Federal Court  Cour fédérale

Date: 20140915

Docket: T-1736-10

Citation: 2014 FC 876

Toronto, Ontario, September 15, 2014

PRESENT: Case Management Judge Kevin R. Aalto

BETWEEN:

APOTEX INC.

Plaintiff

and

PFIZER CANADA INC., WARNER LAMBERT COMPANY LLC AND PFIZER INC.

Defendants

AND BETWEEN:

WARNER LAMBERT COMPANY, LLC AND PFIZER INC.

Plaintiffs by Counterclaim

and

APOTEX INC.

Defendant by Counterclaim

ORDER AND REASONS

The best laid schemes o' mice an' men / Gang aft a-gley.*

[1] "And so it goes" ** for case management decisions as well. This is a further chapter in the ongoing saga of Apotex Inc.'s (Apotex) claim for Section 8 damages relating to the Defendants/Plaintiffs by Counterclaim's (Pfizer) branded drug product Lipitor, the active pharmaceutical ingredient (API) being atorvastatin.

[2] The motion before the Court is brought by Pfizer to further amend its Further Fresh as Amended Statement of Defence and Counterclaim (Defence). Given that no discoveries have yet taken place even though the action was commenced in 2010, it would be almost axiomatic that these amendments if meritorious would be granted. However, this motion is vigourously opposed as it arises five months after a Bifurcation Order was made relating to an issue which, on the unique facts of this case, is novel [see *Apotex Inc. v. Pfizer Canada Inc. et al*, 2014 FC 159]. The simplified statement of the bifurcated issue is: "What is the start date for the Section 8 damages claimed by Apotex?" (Start Date Issue).

Background

[3] By way of brief background, the Start Date Issue arises because the Minister of Health (Minister) has issued two patent hold letters for different dates relating to Apotex' two different

* "To a Mouse," (1785) by Robert Burns, often paraphrased from the Gaelic into English as: "The best-laid plans of mice and men / Often go awry".

** With apologies to Kurt Vonnegut and Billy Joel

atorvastatin formulations. The following facts are summarized from the reasons for the Bifurcation Order.

[4] Pfizer has certain patents listed on the Patent Register against the drug Lipitor including patents relating to various polymorphic forms of Atorvastatin. Pfizer sells generic pharmaceutical products in Canada through its GenMed Division and received an NOC in respect of GD-Atorvastatin on November 15, 2006.

[5] On September 27, 2006 Apotex served two Notices of Allegation (NOA) in respect of Pfizer's polymorphic patents. Apotex's submission for its amorphous atorvastatin product (First Apotex Product) was placed on "patent hold" by the Minister of Health on May 15, 2007. Notices of Application were issued by Pfizer pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (*Regulations*) seeking prohibition orders. Those applications were eventually discontinued.

[6] On February 19, 2009 Apotex delivered NOA's in relation to its submission to Health Canada for an Apotex product containing atorvastatin propylene glycol solvate (Second Apotex Product) in respect of Pfizer's polymorphic patents. Notices of Application under the (*Regulations*) were commenced by Pfizer in response to the February 19, 2009 Apotex NOA's. Apotex's submission for the Second Apotex Product was placed on patent hold by the Minister of Health on February 22, 2010.

[7] Apparently, the Second Apotex Product indicates one of the problems the inventors sought to overcome was reduced stability associated with forms of atorvastatin such as the amorphous atorvastatin formulation being the First Apotex Product.

[8] Apotex obtained NOC's for both its First Apotex Product and its Second Apotex Product on May 19, 2010. Subsequently, Apotex marketed in Canada only the Second Apotex Product. At the time of Apotex's launch of its Second Apotex Product, it issued a press release dated May 19, 2010 which explained that by virtue of its own crystal form of atorvastatin it had essentially solved the stability issues associated with other forms of atorvastatin. Apotex stated in its press release that it had "spent many years and many millions of dollars on the development and litigation processes for this product". The prohibition applications commenced by Pfizer in response to Apotex's NOA's were discontinued on consent on May 26, 2010.

[9] There are, apparently, a number of generic pharmaceutical manufacturers who have delivered NOA's in respect of one or more of the patents listed on the Patent Register against Lipitor. On May 19 and 20, 2010, the Minister, in addition to the NOC's issued to Apotex, issued seven other generic pharmaceutical manufacturers NOC's in respect of generic atorvastatin products. Subsequently, an additional six pharmaceutical manufacturers received NOC's for their respective atorvastatin products.

