Federal Court  Cour fédérale

Date: 20170330

Docket: T-1496-13

Citation: 2017 FC 332

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

PFIZER CANADA INC.,
WARNER-LAMBERT COMPANY and
WARNER-LAMBERT COMPANY, LLC

Defendants

PUBLIC REASONS FOR JUDGMENT

(Confidential Reasons for Judgment issued March 30, 2017)

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PHELAN J.

I. INTRODUCTION

[1] Teva Canada Limited [Teva] claims in this action damages under s 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [PMNOC Regulations or Regulations]. The claim stems from Pfizer Canada Inc's [Pfizer] commencement of applications under s 6 of the Regulations against Ratiopharm Inc [Ratiopharm] and against Teva to prevent the federal Minister of Health from issuing Notices of Compliance [NOCs] authorizing the sale of the generic version of Pregabalin. The effect of those s 6 applications was to prevent Teva from entering the Canadian market with that drug until February 14, 2013 (Teva took over Ratiopharm).

[2] Lyrica is a popular pharmaceutical for the management of neuropathic pain. It was the reference product for both Ratiopharm's and Teva's Pregabalin drug, which was the subject of NOC proceedings. This action for damages arises out of those NOC proceedings, which were commenced by Pfizer in 2009 to prevent NOCs being issued for Ratiopharm's Pregabalin product and for Teva's Pregabalin product. These proceedings were discontinued on February 14, 2013 (Court File Nos. T-1422-09 and T-1868-09).

[3] The Defendants are interrelated companies and are hereinafter referred to as Pfizer unless otherwise indicated.

[4] The parties are in agreement that Teva is entitled to recover its losses or damages, but they disagree about many important aspects of how those losses should be determined.

[5] However, there is agreement that the Court should determine the issues that remain unresolved so that a precise calculation of Teva's damages can be settled between the parties. There is also agreement that the Court should remain seized of the matter and can receive submissions and determine any matter arising from this Judgment.

[6] The Court concurs with the above as it makes little practical sense for the Court to engage in the accounting and mathematical calculations which will give rise to a final damages number.

II. LEGAL FRAMEWORK

[7] There is no dispute as to the steps which the Court should follow in assessing damages. These are well laid out in *Apotex Inc v Sanofi-Aventis*, 2012 FC 553, 410 FTR 78, aff'd 2014 FCA 68, aff'd 2015 SCC 20.

[8] The five steps can effectively be described as follows in respect of the relevant drug:

- determine the duration of the period of liability [the Liability Period];
- determine the overall size of the Pregabalin market during the Liability Period;
- determine the portion of the Pregabalin market that would have been held by Teva and any other generic manufacturers during the Liability Period – the generic market;

- determine the portion of the generic market that would have been held by Teva – its lost volumes; and
- quantify the damages that would have been suffered by Teva in respect of its lost volumes (net lost profits).

There are subsets to each of these steps as well, depending on the circumstances.

[9] These steps are part of the Federal Court of Appeal mandated construction of the "But For World" [BFW] – a world where Teva (or Ratiopharm) would not have been prevented from entering the Canadian market solely by virtue of the automatic stay under the PMNOC Regulations. It is a somewhat artificial world akin to lost business opportunity analysis, but it is grounded in real world experience. It is not a dream world or an ideal world. The NOC Regulations otherwise continue to operate, and real events happen and/or inform the BFW. (See, for example, *Merck Frosst Canada & Co v Apotex Inc*, 2011 FCA 329, 210 ACWS (3d) 224, and *Teva Canada Limited v Sanofi-Aventis Canada Inc*, 2014 FCA 67, 239 ACWS (3d) 180.)

[10] The Court of Appeal recently confirmed that the fundamental question for the Court is what would have happened if Pfizer had not commenced prohibition proceedings against Ratiopharm and Teva (*Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161, 267 ACWS (3d) 628 [Venlafaxine decision]; see also: *Apotex Inc v ADIR*, 2017 FCA 23).

[11] In the Venlafaxine decision, the Court of Appeal, in addition to reiterating the applicability of the Hearsay Rule (which is referred to again later in this Judgment), also emphasized that the Court must examine both what could have happened and what would have

happened. This is Teva's burden that it could have and would have come to market in the timeframe alleged.

[12] The Court of Appeal in the Venlafaxine decision summarized this two-sided analysis thus:

> [50] Both "would have" and "could have" are key. Compensatory damages are to place plaintiffs in the position they would have been in had a wrong not been committed. Proof of that first requires demonstration that nothing made it impossible for them to be in that position—*i.e.*, they *could* have been in that position. And proof that plaintiffs would have been in a particular position also requires demonstration that events would transpire in such a way as to put them in that position—i.e., they *would* have been in that position.
>
> [51] Both elements have to be present. "Could have" does not prove "would have"; "would have" does not prove "could have":
>
> - Evidence that a party would have done something does not prove that it could have done something. I might swear up and down that I would have run in a marathon in Toronto on April 1 aiming to complete it, but that says nothing about whether I could have completed it. Maybe I am not fit enough to complete it.
>
> - Evidence that a party could have done something does not prove that it would have done something. A trainer might testify that I was fit enough to complete a marathon race in Toronto on April 1, but that says nothing about whether I would have completed it. Perhaps on April 1 I would have skipped the marathon and gone to a baseball game instead.

