-10 below.
[3] *Patent Act*, RSC 1985, c P-4
[4] *Patented Medicines (Notice of Compliance) Regulations*, SOR/99-133

Drug Submission (ANDS) which is usually filed by a second person generic manufacturer in which the second person claims that its product is the "pharmaceutical equivalent" of the patented product.

[7] When a second person seeks a NOC by filing an ANDS, it relies on the data and clinical studies submitted by the first person in its NDS. Given that it can take up to 10 years and cost hundreds of millions of dollars to bring a patented drug to market, allowing the second person to rely on the first person's NDS and NOC can save the second person substantial time and money.

[8] When filing an ANDS, the second person has a choice to make about how to treat the patent. It can accept that the NOC will not be issued until the patent expires or it can allege that the first person's patent does not present an obstacle to issuing a NOC because the patent is invalid or because the second person's application does not infringe the patent. If the second person alleges that the patent does not constitute a barrier to issuing a NOC, then it must serve a Notice of Allegations on the first person which sets out the basis for the allegation that the patent does not preclude the issuance of a NOC to the second person.

[9] A first person who is served with a Notice of Allegations then also has a choice to make. The first person can choose not to respond to the Notice of Allegations and allow the second person to obtain a NOC. In that case, the first person retains all of its rights under the *Patent Act* to sue the second person for patent infringement once it begins selling the drug. Alternatively, the first person can apply to the Federal Court under s. 6(1) of the *Regulations* for an order prohibiting the Minister from issuing a NOC until the patent has expired (a "prohibition proceeding"). The simple commencement of such a proceeding prohibits the Minister from issuing a NOC for 24 months (the "statutory stay") unless the prohibition proceeding is disposed of within that timeframe. The court has no discretion to lift the statutory stay no matter how weak it may believe the first person's entitlement to a stay is.

[10] If, however, the prohibition application is withdrawn, discontinued, or dismissed, s. 8 of the *Regulations* gives the second person the right to claim compensation from the first person for any loss suffered by the second person during the period when a NOC would have been, but was not, issued because of the statutory stay. In such a case, the Federal Ministry of Health provides the date on which the second person would have received its NOC, but for the statutory stay.

II. Does Apotex Have a Claim Under s. 8?

A. The Apotex Claim

[11] With that overview, I turn to the action before me. It is a claim for damages that Apotex says arise from the fact that Lilly commenced a prohibition proceeding with respect to Apo-Atomoxetine which the Federal Court later dismissed.

[12] Apotex relies on the strict language of s. 8(1) of the *Regulations* which provides:

> If an application made under subsection 6(1)[5] is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
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> (a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, ….
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> ….
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> and
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> (b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

[13] Apotex argues that: (i) Lilly commenced a prohibition proceeding; (ii) the court dismissed the prohibition proceeding; and (iii) the Minister certified that, in the absence of the prohibition proceeding, Apotex would have received its NOC for Apo-Atomoxetine on October 10, 2008 instead of September 21, 2010, when Apotex actually received its NOC (the "liability period"). As a result, Apotex submits it is entitled to damages for loss of sales during the liability period.

[14] I do not view things quite that starkly. In my view, in the circumstances of this case, as set out below, Apotex is not entitled to a claim for damages under the *Regulations.*

[15] I begin my analysis with a history of the ANDS and the prohibition proceeding.

[16] Apotex filed its ANDS for Apo-Atomoxetine on February 29, 2008. When Apotex did so, it also filed what is known as a Form V as required by the *Regulations*. The Form V required Apotex to indicate whether it was challenging the Strattera patent (the "735 Patent)[6] or whether it would wait until that patent expired before asking for the NOC to be issued. Apotex's Form V, which was signed and certified by its Chair and CEO at the time, Dr. Bernard Sherman, stated that it would wait for the Strattera patent to expire before requiring the Minister to issue a NOC. If things had stopped there, Apotex would not be entitled to any damages for any delay in receiving its NOC.

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[5] A prohibition proceeding.
[6] 735 being the last three digits of the Strattera patent more correctly referred to as Canadian Patent No. 2,209,735

[17] Things did not, however, stop there. On May 22, 2008, another generic manufacturer, Teva,[7] began an action in Federal Court to impeach the 735 Patent (the "Teva Action"). Teva was concerned that its generic competitors would piggyback on its action, as a result of which Teva filed its claim under seal. After the Federal Court denied Teva's request to have the action continue under seal, Teva filed a statement of claim publicly on July 17, 2008.

[18] Shortly after Teva's claim was made public, Apotex served Lilly Canada with a Notice of Allegations in respect of the 735 Patent. Apotex did not file any amended Form V to advise the Ministry of Health that it was no longer content to wait for the 735 Patent to expire. In response to Apotex's Notice of Allegations, Lilly commenced a prohibition proceeding on October 10, 2008 which, as noted above, resulted in an automatic 2 year stay on the issuance of any NOC, unless the prohibition proceeding was resolved earlier.

[19] The prohibition proceeding against Apotex and the Teva Action proceeded separately but were heard one after the other by Barnes J. of the Federal Court of Canada. Barnes J. heard the prohibition proceeding from May 3 to 10, 2010 and the Teva Action, on separate evidence, from May 11 to June 9, 2010.

[20] Barnes J. issued his decision in the Teva Action first. In reasons dated September 14, 2010, he declared the 735 Patent to be invalid.[8]

[21] Under s.7(1)(f) of the *Regulations* the Minister is entitled to issue a NOC on the expiry of a patent that is the subject of a prohibition proceeding. Given that the patent expired when Barnes J. found it to be invalid, the Minister granted Apotex its NOC for Apo-Atomoxetine on September 21, 2010

[22] After Barnes J. released his reasons in the Teva action, he invited Lily and Apotex to make further submissions about the appropriate disposition of the prohibition proceeding. It appears that in those submissions, both parties were alive to the effect that the formal disposition could have on any subsequent s. 8 damages action. By way of example, at that point Barnes J could have dismissed the prohibition proceeding on the grounds that Apotex had made out a successful defence on the merits or he could have found that Apotex had not made out a successful defence of the merits but that this no longer mattered given that the 735 Patent had already been set aside. If Barnes J. simply dismissed the prohibition proceeding in the latter scenario, it might give Apotex a better case to claim damages under s. 8 of the *Regulations.*

[23] Barnes J. released his decision in the prohibition proceeding on October 29, 2010 (the "Apotex Decision").[9] Paragraphs 1-96 of his reasons examine Apotex's allegations about why the 735 Patent was invalid. Barnes J. found against Apotex on each of its allegations.[10]

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[7] Now known as Novopharm.
[8] *Teva Decision* at paras. 93, 112, 122.
[9] *Eli Lilly Canada Inc. v. Apotex Inc*., 2010 FC 1065)
[10] *Apotex Decision* at paras. 1-96, 102.

Since Apotex had already received its NOC before Barnes J. released the Apotex Decision, he found the prohibition proceeding to be moot[11] and dismissed it "on the ground of mootness."[12] Barnes J., made clear that by dismissing the prohibition action for mootness, he was not pre-emptively adjudicating any s. 8 issues. In doing so Barnes J. stated:

> In *Eli Lilly v. Apotex*, 2010 FC 952, Justice Johanne Gauthier expressed reservations about whether a s. 8 claim could be advanced where, after an order of prohibition had been issued, the underlying patent was declared invalid in another proceeding. Justice Gauthier may well be correct in doubting that s. 8 damages would be available where the patent in issue has been determined to be invalid in another proceeding between different parties. That issue is not, however, before me.
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> All that is being decided by me in this instance is that none of Apotex's allegations were justified on the record that was before this Court, and that because of the intervening determination that the 735 Patent was invalid, Lilly's application must be dismissed on the basis of mootness. But for that determination, Lilly's application would have been allowed and an order for prohibition would have issued. It remains open to Lilly to defend any claim by Apotex for s. 8 damages on the basis outlined by Justice Gauthier and on the strength of an argument that the expression in s. 8 "dismissed by the court hearing the application" means a dismissal on the merits of the application and not simply for mootness.[13]

[24] I will address the decision of Gauthier J. later in these reasons. In addition, Barnes J. ordered that Apotex pay Lilly's costs in the amount of over $200,000.

[25] Apotex points to the wording of the formal order in the prohibition proceeding, the relevant passage of which states:

> THIS COURT ADJUDGES that this application for an order prohibiting the Minister from issuing a NOC is dismissed with the issue of costs to be reserved.

