Federal Court  Cour fédérale

Date: 20140220

Docket: T-1736-10

Citation: 2014 FC 159

Toronto, Ontario, February 20, 2014

PRESENT: Kevin R. Aalto, Esquire, Case Management Judge

BETWEEN:

APOTEX INC.

Plaintiff

and

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

Defendants

AND BETWEEN:

**WARNER-LAMBERT COMPANY LLC
AND PFIZER CANADA INC.**

**Plaintiffs by
Counterclaim**

and

APOTEX INC.

**Defendant by
Counterclaim**

REASONS FOR ORDER AND ORDER

Introduction

[1] Certainty in litigation is elusive. That is largely because frequently there are a number of variables that give different results and only after trial (or appeal) is there certainty of outcome. In this case, to its credit, the Defendants, Plaintiffs by Counterclaim (Pfizer) seek to establish certainty on one key issue in this complex case.

[2] The claim of Apotex in this proceeding is for Section 8 Damages pursuant to the *Patented Medicines (Notice of Compliance) Regulations (the Regulations)* while Pfizer counterclaims against Apotex for infringement. The drug in issue is Atorvastatin, the Pfizer brand name of which is Lipitor, a cholesterol drug said to be the highest selling drug in Canada.

[3] As Section 8 Damages are an issue, the parties are required to create the "but for" world as if Apotex had been in the market essentially as of the date when the Minister would have certified for sale the Apotex Atorvastatin product. The complicating factor in this case is that the Minister of Health has apparently certified two start dates for Apotex to enter the market with its Atorvastatin product.

[4] The first start date is the period beginning May 15, 2007, the date of the "patent hold" letter for an Apotex product for Amorphous Atorvastatin. A second date which the Minister has certified is February 22, 2010 for a different formulation of Atorvastatin by Apotex being an "atorvastatin calcium propylene glycol solvate" (Atorvastatin PGS). The parties agree the end date is May 19, 2010. This results in Apotex claiming its Section 8 Damages for the Amorphous Atorvastatin

product being a three-year period while Pfizer alleges that the start date is February 22, 2010 being a three-month period.

[5] Pfizer's position that the three-month period is appropriate rests on the fact that Apotex came to market with only its Atorvastatin PGS product. It did not market and does not market its Amorphous Atorvastatin product to which the three-year period applies. Apotex's position is that, had it been able to do so it would have gone to market with its Amorphous Atorvastatin product in May, 2007.

[6] Thus, one of the great uncertainties in this litigation is the extent of the Section 8 Damages and whether it is a three-year period or a three-month period (the Start Date Issue).

[7] To provide further context for this motion, Pfizer has provided a proposed order which provides, *inter alia*, as follows:

> 1. 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.

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

3. 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 matter relating solely to the Other Issues.

4. 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.

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

Facts

[8] The motion for the Court is a bifurcation motion. What is sought to be bifurcated is a determination of the Start Date Issue for the "but for" world and to determine what would have happened had there been no prohibition application by Pfizer. This is not a garden variety

bifurcation motion which in the ordinary course usually seeks to bifurcate liability issues from damages issues. The Start Date Issue on the facts of this case is a novel issue engaging not only factual issues but statutory interpretation of the *Regulations*.

[9] On this motion extensive affidavit material was filed by both Pfizer and Apotex including expert affidavits. Cross-examinations were conducted on several of the affidavits. On behalf of Pfizer, three affidavits were filed including one of W. Neil Palmer, a Consultant on Pharmaceutical Pricing and Reimbursement; Jonathan Cullen, Legal Counsel at Pfizer; and Ross Hamilton, a Chartered Accountant and Expert in Damages Quantification in the pharmaceutical industry.

[10] The thrust of these affidavits was to the effect that if the start date for the "but for" world could be determined at an early stage in these proceedings and it is determined to be the three-month period calculation of damages pursuant to Section 8 will be relatively simple and there is a significant prospect that the case would be settled. Both the Palmer Affidavit and the Hamilton Affidavit spoke to the complexity of developing a three-year "but for" world and the many permutations and combinations of possibilities arising from the entry of other generics into the marketplace and the timing of formulary listings across Canada during that three-year period.