[13] The Federal Court of Appeal's judgment emphasizes that the BFW must be viewed through realistic assessments of the likelihood that the plaintiff's BFW scenario would occur. The real world plays a significant role in the construction of the BFW.

[14] The BFW is to mirror, as much as possible, the real world experiences and circumstances – to use history as the basis for assessing the assumptions advanced in the BFW scenarios.

[15] Consistent with the civil burden of proof, Teva bears the burden of establishing the facts upon which it claims compensation. The Court can rightfully question the "would have" aspect of the analysis where it is based principally on oral evidence of intent. This caution is applicable as well to Pfizer's claims of what it would have done in the face of Teva's asserted BFW conduct.

A. *Teva's Position*

[16] Teva's position generally is set out in the Findings of Fact which it asks this Court to adopt. Those Findings, modified by the Court, parallel the five-step analysis referred to earlier. They also follow, in large measure, the manner in which this case was presented by both sides: issue by issue rather than through a historical or "story line" approach.

[17] Those requested Findings are:

1. **Duration of the Liability Period**

    a. The start date of the Liability Period is May 1, 2010 because:

        i. The conditional NOC [NOC/c] for ratio-Pregabalin would have issued by May 1, 2010.

        ii. In the alternative, the NOC with carve out would have issued by May 1, 2010.

iii. In the further alternative, the NOC for ratio-Pregabalin would have issued on the patent hold date of August 26, 2010.

b. The end date of the Liability Period is February 14, 2013.

2. **Overall size of Pregabalin market**

a. The Court should adopt Dr. Hollis' model of the size of the "but for" generic Pregabalin market.

b. In the alternative, the Court could reasonably adopt the corrected version of Dr. Cockburn's analysis as set out in Dr. Hollis' reply report.

3. **The overall size of the generic portion of the Pregabalin market**

The evidence of Dr. Hollis should be preferred to that of Dr. Cockburn.

4. **The Portion of the generic market that would have been held by Teva**

a. **GenMed**

i. Pfizer would not have launched GenMed in the BFW.

ii. In the alternative, if GenMed had launched, it would not have entered the market until six months after Teva had entered the market.

b. **Mylan**

Mylan would not have been an authorized generic for Pfizer in the BFW.

c. **Other generics**

i. Pfizer would not have had an authorized generic in the BFW.

ii. There is no evidence that any other generic manufacturer could or would have entered the Pregabalin market in the BFW.

d. **Formulary Listings**

Neither Ratiopharm nor Teva would have listed Pregabalin on any formulary outside Quebec during the Liability Period.

5. **Quantification of Teva's Damages**

a. **Ability to Supply**

i. Ratiopharm would have been able to launch its Pregabalin product as early as May 1, 2010 and would have been able to supply the entire Canadian generic market.

ii. After the merger, Teva would have chosen to continue marketing ratio-Pregabalin and would have been able to supply the entire Canadian generic market.

iii. At some time after February 2011, Teva would have chosen to replace ratio-Pregabalin with Teva-Pregabalin and would have been able to supply the entire Canadian generic market.

iv. Active pharmaceutical ingredient [API] issues would not have delayed the launch of ratio-Pregabalin or Teva-Pregabalin.

b. **Ability of other generic manufacturers to supply the market**

No other generics would have entered or could have supplied the Pregabalin market.

c. **Price**

i. Outside Quebec, in a non-formulary market Ratiopharm and Teva would have priced the Pregabalin product at 85% of the Lyrica price.

ii. In Quebec, generic Pregabalin would have been listed on the formulary at 60% of the Lyrica price (until a second generic was listed, when it would be listed at 54%).

iii. Outside of Quebec, when listed on a provincial formulary, Ratiopharm and Teva would have priced Pregabalin in accordance with provincial regulations.

d. **Trade Spend**

i. Ratiopharm's trade spend for ratio-Pregabalin would have been 15% in a sole source market.

ii. Teva's trade spend for ratio-Pregabalin and Teva-Pregabalin would have been 20% in a sole source market (from September 2010 until the entry of a second generic).

iii. Teva's trade spend for ratio-Pregabalin and Teva-Pregabalin would have been 30% in a dual source market (where the second entrant is other than GenMed).

iv. Teva's trade spend for ratio-Pregabalin and Teva-Pregabalin would have been 45% in a multi-source market (which does not arise in the BFW).

e. **Accounting issues**

i. Ratiopharm's allowable expenses do not include inspections.

ii. Teva's API costs do not include the cancelled [redacted] purchase orders.

iii. Ratiopharm's COGS do not include an API overage based on the recipe card error.

f. **Pipe file**

Teva's lost sales include pipe fill volumes.