[10] In this action, Apotex seeks Section 8 damages for a three-year period commencing May 15, 2007 and ending May 19, 2010. Pfizer argues that Apotex's Section 8 damages are limited to the three-month period commencing February 10, 2010 and ending on May 19, 2010. Pfizer's

position is that there can be no Section 8 damages relating to the longer term because the three-year period relates to the First Apotex Product that Apotex never brought to market.

[11] Pfizer sought to have the Start Date Issue bifurcated. The Bifurcation Order was issued February 20, 2014 substantially on the terms sought by Pfizer. Apotex did not appeal.

[12] It is against this background that Pfizer comes again to the Court but this time to amend virtually all of the paragraphs of its Fresh As Amended Statement of Defence and Counterclaim (Proposed Amendments) which are referenced in the Bifurcation Order. To put the issue in context, the Bifurcation Order provides as follows:

> In this Order:
>
> (a) **"Start Date Issue"** means the issue of the relevant date that the period of liability (if any) commenced pursuant to section 8(1)(a) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended. For greater certainty, the Start Date Issue shall include the determination of the issues raised in paragraphs 17-23 of the Amended Statement of Claim dated May 30, 2011; in paragraphs 10-17, 19-21 and 23-25 of the Further Fresh as Amended Statement of Defence and Counterclaim dated April 25, 2012; and in paragraphs 5-9 of the Fresh as Amended Reply and Defence to Counterclaim dated July 28, 2011.

(b) **"Start Date Phase"** means discovery and all other steps up to and including a trial or other determination of the Start Date Issue, including any appeals.

(c) **"Other Issues"** means all issues in the action other than the Start Date Issue.

1. The Start Date Issue shall be determined separately from, and prior to, the Other Issues.

2. Insofar as it raises the Other Issues, this action shall be stayed pending the completion of the Start Date Phase. During the Start Date Phase there shall be no documentary or other discovery on matters relating solely to the Other Issues.

3. The Parties shall confer on the schedule to be followed for the determination of the Start Date Phase. In the event that the parties are unable to agree on a schedule, either party may bring a motion to the Court for directions.

4. The Other Issues shall de determined separately from, and only after the completion of, the Start Date Phase.

[13] At this stage of the proceedings the parties have exchanged affidavits of documents related to some issues but examinations for discovery have not yet been commenced. Both

Apotex and Pfizer complain that the other side has not produced relevant documentation. Discoveries on the Start Date Issue are imminent.

[14] The trial of the Start Date Issue is set for four days commencing June 22, 2015.

[15] Since the Bifurcation Order was issued, Pfizer changed its counsel. This has resulted in some delay as new counsel have been required to get up to speed on the issues in this case. It has also resulted in the current motion seeking the Proposed Amendments.

[16] Of the paragraphs enumerated in the definition of the Start Date Issue, Pfizer now seeks to amend virtually all of those paragraphs. By implication, any amendment to these paragraphs in the Defence will result in a variation of the Bifurcation Order. This motion was filed and argued by Pfizer as a pleading amendment motion and not as a variation of an order motion. However, one cannot ignore the inexorable result of allowing the Proposed Amendments and the impact they will have on the Start Date Issue. The Proposed Amendments are attached to these Reasons as Schedule "A".

[17] The dilemma which these Proposed Amendments create is that, notwithstanding the arguments of Pfizer, the issues on the Start Date Issue case are expanded by virtue of these Proposed Amendments; they were not part of the original case at the time of the bifurcation motion and therefore were not addressed in the context of the bifurcation motion; and, if allowed, the Start Date Issue is lengthened and more complicated. It is no answer, as suggested by Apotex, that the Proposed Amendments, if allowed, not be part of the Start Date Issue. Thus,

as with many proceedings, a balance must be struck to accommodate the interests of all the parties in putting their case forward.

Position of Pfizer

[18] Pfizer argues that the Proposed Amendments "do not **radically** alter the pleaded case nor do they require that the Bifurcation Order be varied" [para. 34, emphasis added, Pfizer's Written Representations]. On the latter point they are correct as the Bifurcation Order simply refers to paragraph numbers and no modification of those paragraphs is required. What this submission misses is that the Proposed Amendments are contained in the current paragraph numbers and to change the Defence is to change the Bifurcation Order by expanding its scope to include the new allegations. With respect to the former point, notwithstanding the very able arguments of counsel for Pfizer, the description of the Proposed Amendments as not "radically" altering the case implicitly acknowledges that they do, in fact, alter the case as pleaded.