[26] Apotex takes that language and applies it to s. 8 of the *Regulations* which provides that a first person is liable to a second person for losses resulting from the statutory stay where

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[11] *Apotex Decision* at paras. 97-98
[12] *Apotex Decision* at para. 104.
[13] *Apotex Decision* at paras. 101-102.

the first person's prohibition application is "dismissed by the court hearing the application" and submits that it is entitled to damages.

B. Analysis

[27] The parties agree on the general approach to the interpretation of statutes and regulations. Statutory instruments are to be read in their entire context, in their grammatical and ordinary sense, harmoniously with their scheme, object and with the intention of Parliament.[14]

[28] In my view, Apotex's position focusses too narrowly on the grammatical meaning of the portion of s. 8 of the *Regulations* that refers to a prohibition proceeding being dismissed and the word dismissed in the formal order. Apotex ignores the principles of context and harmony with the scheme and object of the regulation. In my view, a purposive interpretation of the *Regulations* denies Apotex a claim for damages.

[29] With respect to the language of the formal order, courts can look to the reasons underlying an order to interpret it properly.[15] The reasons of Barnes J. make clear that he dismissed the prohibition proceeding for mootness after having dismissed all of Apotex's allegations on the merits.

[30] With respect to the language of the *Regulations,* the fundamental object of s. 8 is to allow parties whose entry into the market has been delayed by the unjustified imposition of a 2 year stay to seek damages for that delay. Whether the delay is warranted is determined by the content of the second person's Notice of Allegations and the first person's prohibition proceeding.

[31] Barnes J. found that none of the claims in Apotex's Notice of Allegations were justified. He stated expressly that on the record before him in the prohibition proceeding, he would have allowed Lilly's claim for a prohibition order.[16] As a result, Lilly's prohibition application was successful on the merits. It is only an unsuccessful, withdrawn, or discontinued prohibition application that gives rise to s. 8 damages. The Federal Court of Appeal made this clear in *Apotex Inc. v. Merck & Co. Inc*.,[17] when it said the following about s. 8:

> Section 8 was amended in 1998 by SOR/98-166. In the RIAS[18] which accompanied the amendment, it is explained that the amendment was brought in order to provide "a clearer indication

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[14] *Rizzo & Rizzo Shoes, Re*, [1998] 1 S.C.R. 27 at para. 21; *University Health Network v. Ontario (Minister of Finance)* (2001), 208 D.L.R. (4th) 459 (Ont. C.A.) at paras. 31-33; Sullivan, *Sullivan on the Construction of Statutes*, 6th ed. (LexisNexis, Markham: 2014) at 8.89, 8.90 and 8.97; *Apotex v. Merck*, 2009 FCA 187, para. 83.
[15] *McIntosh v Parent*, [1924] 4 D.L.R. 420 (ONCA) at 426
[16] *Eli Lilly v. Apotex* 2010 FC 1065 at para 102.
[17] *Apotex Inc. v. Merck & Co. Inc*., 2009 FCA 187
[18] Regulatory Impact Analysis Statement.

> … as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug". **The amendment makes it clear that liability can be visited on a first person when a prohibition application is withdrawn, discontinued or turns out to be unsuccessful**.[19] [Emphasis added.]

[32] The Regulatory Impact Analysis Statement ("RIAS") that accompanied the 2017 amendments to the *Regulations* make the same point. When comparing the scope of s. 8 before and after the 2017 amendments, the RIAS states:

> As before, the proposed Regulations would allow a second person to seek compensation for losses suffered during the period they were kept off the market as a result of an **unsuccessful** or discontinued proceeding having been brought against them under the proposed Regulations.[20] [Emphasis added.]

[33] Absent the Teva Action, the record that Apotex put before Barnes J. would have resulted in an order prohibiting Apotex from receiving its NOC until the 735 Patent expired in January 2016. What prevented that result was not anything Apotex did. Rather, it was what Teva did in a separate proceeding, on a different record, which resulted in a declaration that the 735 Patent was invalid. Significantly for our purposes here, Teva was not entitled to claim damages for setting the patent aside.

[34] In effect, allowing Apotex to claim damages would allow it to be a free rider. Apotex wants damages not for anything that occurred as a result of its Notice of Allegations or the prohibition proceeding that followed. It wants damages for something that Teva accomplished in a different action even though Teva is not entitled to damages for what it had accomplished.

[35] Viewing the issue from a different perspective, s. 8 awards have been analogized to the undertaking in damages that is often required in interlocutory injunctions. The prohibition proceeding is similar to a motion for an interlocutory injunction, but with the injunction following automatically upon commencement of the proceeding. Although there is no undertaking in damages in exchange for the statutory injunction, the possibility of a damages claim under s. 8 of the *Regulations* is the rough equivalent of the undertaking in damages.[21] In that context, Gauthier J. noted:

> … it would make little sense for such a guarantee against damages to apply in respect of another action or proceeding and even less sense where the parties involved are different.[22]

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[19] *Apotex Inc. v. Merck & Co. Inc.*, 2009 FCA 187 at para. 47.
[20] July 2017 RIAS, Canada Gazette Part II, Vol 151, No 28, p 3332.
[21] *Eli Lilly Canada inc. v. Apotex Inc*., 2010 FC 952 ("*Olanzapine*") at para. 31.
[22] *Olanzapine* at para. 31.

[36] In addition, the strict language of the *Regulations* on which Apotex relies is not quite as helpful to Apotex as it suggests. Section 7(2)(b) of the *Regulations* provides that any statutory prohibition on the issuance of a NOC ceases to apply if a court has declared that the patent is not valid. The *Regulations* do not provide any other remedy where a patent is declared invalid other than the lifting of the statutory stay.

[37] Section 8(5) of the *Regulations* would also appear to give the Court more discretion in a s. 8 claim than Apotex admits. That section provides:

> 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 the delay in the disposition of the application under subsection 6 (1).

[38] Two critical matters to take into account in assessing the amount of compensation to which Apotex might be entitled here are the fact that Apotex's claims failed and the fact that the court would have issued a prohibition order until 2016 in the absence of the Teva action. Those elements are so core to the damages scheme under the *Regulations* that they should lead to an assessment of damages at zero.

[39] Turning to the case law on this issue, while I have not been directed to any case with a fact pattern identical to the one before me, I have been directed to similar cases involving the *Regulations* which suggest that Apotex is not entitled to damages in circumstances like the ones before me.

[40] By way of example, in *Apotex Inc. v. Syntex Pharmaceuticals International Inc*.,[23] the Federal Court of Appeal dealt with a generic producer who failed in a prohibition application (and was therefore subject to the statutory injunction) but who later succeeded in setting the patent aside. In those circumstances, the Federal Court of Appeal held:

> In my view, s. 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation.[24]

[41] In *Olanzapine*,[25] Gauthier J. (as she then was) dealt with a situation where a court had granted a prohibition order that was subsequently lifted when the underlying patent was declared invalid. In finding that this did not give the generic (Apotex) who had been

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[23] *Apotex Inc. v. Syntex Pharmaceuticals International Inc.*, 2010 FCA 155
[24] *Ibid*. at para. 36.
[25] Since many patent cases involve the same parties litigating about different products, they are often referred to by the name of the drug at issue. Olanzapine was the drug at issue in that case. The case if more formally cited as *Eli Lilly Canada Inc. v. Apotex Inc*., 2010 FC 952

disadvantaged by the prohibition order a claim for s. 8 damages, Justice Gauthier explained:

> [32] It is undisputable that the current version of s. 8 was meant to clarify the legislator's intent. When it was adopted after full consultation, it would have been easy to add − had this been Parliament's intent − that the generic was to be indemnified if the patent listed was ever declared invalid. Instead, Parliament chose to focus on all possibilities that could happen in the normal course of a prohibition proceeding (dismissed, discontinued, reversed in appeal, *etc*.).
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> [33] The Court sees no good reason for changing the *status quo* by giving Apotex an opportunity that had ceased to exist when the Federal Court of Appeal confirmed the 2007 order. Apotex had a full opportunity to raise all possible allegations in respect of the invalidity of the 113 patent in its Notice of Allegations. It also had the right to seek expungement from day one. In balancing the issue of fairness, I do not believe that the balance is in favour of Apotex here.

[42] In dismissing Apotex's claim for s. 8 damages, Gauthier J. found "[p]articularly telling" the statement by the Federal Court of Appeal in *Syntex* that "s. 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding."[26]

[43] As in *Olanzapine,* Apotex had the ability to raise whatever allegations it wanted in its Notice of Allegations about the invalidity of the 735 Patent, including those that Teva raised in the patent infringement proceeding. Apotex chose not to. It must accept the consequences of that decision.