[11] In response, Apotex filed four affidavits: Bernard C. Sherman, the Chair of Apotex; Gordon E. Fahner, the Vice-President, Business Operations and Finance at Apotex; Howard Rosen, a Damage Quantification Expert; and Nicole Roth, a Law Clerk with the firm of Goodmans LLP. The thrust of these affidavits were to the effect that it makes no difference whether it is a three-month or a three-year "but for" world, the work required would be similar and that quantification

experts in Section 8 cases develop robust models for creating the "but for" world and that once they are created inserting however many variables is not significantly different between three-months and three-years.

[12] The affidavit of Dr. Sherman (who was not cross-examined) spoke to the issue of bifurcation in this case as generating unnecessary expense and delay for the parties and that considering all of these issues at one trial was the most efficient and cost effective way to proceed. Palmer, Hamilton and Rosen were all cross-examined on their affidavits. The focus of the cross-examinations was to demonstrate whether or not it would be in fact simpler to determine the Start Date Issue prior to commencing the massive undertaking of production, discovery and the preparation of expert reports relating to the Section 8 Damages quantification.

[13] 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.

[14] 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 was placed on "patent hold" by the Minister of Health on May 15, 2007.

[15] On February 19, 2009 Apotex delivered an NOA in relation to its submission to Health Canada for the Apotex Atorvastatin PGS in respect of Pfizer's polymorphic patents. An application

under the *Regulations* was commenced by Pfizer in response to the February 19, 2009 Apotex NOA. Apotex's submission for the Atorvastatin PGS was placed on patent hold by the Minister of Health on February 22, 2010.

[16] Apparently, the Apotex Atorvastatin PGS indicates one of the problems the inventor sought to overcome was reduced stability associated with forms of Atorvastatin such as the Amorphous Atorvastatin.

[17] Apotex obtained NOC's for both its Amorphous Atorvastatin and Atorvastatin PGS products on May 19, 2010. Apotex markets in Canada only the Atorvastatin PGS product. At the time of Apotex's launch of its Atorvastatin PGS 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.

[18] At this stage of the proceedings the parties have exchanged affidavits of documents related to issues but examinations for discovery have not yet been commenced nor scheduled.

[19] 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 Health Canada issued NOC's to Apotex and seven other generic

pharmaceutical manufacturers in respect of generic Atorvastatin products. Subsequently, an additional six pharmaceutical manufacturers received NOC's for their respective Atorvastatin products.

Positions of the Parties

[20] As noted, in Section 8 Damages cases, the parties must construct for the Court's consideration a hypothetical "but for" world during the defined period of time in the past to determine the damages that Apotex suffered because it was unable to sell its Atorvastatin product during that defined period. Madam Justice Judith Snider in *Apotex Inc v Merck & Co., Inc.*, 2012 FC 620 has set out the requirements for determining the "but for" world. The elements required to be covered include the following:

(a) What is the relevant period?

(b) What is the overall size of the Atorvastatin market during the relevant period?

(c) What would the generic share of the Atorvastatin market be during that period?

(d) What would have been Apotex's share of the generic Atorvastatin market during the relevant period?

(e) What is the price that Apotex would have sold its Atorvastatin product?

(f) What deductions, if any, are there that should be applied to Apotex's selling prices to allow for rebates or other allowances?

[21] As noted, the relevant period of the "but for" world is the starting point for determination of the Section 8 Damages Claim.

[22] A further complicating factor in this case apart from the number of generic pharmaceutical companies granted NOC's is the changes to pricing in various provinces. For example, in Ontario the enactment of *Transparent Drug System for Patients Act to Patents Act* (Bill 102) affected prices upon which the first generic entered into a market could charge for a particular drug. Similarly, in British Columbia, PharmaCare which governs how pharmaceutical products are sold in British Columbia has changed its pricing structure and has introduced other programs including its Maximum Allowable List Price for generic products. Alberta and Quebec also have pricing policies relating to the sale of generic products.

[23] Another complicating factor is the time of listing on the provincial formularies. The Palmer Affidavit filed on behalf of Pfizer spoke at length about the issues surrounding when a generic product might be listed on a provincial formulary. There are many variations in respect of the time to listing which adds to the complexity of the quantification given the number of generics in the market.

[24] Finally, there is a consideration of rebates and allowances which generic drug manufacturers offer to pharmacies to stock, and/or sell and substitute their Atorvastatin products for those of other generics. These rebates and allowances are regulated in some provinces and are capped in others and add another level of complexity to the quantification of Section 8 Damages.