[19] Pfizer argues that the Proposed Amendments fall into three broad categories: 1) the NOA Amendments; 2) the Election Amendments; and 3) the Updating Amendments.

[20] With respect to the NOA Amendments, Pfizer seeks to amend various paragraphs of the Defence to plead that Apotex's 2006 NOA's have no legal effect because those NOA's did not include the information required by the *Regulations*. This was an allegation made by Pfizer in the prohibition proceedings but was never determined as those proceedings were discontinued. Pfizer argues that Apotex was aware of this allegation and it is nothing new and there is no injustice or prejudice to Apotex by allowing these amendments. They argue that it is essential

for the judge hearing the Start Date Issue to have the full picture on all issues and this amendment is part of the picture. However, the legal effect of the NOA's was not part of the bifurcation motion nor was it addressed in that context.

[21] The Election Amendments raise an esoteric issue of law regarding Apotex's decision to market only the Second Apotex Product. The election to do so, as Pfizer argues disentitles Apotex to damages for the three-year period. These amendments also deal with Apotex's decisions to change the drug formulation and drug substance of its products and then enter the market with only the Second Apotex Product. In support of its argument that these Election Amendments do not alter the Bifurcation Order, Pfizer notes that these amendments are simply a legal argument and that the amendments clarify and particularize these arguments. One wonders that if the issue is already part of the current pleadings, why these amendments are required?

[22] With respect to the Updating Amendments, they reflect the importance, as Pfizer argues, of accurate pleadings. The Updating Amendments simply correct references in Pfizer's Defence and do not broaden the scope of the Start Date Issue. For example, in paragraph 13 Apotex's 2009 NOA's state that Apotex made an "abbreviated drug submission" relating to the Second Apotex Product while the documentation from the Minster states that it was a "supplemental abbreviated new drug submission". Of all of the Proposed Amendments, this group is closest to being housekeeping or clarification amendments.

[23] In summary, Pfizer argues that there is no prejudice to Apotex and the interests of justice require that these "routine" Proposed Amendments be granted.

Apotex's Position

[24] For its part, Apotex strenuously disagrees with Pfizer's position that the Proposed Amendments will not lengthen or broaden the Start Date Issue. Apotex argues that the Proposed Amendments "are real, are substantial and demonstrate prejudice". Apotex argues that the Proposed Amendments are neither clarifications, particularizations nor housekeeping but substantive new elements which fundamentally alter the scope of the Start Date Issue to the detriment of Apotex. The thrust of Apotex's argument opposing the Proposed Amendments is with respect to the prejudice which Apotex will suffer respecting the trial of the Start Date Issue.

[25] Apotex argues that the Proposed Amendments are objectionable as they (i) seek to amend and expand the Start Date Issue; (ii) constitute a "radical change" in the position of Pfizer; (iii) are not relevant or fail to disclose a reasonable cause of action; and, (iv) ought to have been raised earlier.

[26] Given the outcome of this motion, it is not necessary to review Apotex's position on each of the Proposed Amendments in detail. A brief review will suffice. For example, Apotex argues that the Proposed Amendment to Paragraph 14 is not a defence to a Section 8 claim as it invites a reconsideration of whether or not Apotex's 2006 NOA's were proper and whether they had any effect under the *Regulations*. This, so Apotex argues, reopens the proceedings under the *Regulations* and, if allowed, would require expert evidence on regulatory matters and further evidence as to the scope of those discontinued proceedings.

[27] Similarly, the Proposed Amendment to Paragraph 13 puts in issue the Minister's regulatory decision to issue NOC's to Apotex and whether Apotex's products are different not only because they are different formulations (amorphous v. propylene glycol solvate) but are also a change in drug substance. This allegation will require more scientific evidence involving the Apotex products and the Apotex API.

[28] Apotex's arguments respecting other parts of the Proposed Amendments point to the fact that the issues now raised were not argued as part of the bifurcation motion. The issue of election, the propriety of the NOA's and the involvement of the Minster and the Minister's discretion will require additional discovery and evidence. Apotex argues that the additional time to be ready in 9 months and the extra issues cannot be dealt with in the four days of trial time set aside for the Start Date Issue.