[44] As Gauthier J. observed in *Olanzapine,* Apotex had the right to have the Strattera patent declared invalid from day one. It did not do so. Indeed, it initially did the opposite. It was content in its Form V to wait for the Strattera patent to expire before seeking to produce its own generic version of the drug. Apotex only changed its view in that regard and served a Notice of Allegations when it discovered that Teva had commenced a proceeding to set the patent aside.

[45] The decision of Hughes J. in *Pfizer v. Ratiopharm*[27] is similar to that of Gauthier J. in *Olanzapine.* In *Ratiopharm,* Pfizer, the innovator, succeeded in its prohibition application.[28] After the patent at issue was subsequently invalidated, Ratiopharm sought to change the disposition of the prohibition application so that it could pursue s. 8 damages.

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[26] *Eli Lilly v. Apotex*, 2010 FC 952 at para. 19.
[27] *Pfizer v. Ratiopharm,* 2009 FC 1165.
[28] *Pfizer v. Ratiopharm*, 2006 FCA 214, rev'g 2006 FC 220.

[46] Hughes J. rejected Ratiopharm's request. In doing so he noted that prohibition applications are decided based solely on whether the claims in Notice of Allegations are justified.[29] Like Gauthier J., he noted that Ratiopharm "had its day in Court, raised the issues that it believed to be important, adduced the evidence that it chose and, made the arguments that it wished."[30] If those arguments do not succeed but different arguments in a different case do succeed, that does not give Ratiopharm a basis for claiming damages.

[47] The importance of the second person's Notice of Allegations cannot be overstated in this analysis. When a second person decides to issue a Notice of Allegations, it chooses what allegations to make. The nature of those allegations inevitably affects the first person's decision about whether to commence a prohibition application or whether to let the NOC issue and then pursue the second person for breach of patent. The combination of the allegations Apotex made and the prohibition application Lilly commenced led Barnes J. to conclude that the Minister should be prohibited from granting Apotex a NOC until the 735 Patent expired. Once that issue has been decided, Apotex should not get a second chance to raise new and better arguments that might have led to a different outcome. That principle is no different than core principles of issue estoppel which require a litigant to raise all issues in a single proceeding.

[48] The only difference between *Syntex, Olanzapine,* and *Ratiopharm* on the one hand and this case on the other, is that Barnes J. released reasons in the Teva action before releasing his reasons in the prohibition proceeding. Had he reversed the order of the releases, the situation here would be identical to those in *Syntex, Olanzapine,* and *Ratiopharm*. Results of cases should turn on matters more substantive than the order in which a judge chose to release reasons in related cases.

[49] Apotex raises a number of arguments to support its right to claim damages. First, it relies on statements made by the Ontario Court of Appeal in *Apotex Inc. v. Eli Lilly*,[31] a parallel claim to this one. In that case, Apotex had sued Eli Lilly for unjust enrichment and claimed disgorgement of the profits Eli Lilly had earned from Strattera before Apotex received its NOC. The Court of Appeal dismissed the action holding that Apotex was limited to damages under s. 8 of the *Regulations*. In dismissing the claim, the Court of Appeal made the following statements which Apotex submits bind me and which give it a right to s. 8 damages:

> [1] … Because Lilly's patent was later invalidated, Apotex became entitled under the *Regulations* to recover the damages it suffered during the period it was excluded from the market.
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> …

[29] *Ratiopharm v. Pfizer*, 2009 FC 711 at para. 27.
[30] *Pfizer Canada Inc. v. Canada (Health)*, 2009 FC 1165 at paras. 27, 29.
[31] *Apotex Inc. v. Eli Lilly*, 2015 ONCA 305 at paras. 1, 10, 13 and 14

> [10] Lilly's prohibition application against Apotex was dismissed on October 29, 2010, again based on the invalidation of the 735 Patent in the Teva action. Apotex then became entitled to recover from Lilly, under s. 8(1) of the *Regulations*, the loss it suffered as a result of its exclusion from the market.
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> …
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> [13] Section 8(1) of the *Regulations* provides that where the application of the person relying on the patent (in this case Lilly) is dismissed, that person is liable to the person that was kept out of the market (in this case Apotex) "for any loss suffered" during the period commencing when the NOC would have been issued and ending on the date the application was withdrawn, discontinued, dismissed or reversed.
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> [14] Apotex is therefore entitled under s. 8(1) of the *Regulations* to seek compensation from Lilly for the losses it suffered during the exclusion period. …[32]

[50] Those statements do not, in my view, constitute binding determinations of the Court of Appeal to the effect that Apotex is entitled to s. 8 damages. They merely indicate that Apotex is entitled to commence a claim for s. 8 damages. The description of s. 8 in the Court of Appeal's reasons was not intended to rule on the validity of Apotex's s. 8 claim but merely to indicate that Apotex's remedy was not a claim for unjust enrichment but a claim under s. 8. Whether Apotex is actually entitled to an award on the merits under s. 8 is an entirely different question on which the Court of Appeal did not rule.

[51] In addition, Apotex relies on three Federal Court cases which it submits support its position. I read those cases differently.

[52] In *Teva v. Pfizer* ("*Venlafaxine*"),[33] the second person (Teva) delivered a Notice of Allegations alleging non-infringement and invalidity in response to which the first person (Pfizer) commenced a prohibition proceeding. Teva then moved under s. 6(5) of the *Regulations*, to dismiss the prohibition proceeding on the ground that the patent was not properly listed on the patent register. Teva's motion was allowed, and the prohibition proceeding was dismissed.[34] Teva then commenced an action under s. 8. The Federal Court of Appeal noted that Pfizer should never have listed the patent at issue on the patent register and should not have brought a prohibition application. By doing so Pfizer had improperly

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[32] *Apotex Inc. v. Eli Lilly*, 2015 ONCA 305 at paras. 1, 10, 13 and 14.
[33] *Teva v. Pfizer*, 2016 FCA 161.

[34] *Teva v. Pfizer*, 2014 FC 248, para. 18, rev'd on other grounds, 2016 FCA 161..

kept Teva's version of venlafaxine off the market which in turn allowed Teva to seek damages under s. 8 of the *Regulations*.

[53] I do not see how *Venlafaxine* assists Apotex. It was a case in which the prohibition application was dismissed based on successful arguments by the second person. Those arguments were based on grounds that were specifically enumerated in the *Regulations*, namely, that the patent at issue was improperly listed. That sort of dismissal entitles the second person to damages. The point in the case before me is that all of the arguments Apotex made in the prohibition application and in its Notice of Allegations were unsuccessful.

[54] The second case on which Apotex relies is *Apotex v. Sanofi-Aventis* ("*Sanofi*").[35] According to Apotex, in that case the second person delivered a Notice of Allegations in respect of certain patents known as "the HOPE patents". The first person, Sanofi-Aventis, commenced a prohibition proceeding. The Supreme Court of Canada subsequently issued a decision in another proceeding that led the Minister of Health to conclude that the second person did not have to address the HOPE patents to obtain a NOC. As a result, the prohibition proceeding was dismissed as moot. The second person then brought a s. 8 action and was permitted to seek damages even though it was another proceeding that led to the finding that the second person did not have to address the Hope patents.

[55] The difficulty with that description is that is leaves out material, distinguishing facts. In *Sanofi,* the first person had brought a series of prohibition proceedings. The s. 8 damages were granted with respect to four of those prohibition proceedings, all of which had been dismissed on the merits. The s. 8 claims did not relate to the proceeding that was dismissed for mootness.

[56] The third case on which Apotex relies is *Apotex Inc. v. Syntex Pharmaceuticals International Limited*.[36] Apotex *relies* on that case for the propositions that: (i) s. 8 damages are available if a patent is set aside in a subsequent proceeding, and (ii) damages are available if a prohibition proceeding is dismissed regardless of the circumstances.

[57] In *Syntex* the second person (Apotex) delivered a Notice of Allegations, in response to which the first person (Roche, the successor to Syntex) started a prohibition proceeding and obtained a prohibition order from Justice Reed of the Federal Court. After the prohibition order was granted, Apotex began a separate action to impeach the patent. That action also came before Justice Reed who declared the patent invalid. Apotex then tried to obtain its NOC on the grounds that the patent was invalid. The Minister refused because the prohibition order remained in place. The Minister advised Apotex to have the prohibition order the varied and have the prohibition proceeding dismissed. Apotex did so. Reed J. granted the motion to vary and dismissed the prohibition proceeding.