Pfizer's Position

[25] In general, the argument of Pfizer is that the determination of the Start Date Issue will result in a more focused proceeding. The parties, rather than speculate and develop several different

models of Section 8 Damages would only be developing one. Production and discovery would therefore be shortened as it would be clear which Section 8 Damages time frame was involved. And, especially if it is determined that it is a three month period for the Apotex Atorvastatin product, the number of variables and permutations and combinations thereof would be limited and the calculations of any such damages would be a far simpler and cost-effective exercise.

[26] In large part the bifurcation of the Start Date Issue will meet the requirements of Rule 3: "These rules shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits". Otherwise, so argues Pfizer, production will cover everything for a period of at least three-years, the discoveries will be endless and production will be an avalanche of paper.

[27] In support of its positions, Pfizer put forward the Palmer, Cullen and Hamilton Affidavits. These affidavits highlighted the many variables in play in this proceeding. The Palmer Affidavit speaks to the formulary listings and timing thereof; market access; reimbursement policies; and, the various damages scenarios. The Cullen Affidavit points out that other generics, as many as 8 may form part of the various scenarios to be worked out if there is no bifurcation. He also makes the statement that if it is determined that the three-month period is the correct start date, then the case will settle. Finally, the Hamilton Affidavit addresses damages quantification, the manner of determining lost profits and the complexity of the two scenarios involved in the Start Date Issue. Like his counterpart, Mr. Rosen for Apotex, Mr. Hamilton is a respected and experienced expert in this field.

Apotex's position

[28] Apotex argues that there is neither any time nor costs saved by bifurcating this action. It submits that on the basis of the evidence of the experts filed in this motion that it is simply a matter of changing the accounting and econometric models which need to be built in any event to adjust for whichever time frame is determined to be appropriate.

[29] Apotex argues that litigants have a "right" to a single proceeding unless the preponderance of evidence demonstrates a departure from this rule. As litigation is always subject to the right of a Court to control its own process, a litigant's preference for a single proceeding must always bow to the right of the Court to determine in the circumstances the appropriateness of a single proceeding versus a bifurcated proceeding.

[30] Apotex argues that the issue as posed by Pfizer in this motion does not dispose of the litigation, it merely doubles the effort and expenditure as two trials will be required. As such, there is no benefit to be obtained by bifurcating the issue. Apotex argues that the determination of the Section 8 time frame is not a "threshold" issue which will determine the case such as liability. Bifurcation would only lead to further proceedings as there is a claim by Pfizer for damages in either of the two time frames alleged. Thus, a second trial is inevitable.

[31] As noted, there was a substantial record filed by both parties which contained not only expert affidavits but cross-examinations on those affidavits. Those affidavits and cross-examinations dealt with the issue of what, if any, time saving might be had if the issue of the Section 8 time frame was resolved first.

[32] The Court was encouraged to read all of the affidavits and cross-examinations carefully to understand fully the nature of the time period and the work required no matter which time period the Court will ultimately find. In particular, the admission that if the Court finds a period longer than three-months much if not all of the time savings and costs will be lost. It is pointed out that the Court has other options apart from the two time frames proposed and it is open to the Court to determine that an entirely different period applies.

[33] It is also argued that there is no benefit to bifurcation as there is still the counterclaim for infringement to be dealt with. There are no savings in time or cost as the Start Date Issue does not affect this issue. Thus, there will still be production necessary relating to financial information and all the other trappings of an infringement claim. The simple answer of course is to bifurcate damages on the infringement claim, an approach built into Pfizer's proposed order.

[34] In reviewing the evidence in detail, counsel for Apotex pointed out that Mr. Hamilton (a Pfizer expert) admitted that the assessment of the three-year period would only be "a little bit harder" than the three-month period.

[35] Dr. Sherman's evidence was unchallenged. He deposed to be concerned about the delay two proceedings would require as well as the expense of such proceedings. He also opined that in his opinion full disclosure helped accelerate and streamline resolution. He also observed that this motion could be the thin end of the wedge and that if this issue is bifurcated it could lead to further bifurcation regarding liability and quantum. However, this latter point is of no moment. The bifurcation sought will significantly reduce the time of this proceeding and no further bifurcation

will be considered by the Court in this case managed proceeding. As well, given that Lipitor is said to be the highest selling drug in Canada, the expense involved in this case is not really an issue.