B. *Pfizer's Position*

[18] Pfizer takes the position that there are significant issues surrounding the nature and quality of the evidence advanced by Teva.

[19] It also argues that the BFW constructed by Teva was based on wishful thinking – that it excluded consideration of real world events, contemporaneous documents, and information the Court could reasonably expect to be before it. From this assertion, Pfizer asks the Court to draw adverse inferences on a number of issues.

[20] Pfizer asserts that the absence of key evidence deprives the Court of what it needs to determine the case and deprives Pfizer of the opportunity to fully cross-examine on the issues in this litigation.

[21] Pfizer criticizes Teva's evidence for what was presented and what was not presented. This general approach infused Pfizer's submissions on most, if not all, of the issues.

[22] The difficulty with part of Pfizer's argument is that it asks the Court to assume that there was better evidence available or a better witness to give evidence. The Court, however, must

decide the case on the evidence presented. It can assess the quality of the witnesses' testimony but, except in the clearest of cases, it cannot speculate on what evidence it could have heard. It can comment on evidence it heard and its strength and weakness. The discovery process is the proper method of ferreting out the assumed missing evidence; if a party did not exercise those rights fully, it cannot ask the Court to assume that witnesses are not forthright and that counsel aided and abetted in hiding documents.

[23] However, as will be seen later in these Reasons, Pfizer's argument has some merit particularly in assessing the Liability Period and the actions/inactions of Ratiopharm.

III. WITNESSES

[24] During the trial Teva called eleven (11) witnesses, while Pfizer called fifteen (15), both factual and expert.

While credibility is always in issue, much of the determination of what evidence was persuasive turned on weight rather than honesty or believability.

[25] It is not the intention of the Court to give a lengthy summary of each witness' evidence, nor in the following brief summary to make comments on the acceptance of or preference for some witnesses over others. To the extent necessary, those comments are reflected in the findings on the issues.

A. *Teva's Fact Witnesses*

[26] Teva called eight (8) fact witnesses including Brent Fraser, a senior public official previously at the Ontario Drug Benefit Plan. Given Fraser's experience and understanding of the provincial regulation and pricing, he may be a fact witness but his evidence is based on deep expertise.

[27] Teva's other fact witnesses included two from Ratiopharm, four from Teva, and one from MSN Pharmachem Pvt Ltd [MSN].

(1) Mr. Kent Major

[28] Major was the most significant corporate witness to address issues related to Ratiopharm and his evidence is critical to the assessment of whether Ratiopharm could and would have launched its Pregabalin product on or about May 1.

[29] Major was formerly the second most senior officer at Ratiopharm in Canada, Vice President Research and Development and Regulatory Affairs. As such, he was the senior member of the executive team responsible for product development and management. After March 2010, he was part of the Ratiopharm integration team following acquisition by Teva. Amalgamation of Ratiopharm into Teva occurred on August 10, 2010, after which he left the company.

[30] He testified as to the history of Ratiopharm's project and its status as of August 2010. He gave specific evidence on the issuance to Ratiopharm of the Health Canada patent hold letter, its trade spend rate, and the prices at which Ratiopharm Pregabalin would be sold. He also gave his view of the BFW.

[31] As discussed more fully under the Liability Period section of these Reasons, from April to August, Ratiopharm did next to nothing to advance its product or secure a patent hold letter. While Major suggests that this was likely an administrative error which would not be repeated in the BFW, it represents a major flaw in Teva's construct of the BFW.

[32] Pfizer is critical of Major's evidence as being out of touch, out of date, and documentarily deficient. They suggest that there were other Ratiopharm employees who could have provided better evidence. While there were gaps in his memory (he had not been involved in these matters since September 2010) and contemporaneous Ratiopharm documents had not been produced, it is speculation that there was some other senior officer to be called. The Court must take Major and Ratiopharm's evidence as it is.

[33] Major was in a senior position in the relevant area at Ratiopharm. He is an appropriate corporate officer to be called to speak to the issues. In a BFW analysis, which is itself somewhat speculative, a senior officer is appropriate to speak to what was done, planned, capable of being done, and whether it would have been done.

As indicated later, Ratiopharm's evidence, particularly as to the start of the Liability Period, was not persuasive or helpful to Teva.

(2) Mr. Brent Fraser

[34] In the Liability Period, Fraser was Director, Drug Program Services of Ontario Drug Programs. He testified for both parties and it is fair to say that he gave complete, helpful, and cogent evidence. It was extremely useful in assessing what had been occurring in respect of Ontario's policy on formulary listings (the provincial drug reimbursement plan as followed by multiple private plans) and what could or would have happened.

[35] In summary, his evidence was that Ontario would have listed Pregabalin and Lyrica as a general benefit on the Ontario formulary when there were three generics in the market or about to enter the market.

(3) Mr. Douglas Sommerville

[36] From 2014 through to trial, Sommerville was Senior Vice President and General Manager at Teva. He was also the Vice President of Sales and Marketing at Teva during the Liability Period.