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[35] *Apotex v. Sanofi-Aventis*, 2014 FCA 68 at paras. 93, 95 and 152 (per Mainville J.A., in dissent but not on this point), aff'd 2015 SCC 20;
[36] *Apotex Inc. v. Syntex Pharmaceuticals International Limited*, 2009 FC 494

[58] Apotex then brought a s. 8 action on the basis that the prohibition proceeding had been dismissed. That action came before Justice Hughes of the Federal Court. One of the issues was whether the 1993 or 1998 version of the *Regulations* applied. Hughes J. found the 1993 version to be applicable and held that it did not give Apotex a claim. Hughes J. then went on to find that, under the 1998 wording, Apotex would have been able to pursue s. 8 damages:

> The triggering event under the 1998 version of s. 8 is that an application must be "withdrawn...discontinued... or dismissed by the Court hearing the application [or] ...on appeal".
>
> In the present circumstances the Court that heard the original application, Reed J., dismissed the application by the Order dated April 30, 1999. She did two things in that Order. The first was to vary the original Order so as to remove the prohibition. The second was to dismiss the application. Perhaps a dismissal was unnecessary, but it was done. Roche did not appeal that Order.
>
> Plain and simply, the 1998 Regulations, s. 8(1) if they were to be applicable, which they are not, would be triggered by the circumstance applicable in this action because of the dismissal.[37]

The wording of s. 8 in the 1998 version is the same as the wording applicable to this case.

[59] Apotex notes that the decision of Hughes J. was upheld by the Federal Court of Appeal. Although the Federal Court of Appeal upheld the decision of Hughes J., in doing so it stated:

> In view of his findings, it was unnecessary for the Judge to rule on the other issues raised by Apotex. He did so for the "almost inevitable" appeal. One such issue was whether Roche would be liable for damages if the 1998 version of the Regulations applied. On this appeal it is not necessary to consider the Judge's interpretation of s. 8 of the 1998 version of the Regulations. Therefore, no comment is made about the correctness of that interpretation.[38]

[60] Moreover, in *Syntex,* the Federal Court of Appeal also expressed the view set out earlier to the effect that:

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[37] *Apotex v. Syntex*, 2009 FC 494 at paras. 47-49..
[38] *Apotex Inc. v. Syntex Pharmaceuticals International Inc*., 2010 FCA 155 at para. 19

> … s. 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation.[39]

[61] In *Pfizer v. Canada*,[40] the Federal Court of Appeal confirmed that this interpretation was equally valid under the 1998 version of the *Regulations* as under the 1993 version. That interpretation has been applied to the 1998 version of the *Regulations* by other courts since.[41]

[62] In light of the foregoing, I find that Apotex's right to section 8 damages has not been triggered. I would dismiss the claim on that ground alone. In the interests of having a full record, I will nevertheless go on to address other arguments that the parties raised.

C. The Effect of *AstraZeneca v. Apotex*

[63] In addition to the arguments above, which I have accepted, Lilly also argues that damages should not be awarded in this case because Barnes J. invalidated the 735 Patent in 2010 based on what is known as the "promise doctrine;" a doctrine that the Supreme Court of Canada has since found to be erroneous.

[64] The issue arises out of s. 2 of the *Patent Act* which requires an invention to be "useful" to receive a patent. Under the promise doctrine, if a patent contained a promise of a specific result, courts required the first person to demonstrate that the promise had been established by the date on which the patent was filed.[42]

[65] In 2017, in *AstraZeneca v. Apotex*,[43] the Supreme Court of Canada unanimously rejected the promise doctrine as being too onerous and as having no basis in the *Patent Act.* In doing so, the court noted that the *Patent Act* does not prescribe the degree of usefulness required and held that a "scintilla of utility" would suffice to issue a patent.[44] Considerable time was spent at trial attempting to prove or disprove that the 735 Patent would have met the scintilla of utility test.

[66] I decline to engage on that issue and find that Lily is not entitled to reargue the Teva invalidity decision based on a subsequent change to the law in *AstraZeneca*.

[67] The Federal Court of Appeal has dealt with this issue in circumstances more compelling than the ones before me. In *Eli Lilly v. Teva,* ("*Olanzapine Damages FCA*")[45] the Federal Court had declared that Lilly's 118 Patent was invalid. Teva then successfully brought a

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[39] *Ibid*. at para. 36.
[40] *Pfizer v. Canada*, 2011 FCA 215 at paras. 18-19
[41] *Bayer v. Apotex*, 2014 FC 436 at para. 31; *Bayer v. Cobalt*, 2013 FC 1061 at para. 32.
[42] *AstraZeneca v. Apotex*, 2017 SCC 36 at paras. 28-31.
[43] *AstraZeneca v. Apotex*, 2017 SCC 36
[44] *AstraZeneca*, 2017 SCC at paras. 54-55.
[45] *Eli Lilly v. Teva*, 2018 FCA 53 ("*Olanzapine Damages FCA*")

claim for s. 8 damages. AstraZeneca was released five months after s. 8 damages were awarded in favour of Teva. Lilly appealed on the ground that the 118 Patent had been invalidated on the basis of the promise doctrine which had subsequently been rejected by the Supreme Court of Canada. In rejecting Lilly's argument, the Federal Court of Appeal stated:

> Standing back and taking into account the entirety of the circumstances, I conclude that it would not work an injustice to apply issue estoppel in this case. As noted above, there is no presumptive right to relitigate an issue on account of a change in the law. If the discretion were exercised in this case, it would be difficult to resist its exercise in any case in which there was a change in the law on the basis of which a substantial judgment had been granted or refused. That would turn a "special circumstances"[46] exception into a general rule, and seriously impair the principle of finality.[47]

[68] If the Federal Court of Appeal refused to reconsider the decision to strike the 118 Patent in circumstances where *AstraZeneca* was decided only five months after the court awarded s. 8 damages, it would be even more inappropriate to reconsider the striking of the 735 Patent when *AstraZeneca* was decided seven years after the 735 Patent was struck out.

[69] The Federal Court reached a similar result in analogous circumstances in *Merck v. Apotex*.[48] In that case, the Federal Court held that a patent known as the 350 Patent was valid and was being infringed by Apotex. The Federal Court rejected Apotex's invalidity argument on the authority of *C.H. Boehringer Sohn v. Bell-Craig Ltd.* ("*Boehringer*").[49]

[70] While Merck's case for patent infringement was proceeding, the Supreme Court of Canada released a decision that expressly overruled *Boehringer*.[50] When Apotex tried to amend its pleadings to argue that the 350 Patent was invalid after all, the Federal Court rejected the proposed amendments because they amounted to a collateral attack on the prior determination of validity:

> "…Apotex seeks to do an end run around the Liability Judgment, which was appealed unsuccessfully all the way to the Supreme Court of Canada. . . . It is plain and obvious that Apotex's proposed

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[46] That is to say, that is to say that *res judicata* and issue estoppel apply unless there are "special circumstances" that make it unjust to apply those principles.

[47] *Olanzapine Damages FCA* at para. 68.

[48] *Merck & Co. Inc. v. Apotex Inc.*, 2006 FC 524 at paras. 116, 186-187.

[49] *Merck & Co. Inc. v. Apotex Inc.*, 2006 FC 524 at paras. 116, 186-187.

[50] *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at paras. 54-68.

> amendments disclose no issue that is relevant to determining the quantum of damages."[51]

[71] Although a court retains a residual discretion not to apply principles of res *judicata* or issue estoppel, that discretion that should only be exercised sparingly.[52]

[72] In response to these arguments Lilly relies on *Apotex Inc. v. Schering Corporation* ("*Schering*").[53] In that case, the patent had been set aside and Apotex sought damages. After *AstraZeneca* was released, Schering moved to amend its defence to plead that, as a result of *AstraZeneca,* the patent at issue should never have been struck. The motions judge rejected the amendments based on principles of *res judicata* and collateral attack.[54]

[73] The Court of Appeal applied the special circumstances exception to allow the amendments. In doing so, the Court of Appeal noted, however, that it was addressing this issue only from a pleadings perspective and held that the defendants should not be precluded from advancing special circumstances at the pleadings stage: "[A] change in the law only provides the opportunity to argue that issue estoppel ought not to be applied. It does not dictate that that should be the result."[55] As in *Schering*, Lilly has been allowed to argue special circumstances in the case before me.

[74] Given the seven year gap between the time Justice Barnes's struck out the 735 Patent and the release of *AstraZeneca,* I do not think it would be advisable to apply the special circumstances exception here. To do so in the circumstances before me would mean that any change in the law could result in claims to reopen issues that were decided many years before the law changed. There would be no principled basis on which to limit the time to re-examine decided cases to the seven years applicable here. If cases could be re-opened after seven years, why not after 10, 15, 20 or more?