Analysis

[29] Although the Proposed Amendments amend the Bifurcation Order, given the disposition of this motion, the analysis applied is that of amending pleadings. Whether amendments should be granted is in the discretion of the Court.

[30] There is considerable jurisprudence dealing with the provisions of Rule 75 and the factors to be considered on motions to amend. Rule 75 provides that the Court may at any time allow a party to amend "on such terms as will protect the rights of all parties." The jurisprudence, [see, for example, *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 at para. 3 (FCA); *Merck & Co. v. Apotex Inc.* (3302), 30 C.P.R. (4th) 40; and, *Bristol Myers Squibb Co. v. Apotex Inc.*, 2011 FCA 34], sets

out the basic approaches to amendments. The classic statement on amendments is found in *Canderel* as follows at p. 10:

> A pleadings amendment should be allowed for the purpose of determining the real questions in controversy, provided that allowing the amendments would not result in an injustice to the other party that is not capable of being compensated by an award of costs and the amendment would serve the interests of justice.

[31] Subsequent cases have noted that the discretion to allow amendments is to be guided by two factors: (1) prejudice; and (2) interests of justice. Both criteria should be met by the moving party. All relevant factors must be considered by the Court in assessing any amendments. Among the factors to be considered, if applicable, include:

> Do the amendments withdraw admissions of result in "radical" change of the matters in controversy;
>
> Will the amendments facilitate the Court's consideration of the real issues in dispute;
>
> Have the amendments been considered at a pre-trial conference;
>
> Has a position of a party led the opposite party to pursue a course of action that may be difficult to alter;
>
> The conduct of the parties and specifically the conduct of the party proposing the amendments;
>
> Will the amendments delay the expeditious trial of the matter;
>
> The timeliness of the motion to amend; and,
>
> Prejudice which is non-compensable by costs or otherwise.

[see, generally, Merck & Co. v. Apotex Inc. 2003 FCA 488 at para. 30 and *Bristol Myers Squibb Co. v. Apotex Inc.*, 2011 FCA 34, at paras. 4, 5, 28 and 33]

[32] All of these factors do not apply here as there has been no pre-trial and the action, for all the steps taken to date, is still in its relative infancy notwithstanding four years have elapsed since its inception as no discoveries have yet taken place.

[33] A further factor that must be considered is whether the Proposed Amendments disclose a reasonable cause of action or defence. Dealing with this point, although Apotex argues that the Proposed Amendments, in large part, do not amount to a recognized defence to a Section 8 damage claim, the novelty of a defence or a claim, if it has some semblance of possibility, should not be determined at the pleadings stage. Section 8 damage cases are an evolving area of law and one should not arbitrarily close the door to possible defences without the benefit of a full record before a trial judge. Unless a claim or a defence is "bereft of any chance of success" [see *Hunt* v. *Carey Canada Inc*., [1990] 2 S.C.R. 959], subject to the overriding considerations of justice and prejudice, it should be allowed. At this juncture, I am not prepared to find that any of the Proposed Amendments are bereft of any chance of success.

[34] Turning to a consideration of the applicable factors set out above, it is my view that, on balance, the Proposed Amendments should be granted. While the amendments change some of the matters in controversy they are not so radical as to amount to a new and different case. Further, these issues have been on the periphery given the prior proceedings under the *Regulations* between these parties.

[35] The Proposed Amendments have not caused Apotex to pursue a course of action that cannot be altered save and except for a consideration of the Start Date Issue considered in greater

detail below. Apotex criticizes Pfizer for the timeliness of this motion and for bringing it after the hearing of the bifurcation motion. Pfizer knew about all of the issues that form the Proposed Amendments well prior to the argument of the bifurcation motion. However, Pfizer has changed counsel and these concerns of Apotex can be addressed by way of remedy. This is particularly so since these Proposed Amendments affect the expeditious determination of the Start Date Issue.

[36] In my view, the interests of justice and any prejudice can be compensated by way of remedy.

Conclusion

[37] I am in substantial agreement with the position of Apotex regarding the impact of the Proposed Amendments on the Bifurcation Order. Without directly seeking a variation of the Bifurcation Order, Pfizer is indirectly amending the Bifurcation Order. All of these Proposed Amendments expand significantly the scope of the Start Date Issue and make it virtually impossible for the Start Date Issue to be determined as originally contemplated when Pfizer sought and obtained the Bifurcation Order.