[36] Mr. Fahner addressed the scope of document production in his affidavit. He deposed that the productions relative to the longer period is not an onerous task as most of it is maintained electronically and lost revenues are "easily calculated". He is of the view that there would be no timesaving or otherwise from a bifurcation. That is not fact, it is merely speculation and opinion albeit based on Mr. Fahner's prior involvement in Section 8 proceedings.

[37] Mr. Rosen is an experienced accountant and expert in the quantification of damages. His evidence that no matter the time frame an identical analysis of available information is necessary. His opinion is diametrically opposed to Pfizer's experts, Messrs. Palmer and Hamilton. Mr. Rosen is of the view that while there may be more data to review for the longer period this does not make the task of analysing the data more complex. There is simply more of it.

[38] In his affidavit, Mr. Rosen provides a detailed step by step outline of the model which is developed to calculate the Section 8 Damages and the various scenarios. The models are developed for the most likely scenarios. Once those are completed the models can be adjusted to account for variations and findings of the Court.

[39] Having reviewed all of the evidence and the cross-examinations as the Court was invited to do by Apotex, the evidence for the most part is almost diametrically opposed between the parties.

ISSUE

[40] While the issue is simply stated – will bifurcation of the Start Date Issue lead to an efficient and cost effective resolution of this litigation both for the parties and the Court - the answer on these diametrically opposed motion records is not.

Analysis

[41] The law on bifurcation is relatively well-known. The tests for bifurcation flow from various cases [see, for example, *Garford Pty. Ltd. v. Dywidag Systems International, Canada, Ltd.*, 2010 FC 581 at para. 19; and *Merck & Co. v. Brantford Chemicals Inc.*, (2004) FC 1400].

[42] The *Merck* case provides a useful summary of principles to be considered:

> The onus on a motion for a bifurcation order is always on the applicant (*Apotex Inc. v. Bristol-Myers Squibb Co.*, 2003 FCA 263 at para. 10 (F.C.A.), (2003), 26 C.P.R. (4th) 120 (F.C.A.)). The order may be made where the Court is satisfied, on a balance of probabilities, that, in light of the evidence and all the circumstances of the case (including the nature of the claims, the conduct of the litigation, the issues and the remedies sought), severance is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on its merits (*Illva Saronno S.p.A. v. Privilegiata Fabrica Maraschino "Excelsior"*, [1999] 1 F.C. 146 at para. 14 (F.C.T.D.); (1998), 84 C.P.R. (3d) 1; *Illva Saronno S.p.A. v. Privilegiata Fabrica Maraschino* (2000), 183 F.T.R. 25 at para. 8 (F.C.T.D.), [2000] F.C.J. No. 170 (F.C.T.D.) (QL)).
>
> > [5] At page 2 of her order, Prothonotary Milczynski sets out a number of "practical and economic considerations" for determining whether or not to order separate trials on the issues of liability and damages. Those include:
> > - the complexity of issues to be tried;
> > - whether the issues of liability are clearly separate from the issues of remedy;

- whether the factual structure upon which the action is based is so extraordinary or exceptional that there is good reason to depart from normal practice requiring the single trial of all issues in dispute;
- whether the trial judge will be better able to deal with the issues of the injuries of the plaintiff and the plaintiff's losses, by reason of having first assessed the credibility of the plaintiff during the trial of the issue of damages;
- whether a better appreciation of the nature and extent of injuries and consequential damages to the plaintiff may be more easily reached by trying the issues together;
- whether the issues of liability and damages are so inextricably interwoven if bound together that they ought not to be severed;
- whether, if the issues of liability and damages are severed, there are facilities in place which will permit these two separate issues to be tried expeditiously before one court or before two separate courts, as the case may be;
- whether there is a clear advantage to all parties to have liability tried first;
- whether there will be a substantial saving of costs;
- whether it is certain that the splitting of the case will save time, or will lead to unnecessary delay;
- whether, or to what degree in the event severance is ordered, the trial of the issue of liability may facilitate or lead to settlement of the issue of damages; and
- whether it is likely that the trial on liability will put an end to the action.