D. Form V Issue

[75] Lilly also argues that Apotex certified in its Form V that it would wait for the 735 Patent to expire before seeking a NOC and that Apotex should be held to that statement.

[76] I do not find that argument persuasive. Form Vs are administrative documents for use by the Minister. A first person is not notified of Form Vs and cannot be said to rely on them. Anne Bowes, the Director of the Office of Submissions of Intellectual Property in the

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[51] *Apotex v. Merck*, 2014 FC 883 at paras. 44 and 46-49, 51-52 and 58, aff'd 2014 FC 1058.

[52] *General Motors of Canada Ltd. v. Naken*, [1983] 1 S.C.R. 72 at p. 101; *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460 at paras. 62 and 68-79; *Penner v. Niagara (Regional Police Services Board)*, 2013 SCC 19 at paras. 30 and 42; *Eli Lilly v. Teva*, 2018 FCA 53 at paras. 53-54.

[53] *Apotex Inc. v. Schering Corporation*, 2018 ONCA 890 ("*Schering*").

[54] *Schering* at paras. 15-18.

[55] *Schering* at para. 27; see also para. 32.

Health Products and Food branch of Health Canada testified that although a Form V must accompany an ANDS, a second person is entitled to revise the Form V. In addition, Lilly did not contest the validity of the Notice of Allegations before Barnes J. on the basis of the statement in the Form V. If Lilly wanted to contest Apotex's ability to deliver a Notice of Allegations in the face of a statement in the Form V, it should have done so in the proceeding that involved the Notice of Allegations and the prohibition order, where it could, if successful, have disposed of Apotex's allegations on that basis. Allowing Lilly to raise that issue now would violate principles of issue estoppel.

Conclusion on Liability

[77] In light of the foregoing, I have concluded that Lilly bears no liability for s. 8 damages on the facts of this case. Strictly speaking I need not proceed to an assessment of damages. I will nevertheless do so in the interests of having a full record in the event I am found to be wrong on the question of liability.

PART TWO: DAMAGES

[78] Under s. 8 of the *Regulations*, Apotex is entitled to claim for any loss suffered between the date on which the Minister has certified that the NOC "would have been issued in the absence of these *Regulations*" and the date of the withdrawal, discontinuance, or dismissal of the prohibition proceeding. In this case, the parties agree that the liability period is between October 10, 2008 and September 21, 2010.

[79] The reference to the NOC having been issued in the absence of the *Regulations* has been interpreted as referring to the absence of a prohibition proceeding.[56] Section 8 requires the court to determine what Apotex's loss would have been in a hypothetical world in which no prohibition proceedings existed.

[80] Apotex bears the burden of proving the loss for which it seeks compensation on a balance of probabilities.[57] To do so, Apotex must prove, among other things, that it both could have and would have come to market during the liability period.[58]

[81] The parties have agreed on certain components involved in the calculation of losses under s. 8. With respect to other components, their experts have prepared a variety of damages scenarios based on various contingencies. The parties have asked me to provide answers to each of the questions below, following which the parties will determine which scenario,

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[56] *Teva v. Pfizer*, 2014 FCA 68 at paras. 170-171; *Merck v Apotex*, 2011 FCA 329 at para. 75; *Apotex v. Merck*, 2009 FCA 187 at para. 66.
[57] *Pfizer v. Teva*, 2016 FCA 161 at paras. 44-45.
[58] *Pfizer v. Teva*, 2016 FCA 161 at para. at para. 50-57.

if any is applicable to the quantification of damages or appear before me to argue more specific issues involving the calculation of damages. Those questions are as follows:

(i) Could Apotex have launched Apo-Atomoxetine during the liability period and, if so, when?

(ii) Would Apotex have launched Apo-Atomoxetine during the liability period and, if so, when?

If Apotex could have and would have launched Apo-Atomoxetine during the liability period:

(iii) What would have been the size of the total atomoxetine market?

(iv) What would have been Apotex's share of the atomoxetine market, including whether Apotex would have faced competition from Teva?

(v) At what prices would Apo-Atomoxetine have been sold?

(vi) What, if any, lost sales has Apotex incurred with respect to "pipe-fill" sales?

(vii) What costs would Apotex have incurred with respect to the sale of Apo-Atomoxetine?

(viii) What pre-judgment interest should be applied, if any?

i. Could Apotex Have Launched During the Liability Period and, if so, When?

[82] For the reasons set out below, I conclude that Apotex could have launched its Apo-Atomoxetine product as of October 10, 2008 and made sales throughout the liability period.

[83] Gordon Fahner was Apotex's Vice President of Supply Chain Management during the liability period. In his affidavit and supplementary affidavit, he stated that Apotex had the ability to order sufficient raw materials and manufacture sufficient quantities in advance of October 10, 2008 so as to be ready to launch when it received its NOC on October 10, 2008 in the hypothetical world. Mr. Fahner was not shaken in that evidence.

[84] In its outline of closing argument on damages, Lilly concedes that "in every other s. 8 case, Apotex prepared inventory in advance of the decision in the prohibition application (without knowing if it would be successful or would obtain its NOC) and launched in the real world immediately upon receiving its NOC." In a hypothetical world there would have been no prohibition application. As a result, Apotex would simply have been ordering

product in the absence of an NOC which it arguably had a strong chance of receiving given that it was basing its ANDS on Strattera which had already been approved.

[85] In light of that record, I find that Apotex could have begun taking steps to prepare itself for market entry at the same time that if filed its ANDS on February 29, 2008.

[86] In the real world, Apotex did not begin manufacturing when it filed its ANDS because it initially said that it would await the expiry of the Strattera patent. It did not begin taking steps to enter the market until it received its NOC on September 21, 2010. In the real world, it took Apotex six months after it received its NOC to get to the point of being able to sell 10 mg, 18 mg and 25 mg doses and ten months to sell 80 mg and 100 mg doses.[59] I have not been given any basis to suggest that it would have taken Apotex any more or less time to get to market in the hypothetical world than it did in the real world. I therefore find that it would have taken Apotex a similar six and ten months to get to market in the hypothetical world. In the hypothetical world, however, the six and ten month periods would have commenced on February 29, 2008 when Apotex filed its ANDS. As a result, in the hypothetical world, Apotex would have been ready to market its10 mg, 18 mg, and 25 mg doses when it received its NOC on October 10, 2008 and would have been able to sell its 80 mg and 100 mg doses as of approximately December 29, 2008.

[87] I base those conclusions on the evidence of Dr. Bernard Sherman, Apotex's chair and CEO at the material time. Dr. Sherman was examined for discovery and was asked why it took six months before Apotex was able to sell any product. Lilly read his responses into the record as follows:

> But you should appreciate that you get – API [the active ingredient in atomoxetine] has to be ordered from Pharmachem [the Apotex affiliate responsible for manufacturing atomoxetine]. Pharmachem then has to order intermediates. It doesn't make it from basic elements, so intermediates have to be obtained. Those have to be obtained from third-party suppliers who may have their own timelines for delivery. Those intermediaries have to be obtained, whatever number of months it takes to get them. They've got to be released. It's got to be put through the production processes at Para-chem based on their priorities and other things. So it takes what it takes.[60]

[88] Mr. Sherman returned to the issue at page 150 when examining counsel said he did not understand why it took six months to sell product, Mr. Sherman answered:

> Because […] we didn't know we were going to get the NOC, and it takes months to get through the process of planning; of ordering --

[59] Those periods are calculated from the date of the NOC of September 21, 2010 when Apotex received its NOC to March 16, 2011 when Apotex began selling loser doses and July 18, 2011 when Apotex began selling higher doses.
[60] Examination for discovery of Dr. Bernard Sherman December 8, 2016 page 135.

> getting the intermediates for the chemical manufacturer; making the chemicals; getting them released; getting them shipped to Apotex; getting that tested and released; making the product; getting a released; getting it packaged. All that takes months.

[89] Counsel then went through the exercise of examining each of these components. When addressing raw materials Mr. Sherman answered:

> And if there's limited API, appears that the amount of API was limited because it took some months to get all of the products through, including the 80 mg. So there must have been limitations on the amount of material that was on hand at any particular time. … That's what appears to have been the limiting factor.[61]

[90] In the concluding portion of this section of the examination for discovery, examining counsel asked whether there was anything else that should be on the list of things that needed to be done before product could be sold. Mr. Sherman answered:

> Let me just make sure you've got it complete. Pharmachem has to source its intermediates. It then has to schedule production and produce the material. Then has to test it and release it. Then it has to be shipped to Apotex. We have to receive it, test it and release it. Then we have to get in any other materials that are needed, including empty capsules, which can take time. That may take months to deliver empty capsules. We then have to schedule a production, run that through the capsule manufacturing process, the testing process, and the release process. All that takes time. The major limiting factor usually is the availability of the raw material, which can take anywhere from a few weeks to a few months or even a year, depending on the circumstances.[62]

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[61] Examination for discovery of Dr. Sherman December 8, 2016 page 151.