[38] Notably, Pfizer in its submissions on the bifurcation motion argued, *inter alia*, that "an early determination of the Start Date Issue has the potential to lead to significant savings of time and expense for both parties and for the Court" [para. 90] and that the determination of the Start Date Issue "is likely to lead to fewer interlocutory disputes between the parties, thereby decreasing the time to trial" [para. 108].

[39] The latter point already rings hollow. The number of interlocutory motions is increasing. A production motion was brought by Pfizer in conjunction with this motion. That motion was brought notwithstanding that on the bifurcation motion it was asserted in Pfizer's written representations that the parties had exchanged affidavits of documents and productions. The production now requested of Apotex relates primarily to the Proposed Amendments. That motion was not dealt with on the merits pending the outcome of this motion.

[40] Next, Apotex advised at the hearing of this motion that it seeks to bring its own production motion because Pfizer did not meet a date in a scheduling order for the production of financial data. Correspondence sent to the Court subsequent to the hearing of this motion underscores vividly that these parties are still not in agreement on production and that the Court's intervention will be required. All of these interlocutory steps not only have eliminated the Start Date Issue trial dates but further interlocutory proceedings may very well jeopardize the actual trial dates.

[41] Given the timeframes and the ongoing sparring of the parties over production, I have no confidence that the Start Date Issue can be ready for mid-2015 given the Proposed Amendments and, more importantly, the penchant for these parties to litigate every single issue to the Nth degree. As noted, the Court has recently received recent correspondence from each side relating to the other sides failure to produce relevant documents.

[42] Further, as Case Management Judge, I am reminded, virtually on every case conference and motion, that this is the "biggest" section 8 case or that there is the prospect of a billion dollar

plus damage award. Cost-saving, as contemplated by Rule 3, is simply not a realistic objective in this case. There is nothing in this case that raises an earth-shattering issue which would fundamentally affect society or even big pharma litigation generally. It is simply about money and the number of zeros on the damage award to either one of two very sophisticated entities. This case will be decided on its own unique facts when the trial commences on April 4, 2016.

[43] Thus, the Proposed Amendments are granted and the Bifurcation Order relating to the Start Date Issue is vacated. The parties shall be ready for trial commencing April 4, 2016 on ALL issues. It is always in the discretion of the trial judge in the conduct of the trial to determine which issue(s) and in which order they will proceed. To that end, and given the propensity for these parties to spar over everything, I also have no confidence that a reasonable schedule can be established between the parties in a timely way to have this matter ready for trial. Thus, it is necessary to unilaterally and arbitrarily impose timelines and restrictions on the conduct of this litigation to ensure the trial commences on time.

[44] In all, the Court's expectation with respect to the Start Date Issue was, as stated in the Reasons for the Bifurcation Order:

> . . . However, in my view, the bifurcation of an issue need not inexorably lead to the resolution of the litigation in its entirety, it is sufficient that if, on a balance of probabilities, the determination of an issue will lead to a shorter trial, a more focused discovery, contained production and less expert evidence. Such is the expectation in this case if the Start Date Issue is first determined.
>
> [2014 FC 159 at para. 47]

[45] And so it goes, these best laid plans have gone completely awry.

ORDER

THIS COURT ORDERS that:

1. Pfizer is granted leave to amend its Further Fresh as Amended Statement of Defence and Counterclaim, in the form of the Proposed Amendments attached as Schedule "A" to this Order.

2. Pfizer shall deliver its Second Further Fresh as Amended Statement of Defence and Counterclaim within 10 days of the date of this Order.

3. Apotex shall deliver its amended Reply and Statement of Defence to Counterclaim within 20 days of being served with the Second Further Fresh as Amended Statement of Defence and Counterclaim.

4. The Bifurcation Order dated February 20, 2014 is hereby vacated and the dates for the trial of the Start Date Issue are hereby released.

5. The trial of this action shall commence on April 4, 2016 on all issues subject to the discretion of the trial judge.

6. The parties shall communicate with one another for the purpose of agreeing upon a schedule for completion of the discoveries which discoveries shall be completed on or before March 31, 2015.