[6] Many of these factors are inspired or directly imported from *Bourne v Saunby* [1993], O.J. No. 2606 (Ont. Sup. Ct.). The same appears to have been recently considered, but not necessarily applied (at least as an integral part), by Rutherford J. in *Roche Palo Alto LLC et al. v. Apotex Inc.*, [2004] O.J. No. 3522. Rutherford J. noted in this regard that "[w]hile that list is helpful in that it sets

> out a number of very good lines of inquiry and although counsel touched on several of these factors in their arguments, the motion materials filed on both sides rely essentially on the opinion of counsel with expertise in patent litigation expressed in lengthy affidavits". In said case, Rutherford J., after summarizing the respective views of counsel, succinctly concluded that "after considering the materials filed and the submission of counsel, I am not persuaded that the circumstances are exceptional or such as to justify a departure from the normal procedures for trial of an action and I am not of the view that the issues for trial should be split off and the procedure bifurcated."
>
> . . .
>
> [9] Neither can I agree, as suggested in *Bourne*, that it must be "certain that the splitting of the case will save time, or will lead to unnecessary delay". As stated by Evans J. in *Illva Saronno, supra*, the applicant has the onus of convincing the Court that bifurcation will *inter alia* result in the saving of time and money, on a balance of probabilities standard, and not on the standard of beyond a reasonable doubt.

[43] Thus, based on all of the evidence on this motion, on a balance of probabilities, will bifurcation result in a saving of time and money to the parties, and of judicial resources?

[44] The answer to this question is not easy based on this record. There are very strong positions put forward by each side as well as very strong evidence supporting each position. A consideration of each factor is essential to a determination of this matter. There is much overlap among the factors and several appear to have evolved from personal injury cases rather than intellectual property cases and the complexities of the *Regulations*. However, an analysis of those factors which bear on the issues in this case must be conducted.

Complexity of the Issues

[45] Notwithstanding the argument and evidence of Apotex that it would be relatively easy to create a tool for the calculation of damages whether it be the three-month or the three-year period, this is still a very complex action. As noted by counsel, there is the issue of infringement, the issue of Section 8 Damages, and then the determination of the Start Date Issue. As noted above, the Start Date Issue is in and of itself filled with many variables and permutations of events in the creation of the "but for" world. A determination of the Start Date Issue will streamline this case. This factor favours bifurcation.

Whether the Issues of Liability are Clearly separate from Damages

[46] This consideration is unique to this case as it is not liability that is being sought to be bifurcated. Rather, it is an issue that will arguably lead to a saving of both time, judicial resources and money for the reasons mentioned elsewhere in these reasons. Although the jurisprudence speaks almost exclusively to bifurcation of liability and damages, there is no reason for that limitation in this Court given the wording of Rule 107(1) of the *Federal Courts Rules* which provides: "The Court may, at any time, order the trial of an issue or that issues in a trial be determined separately". It is open to the Court to bifurcate any issue which will result in the saving of time, cost and judicial resources.

[47] Apotex argues that the Start Date Issue is not a threshold issue which will dispose of the litigation. Rather it is an issue which is intertwined with all of the other issues and that it is but one of the variables which is best left to be sorted out at trial. 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.

[48] As part of its argument, Apotex referred to the decision of Justice Judith A. Snider in *Apotex v. Merck & Co., Inc.*, 2012 FC 620 to support its position that the Start Date Issue is not novel and notwithstanding positions of the parties the Court may find another date that is appropriate other than the three month or three-years. In this case, the start date was an issue. Justice Snider made these observations:

> [13] The parties, however, disagree on the applicable commencement date. Apotex asserts that the appropriate date is April 30, 1996, the date on which it submits that the Minister would have issued an NOC to Apotex except for the *Regulations*. Merck submits that there is no proof of any date "certified by the Minister" on which Apotex would have received an NOC for the non-infringing AFI-4 process. In the alternative, Merck argues that the appropriate date is when Apotex was notified that the Minister had "no objection" to Apotex's Notice of Change switching to the AFI-4 process; specifically, that date was February 27, 1997.
>
> [14] Apotex initially filed a New Drug Submission (NDS) for approval of Apo-lovastatin made by use of a micro-organism referred to as *Aspergillus flavipes* on December 21, 1994. Label drafts were submitted to Health Canada and apparently approved on April 30, 1996. On May 25, 1996, Apotex's NDS was placed on "patent hold", meaning that an NOC for Apo-lovastatin manufactured with *Aspergillus flavipes* would not issue until resolution of the prohibition proceedings or the expiry of the relevant patents (including the '380 Patent)
>
> [15] Merck is correct that there is no Ministerial "certification" of May 25, 1996 as contemplated by s. 8(1)(a). However, I am satisfied that, but for the *Regulations*, Apotex would have received its NOC for Apo-lovastatin no later than May 25, 1996.
>
> [16] Apotex submits that April 30, 1996 is the more appropriate date for the commencement of the Relevant Period. I agree with

> Apotex that its labels for Apo-lovastatin were approved on April 30, 1996. In spite of the testimony of Mr. Hems that NOCs normally follow label approval within a matter of days, I am not persuaded that this date is more appropriate than the "patent hold" date. There can be no doubt whatsoever that the application would have been approved on May 25, 1996, the date of the "patent hold" letter from Health Canada.
>
> [17] In my view, the appropriate date, even though not certified by the Minister, would be the "patent hold" date of May 25, 1996.