[62] Examination for discovery of Dr. Sherman December 8, 2016 page 153. An issue arose at trial about whether these read ins from Dr. Sherman's discovery should be qualified by other read ins. That issue has probably been rendered moot in light of my finding that Apotex could have entered the market based on commencement of steps in this regard as of February 29, 2008. In the event it remains an issue, I address it here. The first "qualifying passage" was an email from Nando DeLuca, one of Apotex's external trial counsel, that was sent on the evening of the day Dr. Sherman provided the evidence quoted above. The thrust of that email is to suggest that the delays in entering the market were attributable to negotiations that Apotex had entered into with Teva for a joint venture to market atomoxetine. The issue I was asked to resolve was whether that email should also be deemed to be a read in. The email was marked as Exhibit 2 on Mr. Sherman's discovery when it continued the next day, December 9, 2016. On the second day of his examination Mr. Sherman confirmed that there were negotiations for a joint venture and confirmed the dates on which submissions were made to the Commissioner of Competition for an advisory opinion to the effect that the joint venture would not violate the Competition Act and the date on which the Commissioner declined to provide such an opinion. What I deemed to be read in is not the text of the email itself but the factual admissions that Mr. Sherman agreed to on the second day of his discovery. The email goes further than factual submissions. The email contains a suggestion by counsel that the delay in getting to market was attributable to the joint venture discussions. Mr. Sherman made no such statement on the second day of his discovery or otherwise.

[91] In other words, it would have taken many months from the time Apotex formed an intention to enter the market before it was actually ready to do so. On the record before me, the time it took to enter the market would be the same in the hypothetical world as it was in the real world. The only difference is that in the hypothetical world Apotex could have begun the process sooner than it did in the real world. As noted, in the hypothetical world it could have started the process when it filed its ANDS. In that case, Apotex could have been ready to sell the 10, 18 and 25 mg doses by July 2008 and the 80 and 100 mg doses by December 1, 2008.

ii. Would Apotex Have Launched and, if so, When?

[92] The next question in the analysis is to determine whether Apotex would have launched its Apo-Atomoxetine products during the liability period. Apotex submits that it was not risk-averse and would have launched Apo-Atomoxetine as of October 10, 2008. For the reasons set out below, I conclude that Apotex would not have launched Apo-Atomoxetine in the hypothetical world any sooner than it actually did in the real world. In the hypothetical world, I find that Apotex would have launched all of its products in March 2011.

[93] Although Apotex asserts that it was not risk-averse, its behaviour in the real-world suggests otherwise, at least with respect to atomoxetine. The Federal Court of Appeal has recognized that a party's conduct in the real world is a good proxy for what its conduct would have been in a hypothetical world.[63]

After having the email put to him during the second day of discovery Mr. Sherman made no statement to the effect that the email now refreshed his memory about the reasons for the delay in entering the market.

The second email from Mr. DeLuca is dated January 9, 2022. Apotex asks me to deem that this second email also amounts to a read in with information that qualifies the evidence of Dr. Sherman about the reasons for the delay in getting to market. In my view it would not be appropriate to treat the email of January 9, 2022 as a read in to qualify Dr. Sherman's evidence. The email of January 9, 2022 is nothing more than legal argument. It was delivered six years after the examination for discovery and five years after Dr. Sherman died in 2017. It consists of a list of documents and extracts from the evidence of other witnesses which purport to provide explanations for the delay in entering the market that are different than the ones Dr. Sherman provided. While Apotex is entitled to urge me to prefer the competing evidence to that of Dr. Sherman, the competing evidence of other witnesses is not treated as a read in which is used to qualify the admissions of a client representative on discovery.

To the extent anything turns on it, I prefer the evidence of Dr. Sherman to that of other witnesses on the issue of why Apotex was delayed in getting to market. When asked about the delays, Dr. Sherman could have said he did not know. He could have said he would have to defer to others on that point. He did not do so. His testimony is given as someone who knew what he was talking about. I find that more reliable than explanations by others whose explanations were developed after the risks of Dr. Sherman's evidence for Apotex became apparent.

[63] *Sanofi-Aventix v. Teva*, 2014 FCA 67 at paras. 83-85; *Teva v. Pfizer* 2014 FC 248 at paras. 64-65.

[94] As a starting point, it is important to note that in the hypothetical world, Lilly continued to hold the 735 Patent until it was struck out by the court. Thus, if Apotex had received a NOC and had launched product, it would have been subject to a patent infringement claim by Lilly. It was clear at trial that Lily was an aggressive litigant that fought energetically to maintain its patent rights. As noted earlier, in the absence of a prohibition proceeding, Health Canada has certified that it would have granted Apotex a NOC in October 2008. At that point, the 735 Patent had eight years left before it expired. One could expect Lily to have vigorously defended its patent rights. Indeed, it did so in both the prohibition and the Teva action actions that underlie this case. Both were appealed up to the Supreme Court of Canada. Lilly then sought to appeal the Teva action further under the dispute resolution mechanism of the North American Free Trade Agreement. It is also no secret that generic manufacturers and innovators are highly aggressive litigants. One need only look to the briefs of authorities filed in this case to see that the names of the same innovators and generics reappear constantly.

[95] When Apotex filed its ANDS in the real world, it certified that it would wait until the 735 Patent expired before seeking its NOC and launching any product. This suggests that Apotex was risk-averse with respect to atomoxetine. It suggests that the economics of atomoxetine were such that it made more sense for Apotex to wait for the patent to expire than to incur the time and expense of a Notice of Allegations and a potential prohibition proceeding. That is significant because the downside of a prohibition proceeding was limited to the time of Apotex employees, Apotex's legal fees and the amount of a possible cost award in favour of Lilly if the prohibition proceeding succeeded. Even with that relatively limited exposure, Apotex preferred to wait for the patent to expire.

[96] In the hypothetical world there would have been no prohibition proceeding. Instead, Apotex would have received its NOC and would have been able to launch Apo-Atomoxetine immediately. However, Apotex remained exposed to a patent infringement action by Lilly. Apotex's risk exposure in a patent infringement action was significantly larger than its exposure in a prohibition proceeding. In a patent infringement action, Apotex would, in addition to time and cost, be potentially liable for any damages that Lily suffered because it had lost sales of Strattera to Apo-Atomoxetine.

[97] The economics of innovators and generics make that risk analysis quite different. Generic products are typically priced at 25% to 50% of branded products. As a result, in any patent infringement suit, Apotex was exposed to paying Lilly's lost profit on Strattera sales out of a potential revenue source that was only one quarter to one half the size of Strattera sales. Apotex's exposure was obviously not limited to revenues it earned on Apo-Atomoxetine sales. Lilly could look to all of Apotex's revenue and assets to enforce any damage award. I frame the issue this way only to demonstrate that failure in a patent infringement suit was likely to wipe out all profit Apotex earned on Apo-Atomoxetine and would likely impinge on profits that Apotex earned from other drugs. Launching Apo-Atomoxetine in those circumstances was not a particularly attractive financial proposition. If Apotex preferred to wait for the 735 Patent to expire before incurring the risk of even a prohibition action, it was even more likely to wait for the 735 Patent to expire before incurring the much larger risk of a patent infringement lawsuit.

[98] In the real world, Apotex only changed its risk assessment about a prohibition proceeding when it learned that Teva had launched a separate action challenging the 735 Patent. That action alerted Apotex to the fact that its chief generic competitor in Canada wanted to launch its own atomoxetine product. The evidence at trial suggested that there is substantial benefit to being the first generic entrant on the market. It was only when Apotex was faced with the possibility that Teva might be the first generic entrant that Apotex changed its mind, filed a Notice of Allegations, and was prepared to run the risk of a prohibition proceeding.