[37] His evidence covered Teva's position with respect to:

- price at which Teva would sell Pregabalin;
- pricing strategies and customer profiles;
- Teva's gross profit margin profiles;
- the track spend it would have offered; and

- whether it would have given greater discounts (trade spend) if it received something else in return.

[38] Sommerville, given his position at Teva, was in an excellent position to give evidence of Teva's real world experience and its BFW position.

[39] Sommerville is a "marketer" and the Court appreciates that his enthusiasm for his product and position may colour his perspective. That does not detract from the knowledge he imparted, but it required the Court to approach his BFW scenario with caution.

(4) Mr. Jeevan Reddy

[40] Reddy, head of global sales at MSN Pharmachem in India (a pharmaceutical ingredient supplier), is an experienced market participant and has direct knowledge of MSN's dealings with Teva in respect of Pregabalin.

[41] His evidence was to the effect that MSN could have supplied commercial quantities of Pregabalin to Teva in advance of a product launch in either May or August 2010.

[42] Pfizer challenges Reddy's evidence, firstly because he is a senior salesperson and not a production person, and secondly because of the absence of the type of documentation it says should have been produced. Some documents were produced – sales invoices, certificates of analysis – but not enough documentation.

[43] His position in the company was sufficient to permit him to give evidence of the company's willingness and ability to supply Pregabalin. As a corporate spokesman, he is entitled to rely on what he knows or is told internally about various aspects of corporate operations.

[44] It is not the absence of a substantial record of documents which poses an issue, as MSN's dealings were done in the absence of such documents as supply agreements; rather, it is the credibility of Reddy's assertion that MSN could supply whatever was needed. However, he essentially made that assertion and it was not undercut by cross-examination. Reddy confirmed the availability of the necessary batch size, capacity to manufacture, the market, and pricing of the product. However, there were gaps in his testimony regarding precisely how MSN would scale up for the new market and about "out of spec" situations, which caused some concern.

(5) Mr. Peppino D'Agostinis

[45] De Agostinis is currently an employee of Halo, which took over Teva's Mirabel facility. He had been Ratiopharm's Associate Director of Technical Services, and upon acquisition of Ratiopharm by Teva he joined Teva at the Mirabel plant.

[46] His evidence largely related to the preparation of Ratiopharm's submission to Health Canada, batch sizes, and the validation process. It was confirmatory of Ratiopharm and Teva's ability to supply the Canadian market with Pregabalin. His evidence was straightforward, balanced and fair. He was also consistent with other Ratiopharm's witnesses in that there was a noticeable absence of documentation – a common theme and criticism running through Pfizer's submissions.

(6) Mr. Christopher Morin

[47] During the Liability Period, Morin, now Director of Financial Operations, worked in Teva's finance group as Senior Manager, Solid Dose Products. His evidence covered aspects of both Mirabel and Stouffville production operations, various aspects of costing of goods, and errors in certain documents and the necessary adjustment to the calculations of costs to adjust for the errors.

[48] He also spoke to the capacity of Stouffville to produce and to increase production with the equipment in place, as well as problems with particle sizing and shortages of product.

(7) Dr. Brian Des Islet

[49] Des Islet was Teva's Executive Director of Scientific Affairs in the Liability Period. He had overall responsibility for the pipeline of products and was knowledgeable about the research and development of Teva's Pregabalin. Pfizer accepts, as does the Court, that he was forthright, objective, and helpful.

[50] His evidence included the required development process for bringing a product to market. He gave a reasonable explanation of the BFW from Teva's perspective, including recognition of past problems with API from India and Israel and a confirmation that Teva would have used MSN - Ratiopharm's API supplier - as Teva's supplier.

[51] Importantly, Des Islet was part of the Integration Team dealing with Ratiopharm. However, he had little information about Ratiopharm's ability and willingness to go to market. As Pfizer has pointed out on numerous occasions, there was a dearth of Ratiopharm documentation about its ability and willingness to come to market which cannot be explained away simply by saying that Ratiopharm was on patent hold and therefore no other company would be looking at coming to market.

[52] While Des Islet's evidence underscores the weakness in proof regarding Ratiopharm and its coming to market with Pregabalin, the same cannot be said about Teva. Des Islet confirmed key aspects of Teva's ability and intention to come to market. Some documents from the Operations Group were produced. Pfizer says that more should have been forthcoming; however, Pfizer chose not to pursue these other documents and the Court does not know if production was refused and, if so, on what grounds. If Pfizer wished to impeach Des Islet or other Teva witnesses on the basis that other "relevant" documents undermined their testimony, it was incumbent on Pfizer to obtain the documents.

(8) Mr. Barry Fishman

[53] Fishman was the President and CEO of Teva during the Liability Period. He was at Teva from 2003 to 2014.

[54] Fishman provided important evidence of market strategy in respect of products, prices, and Teva's BFW. He addressed the issue of "would Teva launch" from the high level position he held. Many real world aspects were addressed by other witnesses, but Fishman was in an

excellent position to speak to Teva's intent to launch and the application of that intent in Teva's BFW.