7. All affidavits of documents and all productions listed thereon together with all relevant documents relating to the amended pleadings shall be delivered on or before October 31, 2014. For greater certainty and without limitation Pfizer shall

comply the production ordered in paragraph 1 of the Order of the Court dated July 25, 2014 and such productions shall include financial data relevant to the sales of Pfizer's drug product the patent infringement damages including costing, the size of the atorvastatin market, forecasts, marketing information and other such documentation; and, Apotex shall produce documentation relating to the Start Date Issue including correspondence relating to the regulatory submissions of its products as well as documentation relating to formulary listings and rebate information.

8. There shall be no refusals motions. All parties shall answer all relevant questions on the examinations for discovery and in the event of any disagreement over relevance such questions shall be answered in accordance with Rule 95(2).

9. The examinations for discoveries are hereby limited to 8 days for Apotex and 8 days for Pfizer to be set at times mutually convenient to the Court and the parties. To the extent possible the Court will be available to rule on any objections not answered pursuant to Rule 95(2). Should Apotex examine any inventors, Apotex shall be allowed one further day of examination for each inventor in addition to the 8 days.

10. All expert reports shall be delivered by all parties on or before September 18, 2015.

11. All expert reply reports shall be delivered by November 30, 2015.

12. A pre-trial of this action shall be conducted on a date convenient to the Court and the parties during either the week of January 25th or the week of February 1st, 2016.

13. Costs, if necessary, of this motion are reserved to be spoken to.

"Kevin R. Aalto"
Case Management Judge

SCHEDULE A

Proposed Amendments to Pfizer's Further Fresh as Amended Statement of Defence and Counterclaim dated April 25, 2012 (paras. 10-17, 19-21 and 23-25)

Prior Proceedings between the Parties Under the Regulations

10. Apotex first served a Notice of Allegation dated November 18, 2005 relating to amorphous atorvastatin on November 21, 2005. In response to this Notice of Allegation, Pfizer Canada Inc. commenced an application bearing court file no. T-16-06.

11. On January 2, 2008, the application in court file no. T-16-06 was dismissed.

12. In September 2006, Apotex served Notices of Allegation alleging non-infringement of additional patents other than Canadian Patent 2,021,546 (the "Additional Patents") ~~in September, 2006~~pertaining to crystal forms of atorvastatin, inter alia (the "September 2006 NOAs"). ~~The~~While the September 2006 NOAs stated that Apotex had filed an abbreviated drug submission (the "~~First Apotex~~Amorphous ANDS") to the Minister of Health for its products containing anhydrous amorphous atorvastatin hemicalcium (the "First Apotex Product"), Apotex had not in fact filed an ANDS and did not include the requisite certification with its material. The factual basis for the allegations of non-infringement was that the First Apotex Product was amorphous and did not contain any of the crystal forms claimed in the Additional Patents.

13. In February 2009, Apotex served ~~additional~~further Notices of Allegation alleging non-infringement of the Additional Patents (the "February 2009 NOAs"). ~~The~~While the February 2009 NOAs stated that Apotex had ~~made~~filed an abbreviated new drug submission to the Minister of Health on July 9, 2008 ~~(the "Second Apotex ANDS"). The Second Apotex ANDS was for a new~~, the submission was in fact a supplemental abbreviated new drug submission (the "PGS SANDS") for a change in drug substance and formulation of ~~atorvastatin~~drug product, namely, atorvastatin calcium in the form of propylene glycol solvate (the "Second Apotex Product"). The factual basis for the allegations of non-infringement was that the Second Apotex Product did not contain any of the crystal forms claimed in the Additional Patents. Apotex elected to pursue the Second Apotex Product by means of a supplemental abbreviated new drug submission (and not a fresh abbreviated new drug submission) and, as a result, elected to change its formulation and drug substance from the Amorphous ANDS to the PGS SANDS.

14. ~~The proceedings arising from~~In relation to the September 2006 NOAs, Pfizer Canada Inc. and Warner Lambert Company commenced two applications: Court File Nos. T-1995-06 and T-2145-06 (which was later consolidated with T-1995-06) (these proceedings, together with Court File No. T-16-06,

are hereinafter referred to as the "2006 Proceedings"). In the 2006 Proceedings, Pfizer alleged that the September 2006 NOAs were not properly notices of allegation and had no legal effect under the Regulations. The 2006 Proceedings in relation to the September 2006 NOAs were discontinued between May 19, 2010 and June 10, 2010 and never decided on their merits.