[99] Apotex's risk-averse nature with respect to atomoxetine became even more clear when the 735 Patent was set aside. Even though the patent was struck and even though Apotex received its NOC, it still declined to enter the marketplace. Instead, it spent six months pursuing a possible joint venture with Teva and pursuing an advisory opinion from the Competition Bureau to provide comfort that any such joint venture would not violate competition laws. As Apotex explained at trial, it pursued the joint venture because there was still a risk that the patent would be reinstated as a result of further appeals by Lilly. Entering the market as a joint venturer with Teva would ensure a higher sales price for generic atomoxetine than would be the case if there were two generic competitors. That in turn would provide greater profit margins from which to pay any potential damage award in favour of Lilly. Responsibility for any damage award would then also be shared between Apotex and Teva.

[100] Apotex pursued the joint venture in the real world to avoid the risk of an appeal. An appeal to the Federal Court of Appeal would take approximately one year. In the hypothetical world, Apotex would have been exposed to patent litigation which would take at least two years before getting to trial followed by appeals after that. If Apotex was unwilling to take the risk of a one-year appeal period in the real world, it would be even less willing to take the risk of at least two years to trial plus appeal periods after that in the hypothetical world.

[101] Moreover, in the hypothetical world, Apotex would likely have resisted Lilly's claim to patent infringement on the same grounds as those on which it defended the prohibition proceeding. In the hypothetical world, Apotex would not have had the benefit of Teva's more successful arguments to strike the patent. As already noted, Apotex failed in the prohibition proceeding. One could expect a litigant as sophisticated and experienced as Apotex, with counsel as sophisticated and experienced as its counsel are, to be aware of the weaknesses in its arguments and to assess the chance of failure with some degree of accuracy. While one might be prepared to risk failure in a prohibition proceeding where the downside is relatively limited, one would be less willing to expose one's broader profit and asset base to risk in a patent infringement proceeding.

[102] Apotex introduced no evidence at trial to suggest why it would have been less risk-averse in the face of an existing patent in the hypothetical world than it was in face of a judgment that had struck out the patent in the real world.

[103] Apotex's evidence about its risk tolerance in the hypothetical world must be read carefully. Apotex's position in this regard is based on paragraph 35 of Mr. Fahner's affidavit which states:

> With respect to Apo-Atomoxetine, **absent the legal impediments arising as a result of Canadian Patent Number 2,209,735 and the listing of that patent by Lilly on the Patent Registe**r under the PM(NOC) Regulations, Apotex would have received its NOC on October 10, 2008 and would have been highly motivated to enter the market as soon as possible as it would have been the first and only generic entrant at that time, thereby securing a first mover advantage, namely, a permanent long lasting position of strength in the market arising as a result of being the only generic supplier to the market. [**Emphasis added.**]

[104] The bolded language in the quotation above is critical. Mr. Fahner's evidence is that Apotex would have been highly motivated to enter the market but for two related factors. The first is "legal impediments arising as a result of" the 735 Patent. In the hypothetical world, the 735 Patent continued to pose legal impediments in the form of a patent infringement lawsuit. The second factor is the listing of the 735 Patent on the patent register. In the hypothetical world, the 735 Patent would have continued to be listed on the patent register until it was struck out by Barnes J. in September 2010.

[105] The hypothetical world is based on the absence of a prohibition proceeding. It is not based on the absence of legal impediments arising from the 735 Patent or on the absence of the patent itself. Apotex's evidence about being highly motivated to enter the market in the hypothetical world is therefore based on two preconditions which did not exist.

[106] Apotex also argued that its risk analysis would have been different in the hypothetical world because it would have been the sole generic in the atomoxetine market. I do not accept that argument. Teva had in fact filed its own ANDS in December 2007 approximately two months before Apotex. The Minister certified that Teva would have received its NOC on July 31, 2008. In a hypothetical world without a prohibition proceeding, Teva would likely have received its NOC before Apotex. Even if Teva preferred not to enter the marketplace before the patent was set aside, it would likely have entered immediately or shortly after Apotex's entry, just as it did in the real world.

[107] In light of the foregoing circumstances, I do not believe that Apotex would have launched Apo-Atomoxetine in the hypothetical world before the Federal Court set aside the 735 Patent and, even then, it would have continued to pursue the joint venture in the hypothetical world for the same reasons that it has advanced for doing so in the real world.

iii. Market Size

[108] The size of the market for atomoxetine is in dispute. Apotex submits that the real world market for atomoxetine during the liability period is a reasonable proxy for the calculation of losses under s. 8. Lilly submits that the total size of the atomoxetine market in the hypothetical world would have been smaller than the market in the real world. Lilly says that in the real world, the atomoxetine market decreased after the entry of generic products and that the same market reduction would have occurred in the hypothetical world.

[109] I find that the real world market for atomoxetine during the liability period is a reasonable proxy for market size in the hypothetical world.

[110] Lilly bases its view on the report of Dr. Iain Cockburn. Apotex bases its view on the report of Aidan Hollis which responded to Dr. Cockburn's report. For the reasons set out below, I prefer the evidence of Mr. Hollis over that of Dr. Cockburn on the issue of market size.

[111] Dr. Cockburn's analysis is premised on the assumption that the market share of a molecule decreases after the introduction of generic products. He bases this assumption on the fact that branded products invest a great deal into the development of the market but stop doing so after generic products enter thereby leading to a reduction in the size of the overall market. The conclusion that markets decrease after the introduction of generic products is, however, is contrary to the 2012 report of the Patented Medicines Prices Review Board which found that there was no such decrease after the entry of generic competitors. I prefer the analysis of an independent Board of experts in the field to that of Dr. Cockburn.

[112] In addition, Dr. Cockburn's theory of a reduction in the atomoxetine market is based on an economic regression model that excludes Quebec. On cross-examination, Dr. Cockburn admitted that he created an economic regression analysis for all of Canada, including Quebec. That analysis showed growth in the atomoxetine market after the entry of generic products.

[113] Dr. Cockburn justified excluding Quebec from his model because he says it has a different regulatory regime than the rest of Canada. Mr. Hollis took issue with the exclusion of Quebec. Mr. Hollis noted that each province has a distinct regulatory regime, each with very different rules. According to Mr. Hollis, Quebec's regime is no more different than the other provincial regimes are from each other. Mr. Hollis was not challenged on that point during cross-examination.[64] In those circumstances, an analysis that takes into account all of Canada strikes me as more appropriate than one that excludes its second-largest province.

[114] Dr. Cockburn also looks at a decline in atomoxetine sales shortly after the entry of generic products and concludes that the decline is attributable to the entry of generics. He does not appear to have considered whether there were any other changes in the market that would explain a decrease in atomoxetine sales. It appears that there was such a change. Approximately 14 months before generic atomoxetine entered the Canadian market, a

[64] Although Mr. Hollis was referred to something referred to as the BAP 15 rule in Quebec, he was not challenged on the point that Quebec's regime was not any more different than that of other provinces.

competitive molecule to atomoxetine was introduced under the brand-name Vyvanse. It usually takes some time for a new product to establish itself and begin impinging on the sales of pre-existing competitive products. That appears to have been the case with Vyvanse. Although Lilly tired to suggest at trial that Vyvanse did not compete with atomoxetine, its brand plan for Strattera dated August 27, 2010 described Vyvanse as a threat to Strattera.[65]

[115] In these circumstances, I find that if there was any decrease in the atomoxetine market after March 2011, it was attributable to the introduction of Vyvanse and not to the introduction of generic atomoxetine. Vyvanse would not have been a factor in the hypothetical world because there is no evidence that it would have entered the market or that it would have affected atomoxetine sales any sooner in the hypothetical world than it did in the real world.

iv. Apotex's Share of the Generic Market

[116] The submissions at trial on this question did not raise the issue of Apotex's share of the market as such. Rather, the question was whether Apotex would have entered the market as the sole generic or whether it would have entered with other generics. Given my earlier findings that Apotex would have pursued a joint venture with Teva in the hypothetical world and that Teva would have had the same opportunity to enter the market in the hypothetical world as it did in the real world, I find that Apotex's share of the generic market in the hypothetical world would have been the same as it was in the real world.

v. At What Price Would Apo-Atomoxetine Have Been Sold?

[117] Given my finding that Teva would have had the same opportunity to enter the market in the hypothetical world as it did in the real world, pricing competition in the hypothetical world would have matched that of the real world. As a result, I find that Apo-Atomoxetine would have sold at the same prices in the hypothetical world as it did in the real world.

[118] Lilly submits that there would have been no joint venture in the hypothetical world as a result of which atomoxetine pricing would have been lower. Lilly notes that Apotex initially applied for pricing at 75% of Strattera's price and then increased its to 89% when joint venture discussions arose. Lilly suggests that in the absence of a joint venture, pricing would have been lower than 89%. I do not accept that submission because Apotex actually received pricing equal to 89% of Strattera's price even after the joint venture was abandoned.