[55] This witness also addressed aspects of the merger with Ratiopharm and the amalgamation of operations and products. He gave clear evidence that depending on which product was further developed, Teva would have launched either with Ratiopharm or its own Pregabalin.

[56] Fishman gave important evidence about pricing. While he acknowledged that pricing would be at 75% of the brand list, he constructed a BFW scenario at 85% while admitting that he knew of no example of a Teva product being listed at even 80%.

[57] He underscored the importance of Ontario to Teva's market and Teva's general best interest to accede to whatever pricing regime Ontario demands (subject to economic viability).

[58] While Fishman was a strong witness, his evidence was from the "10,000 ft level" and suffered when he was forced to "devil in the detail". Nevertheless, he confirmed that Teva could and would have launched Pregabalin as soon as possible.

B. *Teva's Expert Witnesses*

[59] Much of this case, and the resolution of specific aspects of damages, is directed by the experts called by both sides. The specifics of their respective evidence are also referred to in the analysis of the issues which the Court is asked to address.

[60] Teva called experts in economics, in the industry itself, in regulatory affairs, and in accounting.

(1) Mr. Robert Ferguson

[61] Ferguson was an expert in forensic accounting with expertise in business valuations. He examined four scenarios and calculated Teva's loss in each scenario.

[62] The points of major disagreement with Pfizer's comparable expert Peter Steger (a CPA and business evaluator) were in respect of the cost of API and trade spend rates.

[63] In respect of API, Ferguson relied on the delivered orders placed with MSN. While his acceptance of API is criticized by Pfizer as ignoring real world conditions, in this case it was a reasonable basis for Ferguson's premise because the evidence of Teva was that in a BTW it would have used MSN for reasons of availability and reliability.

[64] With respect to trade spend, Ferguson was to assume that in a sole source trade spend situation the rate would be 15-20%. The validity of that assumption must be established by Teva. An expert can accept an assumption if in their judgment it is reasonable and if ultimately the assumption is shown to be valid.

[65] Ferguson had to make some corrections to his calculations, but these did not alter his overall conclusions. The handling of the Quebec trade spend and the Montreal Group Agreement were somewhat problematic.

[66] Ultimately, the Court concludes that Ferguson was a helpful, credible, and balanced witness whose opinion is deserving of considerable acceptance.

(2) Dr. Aidan Hollis

[67] Hollis is an expert in the economics of the generic pharmaceutical industry. He was clearly a supporter of the generic pharmaceutical industry, and while there was no bias exhibited in favour of Teva the Court does view his evidence in light of a potential predisposition to favour generics.

[68] While his evidence is touched on later, he made a strong case for the "first mover advantage" (the advantage the first generic into the market gains), which has some lasting if diminishing effect.

[69] There was significant disagreement between Hollis and Pfizer's expert Iain Cockburn. This was evident in the use by Cockburn of economic models, contrasted with that of Hollis who used modeling plus observation, experience, and expertise. It is also evident in their respective approaches to the "pipe fill" concept – Hollis favours it, Cockburn does not.

(3) Mr. Ian Hilley

[70] Hilley is a pharmaceutical industry expert and a former senior executive of Mylan Canada and its predecessor GenPharm. He was well versed in the generic pharmaceutical industry.

[71] Hilley gave important evidence on his opinion as to the start of the Liability Period, which turned on Ratiopharm's actions and the status of a NOC/c issued to Lyrica.

[72] Hilley suggested that the start date would be in late April-early May 2010 because Ratiopharm was "regulatory ready" in mid-April 2010. However, despite advocating for an early start date, he was clearly uncomfortable with Ratiopharm's mishandling of the patent hold letter and its failure to follow up on its ANDS – all of which is inconsistent with the notion that Ratiopharm was ready and willing to launch in May 2010.

[73] Hilley exhibited moments of evasiveness and unnecessary stubbornness. The Court is cautious in accepting much of his evidence, and he was less helpful to Teva than they might have expected.

C. *Pfizer's Fact Witnesses*

[74] Pfizer called four of their own fact witnesses: three current employees and a former employee. Pfizer also called representatives of four other and non-related generics to address when and how these other generics would have entered the market. These witnesses were called by Pfizer, and therefore were not subject to cross-examination by other than Teva.

(1) Ms. Cynthia Di Lullo

[75] During the Liability Period, Di Lullo was the marketing Director for Pfizer's Lyrica product. She had 24 years of experience in the pharmaceutical industry, including fourteen with Pfizer.

[76] She gave extensive evidence on the way Pfizer marketed Lyrica. Her most pertinent evidence was the description of how Pfizer managed Lyrica as it moved toward loss of exclusivity [LOE] and what strategies were used. Pfizer had a practice of moving a product from exclusive status to a competitive situation through the Established Products Business Unit.

[77] Di Lullo covered off subjects such as product promotion (including to physicians), as well as dealings with formularies. She also touched upon the elements of LOE strategy to maintain brand market position and to counter competition through its own generic – GenMed – as well as the use of other authorized generics.