15. ~~The proceedings arising from~~In relation to the February 2009 NOAs, Pfizer Canada Inc. and Warner Lambert Company commenced two applications: Court File Nos. T-579-09 and T-580-09 (the "2009 Proceedings"). The 2009 Proceedings were discontinued on May 20, 2010. Apotex elected not to pursue a section 8 claim in respect of the 2009 Proceedings.

16. On May 19, 2010, Apotex received Notices of Compliance ~~in respect of both the First and Second Apotex Products on May 19, 2010~~. The Notices of Compliance ~~approve products containing two different medicinal ingredients, corresponding with the two Apotex Products.~~provide authorization for drug identification numbers solely related to the Second Apotex Product. Apotex submitted a single product monograph for both the Amorphous ANDS and the PGS SANDS which made reference only to the Second Apotex Product. Apotex does not have a product monograph nor a set of drug identification numbers which would permit Apotex to sell the First Apotex Product. Apotex has never been in a position to sell the First Apotex Product.

17. Apotex began manufacturing, using, offering for sale and/or selling Apo-Atorvastatin on or about May 19, 2010. Apotex does not sell and has never sold the First Apotex Product.

Apotex's Claim

19. In its amended statement of claim ("Claim"), Apotex claims entitlement to section 8 damages from May 15, 2007 until May 19, 2010. Apotex has not provided any facts in its Claim to substantiate ~~this~~its proposed start date. In particular, Apotex has failed to:

(a) provide a date certified by the Minister on which a notice of compliance for either the First or Second Apotex Products would have been issued ~~("the relevant date")~~;

(b) identify which of either the First or Second Apotex Products ~~it alleges~~ was allegedly approvable on ~~the relevant~~its proposed start date;

(c) confirm that the product it alleges was approvable on ~~the relevant~~its proposed start date is the product it is currently marketing in Canada as Apo-Atorvastatin.

20. The Defendants deny that either the First or Second Apotex Products was approvable on May 15, 2007 and puts Apotex to the strict proof thereof.

21. Further, the Defendants state that the only product marketed as Apo-Atorvastatin is the Second Apotex Product, for which Apotex did not file an ~~ANDS~~SANDS until July 2008, and in respect of which it did not serve ~~an NOA~~NOAs until February 19, 2009.

~~Delay in the~~ The **Filing of an** ~~ANDS~~SANDS **and Service of NOAs**

23. The Defendants deny that May 15, 2007 ~~represents a relevant~~, or any other date, is an appropriate "start date" for Apotex's Claim, ~~because~~as the product currently marketed as Apo-Atorvastatin is the Second Apotex Product, ~~and~~which was not approvable on May 15, 2007. and was not the subject of the 2006 Proceedings. Apotex cannot claim damages it did not suffer arising from May 15, 2007 since Apotex never served proper notices of allegation and never properly engaged the Regulations in respect of the 2006 Proceedings.

24. ~~Apotex chose to delay the filing of the Second Apotex ANDS until July 2008, and chose to further delay the service of NOAs in respect of the Second~~Further, it is clear from its dealings with Health Canada that Apotex elected to switch its Amorphous ANDS and the First Apotex Product relating to the 2006 Proceedings to the PGS SANDS, to pursue a single set of drug identification numbers and to commercialize the Second Apotex Product relating to the 2009 Proceedings. As a result of the doctrine of election, at law or in equity, Apotex is precluded from pursuing any claims in relation to or in respect of the Amorphous ANDS, the First Apotex Product ~~until~~or the ~~following year~~2006 Proceedings. The Defendants state that these choices disentitle Apotex to any claim for damages.

25. In the alternative, if the Second Apotex Product was approvable on May 15, 2007, the Defendants assert that Apotex chose to continue to pursue the 2006 Proceedings and to delay the service of NOAs in respect of the Second Apotex Product until nearly two years later, namely February 19, 2009. The Defendants further assert that Apotex's choice to delay filing of its ANDS and or SANDS and/or the service of NOAs in respect of ~~its product~~the Second Apotex Product disentitles it to any claim for damages during this period.

FEDERAL COURT

SOLICITORS OF RECORD

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SOLICITORS OF RECORD:

Goodmans LLP	FOR THE PLAINTIFF APOTEX INC.
Norton Rose Fulbright Canada LLP	FOR THE DEFENDANT PFIZER CANADA INC., WARNER LAMBERT COMPANY LLC AND PFIZER INC.