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[65] CaseLines document B1 44 at PDF page 19.

[119] Finally on this point, I was not taken to any evidence at trial that suggests pricing between October 2008 and March 2010 would have been any different than it was in the real world.

vi. Did Apotex Lose Sales With Respect to "Pipe-fill" Sales?

[120] Pipe-fill refers to the amount of increased sales that occur when a product is first introduced to the market. It reflects the initial surge in sales to wholesalers to enable them to have adequate inventory. Lilly submits that Apotex did not lose any pipe-fill sales because of the prohibition proceeding. At worst, Lilly says those sales were delayed until it began selling in the real world. As a result, if Apotex were awarded pipe-fill losses during the liability period, it would be obtaining double recovery.

[121] Given my analysis of when Apotex would have launched product in the hypothetical world, it is, strictly speaking, not necessary for me to address the pipe-fill issue because I have found that Apotex would not have launched during the liability period in the hypothetical world. In the interests of having a more fulsome record in the event of any appeals, I will nevertheless address the issue.

[122] While Lilly's argument about double recovery is initially attractive, it was rejected by the Federal Court of Appeal in the *Olanzapine Damages* case[66] where Lilly made the same argument, based on the same analysis, conducted by the same expert (Dr. Cockburn) as Lilly advances here. In dismissing Lilly's argument, Laskin J.A. noted that s. 8 of the *Regulations* provides compensation for "any loss suffered" during the liability period. Pipe-fill sales are sales losses suffered during the liability period and therefore fall within the definition of losses under s. 8. Laskin J. A. noted that Lilly's position was based on the premise that compensation should be calculated on a make whole basis. The Court expressly noted that a "make whole" approach was not the one contemplated under s. 8. Rather, the *Regulations* compensate for losses that occurred during the liability period even if they result in double recovery for pipe-fill sales. While the Federal Court of Appeal did not expressly say so, the approach under s. 8 that might allow double recovery for pipe-fill sales appears to be the result of a public-policy compromise. Section 8 gives the generic manufacturer only for losses suffered during the liability period. It does not give the generic the chance to claim for losses suffered outside of the liability period. The suggestion in the reasoning of the Federal Court of Appeal is that one *quid pro quo* of having the generic surrender claims for losses sustained after the end of the liability period is the possibility for "double recovery" on pipe-fill sales.[67]

[123] Lilly also takes issue with Apotex's calculation of pipe-fill sales which its expert, Dr. Cockburn says are the result of channel stuffing. As Dr. Cockburn explained it, these are

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[66] *Eli Lilly Canada Inc. v. Teva Canada Limited,* 2018 FCA 53

[67] *Eli Lilly Canada Inc. v. Teva Canada Limited*, 2018 FCA 53 at paras. 154-170 and especially paras. 160 and 167.

excess sales to wholesalers which sales would later be unwound by having wholesalers return product to Apotex.

[124] I do not accept the submission that Apotex engaged in channel stuffing. I have found that sales in the hypothetical world would have mirrored those of the real world. I was not taken to any evidence to suggest that there were returns in the real world of the sort that Dr. Cockburn testified would occur in cases of channel stuffing. In addition, I do not see how channel stuffing would result in excess recovery here. Given the absence of evidence of product returns in the real world, if channel stuffing occurred, it would presumably be offset by lower sales in the period following the channel stuffing. Apotex's expert estimates the pipe-fill period at seven months. Dr. Cockburn says it is six weeks. The liability period is 23 months**.** Thus, even on Apotex's longer view of 7 months of pipe-fill sales, there would be ample time for the benefit of any channel stuffing to be eliminated by lower sales in months 8 to 23.

vii. What Costs Would Apotex Have Incurred in the Liability Period?

[125] The principal issue that arises in this regard is the amount of professional allowances or rebates that would have been provided to purchasers of Apo-Atomoxetine during the liability period. It appears that all generic manufacturers provide rebates to purchasers to incentivize them to purchase their product.

[126] While the parties have not expressly said so, I infer from their submissions that both parties agree that the calculation of rebates in the hypothetical world should be based on the rebates that Apotex granted for Apo-Atomoxetine in the real world. Unfortunately, that does not advance matters much because the parties disagree about the size of rebates that Apotex provided for Apo-Atomoxetine in the real world.

[127] Lilly submits that the Apotex rebates on Apo-Atomoxetine were [ ][68]% when Apotex was alone in the market and [ ]% when faced with competition. Given my finding that Teva would have entered the market at the same time as Apotex, the real issue is the rebate that applies when two or more generics are in the market.

[128] Apotex's position is based on the report of its expert, Andrew Harrington. Mr. Harrington concluded that the best estimate of Apotex's rebate was [ ]% while Apotex was alone in the market and [ ]% when it faced competition from Teva.

[129] Mr. Harrington's conclusion is based on an estimate because the precise size of rebates with respect to individual products is extremely difficult to discern from Apotex's accounting records. It appears that there are no written agreements with purchasers regarding rebates. Any agreements about rebates are oral. Apotex's internal accounting system records global rebates per product. Apotex pays out rebates based on invoices from

[68] Indicates redaction

customers that do not provide any breakdown per product but set out only a total amount which reflects the rebate for all products purchased by the customer. Apotex then issues a cheque in respect of those invoices which also does not provide any breakdown between products.

[130] Lilly's expert, Ross Hamilton, says that this lack of documentary breakdown seems highly unusual. I agree.

[131] Mr. Hamilton notes that Apotex's rebates ranged between $ [ ] million and $[ ] million per year between 2008 and 2012. It strikes me as unusual that payments of that size that are supposedly built up by product would occur by way of global invoices without any product detail and that Apotex would then issue a cheque without any further product detail, unless the fundamental arrangement between Apotex and its customer is a rebate based on a per centage of overall sales after which it is left to Apotex to allocate the rebate between products internally.

[132] According to Apotex, rebates are recorded in its SAP accounting system. I was not, however, taken to any examples of a breakdown by customer or product in the SAP system. I was taken only to Exhibit J of Mr. Fahner's affidavit which was a table that showed global sales and rebate expenses by month for Apo-Atomoxetine. I was not taken to any further SAP records to show how Exhibit J was built up.

[133] It is up to Apotex to prove its damages on a balance of probabilities. That includes proving costs like rebates. Apotex's evidence of rebates is too limited and frail to satisfy the balance of probabilities onus. In those circumstances I find it more appropriate to apply the global rate Apotex recorded during the liability period which is [ ]%.

[134] Apotex submits that the Federal Court rejected this approach in Eli *Lilly v. Teva*.[69] I do not read that case as broadly as Apotex does. In that case, the Federal Court simply declined to accept the approach based on the facts before it. There is no discussion in that case of the presence or absence of record-keeping that would support or detract from the rebate analysis that the parties advanced in that case.

viii. What Rate Of Prejudgment Interest Rate Should Apply?

[135] Apotex submits that prejudgment interest on any award should be calculated based on the simple quarterly interest rates provided in the *Courts of Justice Act* from October 10, 2008 to the date of judgment. Apotex notes that this is the method proposed by Lilly's expert, Mr. Hamilton. Lilly submits no prejudgment interest should be awarded because of the substantial delays in advancing this action to trial. I agree that the delay is substantial. This action did not come to trial until 11 years after it was commenced. I was not, however, given any information about who was responsible for that delay. In the circumstances, if I

[69] *Eli Lilly v. Teva*, 2017 FC 88 at paras 105 – 106.

should be found to be wrong on the question of liability and wrong on the question of whether Apotex would have entered the market in the hypothetical world any sooner than it did in the real world, prejudgment interest should be calculated as Apotex requests.

Conclusion and Costs

[136] For the reasons set out above, I dismiss Apotex's claim. Any party seeking costs arising out of these reasons will have three weeks to deliver written submissions. The responding party will have two weeks to deliver its answer with a further one week for reply.

[137] In the event I have not answered specific questions about damages that the parties need to have determined, I remain seized of this matter to make such determinations. Any party requiring such a determination can make an appointment for a case conference with my judicial assistant. The object of the case conference will be to determine how best to address the issue.

Koehnen J.

Released: March 30, 2023

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COURT FILE NO.: CV-11-420115
DATE: 20230330

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:

APOTEX INC.

Plaintiff

– and –

ELI LILLY AND COMPANY,
ELI LILLY S.A., LILLY DEL CARIBE, INC., LILLY S.A., ELI LILLY EXPORT S.A. and ELI LILLY CANADA INC.

Defendants

REASONS FOR JUDGMENT

KOEHNEN J.

Released: March 30, 2023