[78] In summary, her evidence was that the strategies used for Lyrica and other drugs, including having an authorized generic, would have been used by Pfizer in the Pregabalin BFW. She relied in part on a number of Business Plans created to deal with the LOE anticipated to be in 2013. There were no such plans for 2010 and 2011 because competitors were on patent hold. However, there was in fact a 2011 Operations Plan which she had not seen nor had she seen the GenMed Strategic Plan.

[79] While Di Lullo gave important evidence delivered forthrightly, she also had some key information gaps and was obviously uncomfortable in testifying on some aspects of the plans (particularly regarding generics). Some of the same criticisms levelled by Pfizer against Teva's witnesses could be levelled at this evidence.

(2) Mr. Oscar Mancini

[80] Mancini's evidence focused on supply chain management and outlined how his group prepared for a product launch. He also gave evidence on how it handled the LOE in terms of strategy with GenMed and authorized generics, particularly in respect of Lyrica, its manufacturing (in Germany), labeling, and other such matters.

[81] His evidence was particularly relevant to how the supply chain management system worked for GenMed and its launch in October 2012. He outlined the challenges and feasibility of getting GenMed ready for May 2010 to counter Teva's claim of May 1, 2010 as the start of the Liability Period. His evidence was inconsistent as to the time frame to launch GenMed's Pregabalin or other generics, ranging from under three months to at least six months and leaning generally toward three months depending on real world circumstances. He could not commit to a "hard" date.

[82] Mancini tried to be helpful and did the best he could within the narrow frame of his mandate and experience.

(3) Ms. Rania Cassar-Awe

[83] Cassar-Awe was no longer an employee of Pfizer at the time of her evidence, having moved to Shoppers Drug Mart after 23 years at Pfizer. She had held a number of relevant positions during the events under consideration, including Director of Loss of Exclusivity, Management Generic Strategy, and New Business Development, and Director of Retail Generics. She was instrumental in Pfizer's LOE strategy including Lyrica and GenMed Pregabalin.

[84] Her evidence was wide ranging, both in dealing with real events and in constructing Pfizer's BFW scenarios.

[85] It is not accurate, as suggested by Pfizer, that her evidence was not undermined by cross-examination. Much of her evidence dealt with her own actions and her justification or views of what happened or could have happened. Her interest in her "good name or reputation" was apparent (although not unusual in any witness) and she cannot qualify as a disinterested witness.

[86] Cassar-Awe went through the GenMed set-up and its use. Relevant to this case is her acknowledgement that in 2010 Pfizer took approximately six months for its second or generic product. She suggested it could be narrowed to nine weeks if a generic pushed on to market.

She also acknowledged that in 2010 GenMed was just starting up, and it was not a significant generic provider. One can conclude that GenMed in 2010 was not the more forceful competitor it would become in later years.

[87] Her evidence suffered from an optimistic view of the BFW where Pfizer and GenMed would do everything to defeat new competition without difficulties. Her faith in Pfizer's Toolbox (a series of marketing strategies to be pulled out and applied as if a wrench or screwdriver to fix competition) has to be approached with considerable caution.

(4) Mr. Darren Noseworthy

[88] Noseworthy was general counsel to Pfizer during the Liability Period, but he has since moved on to the UK and become responsible for Pfizer in Europe. He was called to the Bar in Ontario in 1999.

[89] He gave evidence on Pfizer's LOE strategy, including the circumstances for launching GenMed and negotiating authorized generic agreements.

[90] He also outlined Pfizer's strategy against other generics when exclusivity was lost. His evidence was that once the exclusive market was lost, Pfizer would let everyone in and would not attempt an injunction application nor sue for damages, no matter how long was left on the relevant patent. On this basis no generic would ever launch "at risk" – a factor other generics have said deters the numbers of generics who would enter the market.

Teva rightly cross-examined and challenged this proposition. It is inconsistent with concerns raised by other witnesses and tests the Court's ability to accept it. Noseworthy is an officer of the Court, and I accept that it is his honest belief; however, it is inconsistent with usual competition, as pointed out by Teva, that a powerful brand would readily abandon all its

potential legal rights against competitors for not much apparent gain, and this goes to the weight of this evidence.

[91] His evidence about past marketing actions of Pfizer is largely consistent with Cassar-Awe. He also discussed the state of GenMed in 2010. In addition, he discussed some issues of timing of legal actions, adjournments, and other matters. These are to some extent covered in the Joint Submissions whereby the period of the adjournments in T-1422-09 and T-1868-09 (both NOC proceedings) are to be neutral events as between the parties.

[92] In that regard, the Court accepts Pfizer's position that the Court should draw no conclusions about the fact or length of the extensions, stays, and adjournments of the two PMNOC proceedings to either increase, decrease, or award or refuse to award damages under s 8 beyond those which would otherwise be awarded or refused.