[49] What is interesting about this case is that the very determination made by Justice Snider was the Start Date Issue as it applied in that case. Damages were not determined and were left to a subsequent trial. It was a bifurcated case very much the same as this motion seeks.

[50] Further, Apotex points to the cross-examination of Dr. Sherman in that case that Apotex would simply have gone to market with its first product and taken the litigation risks. Dr. Sherman is quoted as saying:

> [P]rior to the regulations, we simply would have launched [Apo-lovastatin]. Then if Merck sued, we would have defended, but we would be on the market getting the revenues. (para. 29)

[51] It may very well be that Apotex takes this position in this case and discovery and production will have to be pursued but it still does not undermine the fact that the determination of the Start Date Issue will lead to clarity and certainty as to what Section 8 Damages, if any, Apotex is entitled to receive.

[52] This factor favours bifurcation.

Is the Factual Structure of the case Unique?

[53] As noted above the facts of this case are novel. There are unique factual issues and novel points of statutory interpretation relating to the *Regulations*. Factually, it is complex because the three month period relates to the drug which Apotex brought to market. That drug is different than the drug which related to the three year period. On discovery the differences between the drugs will need to be explored as well as why one was pursued and the other not as well as the damages which relate to each drug. The factor favours bifurcation.

Will there be a saving of cost and time?

[54] This issue is one of great debate between the parties. It is also a factor which should be given some extra weight in determining whether to bifurcate. There must be, in my view, a demonstrable saving of time and cost. The litigation system and access to justice is already overburdened with procedural and substantive processes and in this day and age the Courts and the parties should be striving to pursue litigation in a way that is both proportional and fair. On the importance of proportionality in litigation see, *Hryniak v Mauldin et al*, 2014 SCC 7 a recent decision of the Supreme Court of Canada.

[55] At first blush, the conclusion with respect to this factor seems simple enough in that determining which of two time periods should be a fairly straightforward part of the proceeding. If the determination is that is the three month period there will be much time and cost saving. There will also be better use of judicial resources. If it is the three year period, there will still be cost saving as the parties and their experts will not be required to develop different models although the time and cost savings will not be as much. The unknown is whether the Court could choose a third

alternative as argued as a possibility by Apotex. It may be that a Court might do so although the likelihood is either of the two proposed scenarios. Even if a third scenario surfaced there would still be certainty as to the time frame for which the parties and their experts would focus their efforts.

[56] Notwithstanding the strong arguments of Apotex, and having considered all of the arguments and the evidence particularly the cross-examinations, I am of the view that on a balance of probabilities a determination of the Start Date Issue will lead to cost savings, time savings and better use of judicial resources. This factor favours bifurcation.

Is the factual structure extraordinary or exceptional that there is good reason to depart from normal practice requiring the single trial of all issues in dispute?

[57] This factor overlaps with prior considerations discussed above which will not be repeated. In my view, this factor favours bifurcation.

Whether the trial judge will be better able to deal with the issues of the injuries of the plaintiff and the plaintiff's losses, by reason of having first assessed the credibility of the plaintiff during the trial of the issue of damages?

[58] This factor does not apply and so is a neutral consideration.

Whether a better appreciation of the nature and extent of injuries and consequential damages to the plaintiff may be more easily reached by trying the issues together?

[59] Again, this factor appears more directed toward a different type of case and implicitly is subsumed in the discussion relating to other factors. Our Rules permit an issue to be bifurcated if on a balance of probabilities it can be reasonably said to reduce time, costs and judicial resources.

Whether the issues of liability and damages are so inextricably interwoven if bound together that they ought not to be severed?

[60] This factor must be considered. Apotex forcefully argues that given the infringement counterclaim there is no real savings in cost or time as a full infringement trial would have to be conducted. However, the order sought by Pfizer seeks to sever this issue as well. The only issue to be determined on the bifurcation proceeding is the Start Date Issue. All other issues including infringement and damages which might flow from that are to be part of subsequent proceedings.