[93] In essence, Noseworthy testified that in a BFW Pfizer would have been ready with GenMed at the point of LOE and/or would have entered into authorized generic agreements.

[94] While he had some knowledge of the history of other events upon which he built his BFW analysis, there were serious gaps which undermine the weight to be given to his testimony.

D. *Other Fact Witnesses*

(1) Generics

[95] Pfizer called six generic drug companies who competed with Teva in the Pregabalin market. All appeared under subpoena and only one agreed to meet with counsel beforehand. Some of the evidence was confidential because of the competitive circumstances.

[96] The Court recognizes the difficulty faced by counsel trying, in direct examination, to elicit positive evidence from competitors, even where such examination is skillfully and artfully done as in this case.

[97] In summary, these witnesses, with one exception, indicated less than overwhelming enthusiasm for entering the market in a BFW scenario. For most it was an exercise too remote from what they did in real life – too theoretical for their comfort. Any indication of market entry was couched with numerous pre-conditions, assumptions, and caveats. Their overall response was the somewhat typically Canadian “entry if necessary but not necessarily entry”.

[98] The Court can draw very little in the way of concrete conclusions from this evidence, except for that of Naguib Fahmy from Mylan. Fahmy made it clear that Mylan would generally not have entered into an authorized generic market. The evidence of Len Arsenault from Sandoz was to the same effect, but less categorical.

[99] The problem for Pfizer is that it continues to insist that Mylan would have entered the market and therefore indirectly impeaches its own witness. This technical problem aside, Pfizer continues to insist that a number of generics would have entered the market and would have done so on specific dates or within certain timeframes when the general weight of the evidence was that they would not.

[100] These generic product witnesses also underscored that there were a number of barriers to entry into the market including not just price but also the potential for "launching at risk" – the potential for being sued by the patent holder. This was a barrier despite Noseworthy's questionable position that Pfizer would never do that.

[101] These witnesses from Pharmascience, Mylan, Sandoz, Riva, Ranbaxy, and Pro Doc were generally not helpful to Pfizer's BFW competitive scenario.

(2) Ms. Laura Meaney

[102] The last witness in this general category was Meaney, an employee of Health Canada who worked directly on Ratiopharm's Pregabalin ANDS approval. She handled the interaction with Ratiopharm on the issuance of the NOC.

[103] The Court accepts her evidence as credible, reliable, and fair.

[104] In summary, Meaney put "paid" to Teva's submissions and some of its witnesses that a NOC/c could and would have been issued by June 1, 2010. She testified that it was practically

impossible for Ratiopharm to receive a NOC/c in the BFW before it received its patent hold letter in the real world.

[105] Her evidence emphasized the importance of the patent hold letter, and it raises again the lack of action or explanation of the approximately four month gap in Ratiopharm's activities from May to August 2010, as discussed earlier.

E. *Pfizer's Expert Witnesses*

[106] Like Teva, Pfizer relied on a number of experts. Details of their opinions are, to the extent necessary, referred to in the Analysis section of these Reasons.

(1) Dr. Iain Cockburn

[107] Cockburn is an expert in economics with extensive experience in the pharmaceutical industry. He has experience on behalf of both generic and brand companies.

[108] Cockburn was called to rebut Teva's expert Hollis. Their opinions are largely similar, but Cockburn based his opinion on the use of an economic model. Hollis, while using a model, based his opinion on observations of facts and experience – a more fulsome landscape.

[109] His five volume report covered a number of areas in this litigation including BFW total market size, generic sales of Pregabalin, Teva's share of the generic market, and generic entrant by entrant effect (versus Hollis' averaging analysis). He reinforces the view that GenMed was

not an effective competitor to Teva because of limits imposed on it. He also addresses the "pipefill" claim and concurs with its reasonableness.

[110] Pfizer asks that the Court accept Cockburn's evidence over Hollis'. However, for reasons that will be shown, the Court favours Hollis.

(2) Dr. Paul Reider

[111] Reider is a professor of organic chemistry at Princeton University. He had both academic and practical experience in the industry having been involved with Merck in the commercialization of various drugs.

[112] Reider offered a wide ranging opinion about particle size, the stability of Ratiopharm's Pregabalin product, and the stability of an excipient. He posed that there were all sorts of obstacles to Ratiopharm coming to the market, including concerns regarding explosions of the API.

The purpose of his opinion seemed to be to suggest that all of his various concerns meant Ratiopharm and Teva would have been delayed beyond August 26, 2010 in a BFW.

[113] It is not necessary to go into the details of how unhelpful and unpersuasive his opinion was. It is sufficient to note that while Pfizer tried to salvage some of his opinion, even it had to admit significant weakness in his evidence.

[114] Reider had limited data, yet he was prepared to express opinions which evidence showed to be unfounded. His explanations tended to be theoretical speculation that was grounded in unestablished assumptions.

[115] Reider's approach to cross-examination was not consistent with solidly based expertise. He lectured, debated, and dodged around points. His credibility, if not already undermined in his report and direct examination, was seriously shredded in a very effective cross-examination.