[61] This is what occurred in *Apotex v. Merck*. While that was only a Section 8 Damages case the parties must have understood that determining the period of Section 8 Damages would be beneficial. Given the proposed order and the facts of the case, I am not persuaded on a balance of probabilities that the issues are so inextricably interwoven so as to defeat the utility of bifurcation.

[62] This factor favours bifurcation.

Whether, if the issues of liability and damages are severed, there are facilities in place which will permit these two separate issues to be tried expeditiously before one court or before two separate courts, as the case may be?

[63] A long trial date has been set in 2016 for all of the issues in this case. This Court can and will accommodate a determination of the Start Date Issue so that the trail date is preserved and the issues for that trial will be focussed.

[64] This factor favours bifurcation.

Whether there is a clear advantage to all parties to have liability tried first?

[65] While Apotex argues at great length that there is no advantage, the Start Date Issue has the benefit of certainty for the parties. The "clear" advantage must be determined on a balance of probabilities. Having reviewed all of the evidence and cross-examinations it is my view that the balance of probabilities favours bifurcation. The advantage of certainty is a clear benefit to all parties and to the Court.

Whether there will be a substantial saving of costs?

[66] This factor has been addressed above in some detail. In my view there is cost savings to be had. This is not a factor solely related to the interests of the parties. Judicial resources are costly. They must be considered as part of the equation. If the Start Date Issue can be solved in a short trial (five to ten days) it would inevitably lead to a shorter time for any subsequent damages/infringement case. One must not lose sight of the fact that there are factual issues which are unique to this case relating to Apotex' entering of the market with Atorvastatin PGS not

Amorphous Atorvastatin. Surely some clarity on the meaning of the *Regulations* insofar as these facts are concerned will save judicial resources and cost to the parties.

Whether it is certain that the splitting of the case will save time, or will lead to unnecessary delay?

[67] Apotex argues emphatically that there will be no savings resulting from bifurcation - only delay. This is the focus of Dr. Sherman's affidavit and his strongly held views. There is no certainty in litigation – the proverbial two sides (or more) to every case. Time savings can be achieved by parties acting reasonably, co-operatively and using common sense. To quote the mantra of the Commercial List in the Superior Court – litigation should be conducted on the basis of the three C's – communication, common sense and co-operation. If applied to complex intellectual property cases such as this, combined with principles of proportionality, counsel following the three C's will most certainly lead to saving time.

[68] Applying the balance of probabilities standard, this factor favours bifurcation.

Whether, or to what degree in the event severance is ordered, the trial of the issue of liability may facilitate or lead to settlement of the issue of damages?

[69] Pfizer has provided direct evidence from in-house counsel that if the Start Date Issue is determined to be three-months the case will settle. There is no evidence whether any other scenario will also lead to this result. But, notwithstanding Apotex's position that the determination of the Start Date Issue will not likely or necessarily lead to settlement, there is some positive evidence that supports such a result. This issue favours bifurcation.

Whether it is likely that the trial on liability will put an end to the action?

[70] If this were the only factor, bifurcation would not be ordered. Bifurcating the Start Date Issue will not put an end to the action. There are other issues which must ultimately be resolved no matter which way the Start Date Issue is decided. Thus, while this factor does not favour bifurcation, as noted in the discussion above bifurcation does not need to result in the end of the proceeding. Rule 107 (1) allows an issue to be bifurcated. Such is the case here.

CONCLUSION

[71] In considering all the factors, on a balance of probabilities, it is my view that bifurcating the Start Date Issue will be lead to saving of cost, time and judicial resources.

[72] While a long trial date of some 35 days is already set for 2016 for all of the issues, the Court will accommodate an early determination of the Start Date Issue.

[73] As for costs of this motion, while it is noted that Pfizer offered Apotex an opportunity to accept its proposed draft order so that there could be an earlier determination of the issue and seeks its costs, in my view, this has been a very novel motion and each party should bear its own costs.

[74] The Court appreciates the excellent submissions of counsel and the courteous manner in which this motion was argued.

ORDER

THIS COURT ORDERS that:

1. The Motion is granted.

2. 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.

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

4. 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 matter relating solely to the Other Issues.

5. 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.

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

7. There shall be no costs of this motion.

"Kevin R. Aalto"
Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

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