[116] The Court can give his evidence no weight. His core propositions, particularly his BFW conclusion, were not established.

(3) Mr. Peter Steger

[117] Steger is a chartered accountant and business valuator with experience in forensic accounting. His evidence related to the quantification of Teva's loss. In that regard his evidence, to the extent there was disagreement, countered that of Ferguson.

[118] There were four areas of disagreement: trade spend, API volumes, API costs, and labour and inspection.

[119] His evidence, to the extent that his assumptions and understandings were proven correct, was given professionally, thoroughly, and fairly. However, it is not entirely accurate to suggest Steger was unconstrained by assumptions, as suggested by Teva – Steger had a number of

assumptions and impacts. He used a form of model which he said could be used to refine damages once certain findings had been made.

[120] His approach – quantification analysis of trade spend "molecule by molecule" – was different from that of Teva's accounting process, which blended spending by customer.

[121] Steger concluded that Teva's trade spend in a sole source BFW market would be 30% and in a multi source market it would vary between 52.9% and 55.6% (in 2010 he used 36.9% - a significant variance).

[122] On API, Steger tended to agree with Ferguson as to quantity available, subject to adjustment, but he was further apart from Ferguson on API costs.

[123] On labour and inspection costs, there was disagreement whether inspection costs should have been included which increased the loss. This is but one area where the differences between Ferguson and Steger increased the assumed loss. Steger made various corrections to his calculations because some of his assumptions were not supported.

[124] As discussed later, with all due respect to Steger, Ferguson had a more realistic grasp of Teva's loss and the components used to construct that loss.

(4) Mr. Neil Palmer

[125] Palmer is an experienced pharmaceutical industry consultant. He gave important evidence which addressed matters raised by other witnesses such as Hilley, Teva's proposed expert Bacovsky, and Fraser.

[126] His key opinion was that in the BFW, Teva would have priced Pregabalin at between 70-75% of the Lyrica price – not an unreasonable assumption and contrary to Ferguson's estimate of 83%.

[127] He addressed issues of provincial formulary policies and practices, and his evidence was consistent with Bacovsky with respect to formulary listing dates and consistent with Fraser's as to the regulatory rules and practices.

[128] Palmer did admit to no consulting experience with generics. While this does not show bias, it does suggest that his numbers may be on the more conservative side of a reasonable price spectrum – consistent with the brand view of generic pricing. He also admitted to seeing 85% of brand demanded in a situation of sole source off-formulary – this suggests the outer range of the same reasonable price spectrum. Palmer did admit that it was possible to have pricing over 75%.

[129] Palmer was a credible and forthright witness whose evidence must be taken seriously.

[130] Further comment on the evidence is contained in the Analysis and Findings section of these Reasons.

IV. ANALYSIS AND FINDINGS

[131] The following paragraphs address the findings which the Court has been asked to make to allow for a final calculation of Teva's damages.

The starting point must be the Liability Period.

A. *Liability Period*

[132] The end date of the Liability Period is agreed to be February 14, 2013.

[133] It is Teva's contention that the Liability Period should commence sometime between mid-April and May 1, 2010. It argues here that the start date should be May 1, 2010.

In the final alternative, Teva argues for an August 26, 2010 commencement date in respect of Ratiopharm's Pregabalin, which would be switched out for Teva's Pregabalin in February 2011.

[134] Pfizer argues that the earliest start date is August 26, 2010, but that Teva/Ratiopharm would be delayed in effectively launching due to operational problems including availability and stability of API.

[135] Paragraph 8(1)(a) of the Regulations describes the scope of the start of the Liability Period. Unless the Court orders otherwise and establishes a different date, the presumption is that the start date of the Liability Period is the patent hold date – in this case the date Ratiopharm was put on patent hold.

[136] Paragraph 8(1)(a) of the Regulations is as follows:

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

is more appropriate, or	postérieure à celle-ci est plus appropriée,
(ii) a date other than the certified date is more appropriate; and	**(ii)** soit qu'une date autre que la date attestée est plus appropriée;
(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	**b)** se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

[137] For purposes of this case, the date on which Ratiopharm was put on patent hold is August 26, 2010.

[138] While the patent hold date or the patent hold letter may not be a perfect surrogate for the NOC date (that is, the date of issuance of the NOC in the BFW), it is a useful point in time from which to assess whether the sole generic would and could have launched. Real world actions in and around the patent hold letter give some insight into what would or could have happened in the BFW.

[139] The onus is on Teva to establish that some other date is the appropriate date for the commencement of the Liability Period.

The Court has a discretion based upon its assessment of the evidence presented to establish a different date than the patent hold date (see *Teva Canada Limited v Sanofi-Aventis Canada Inc*, 2014 FCA 67 at para 76, 239 ACWS (3d) 180).

[140] Health Canada had completed the examination of Ratiopharm's ANDS on April 14, 2010. There was one issue to be resolved – whether Health Canada would issue a conditional indication, a matter related to issues with the reference product Lyrica.

[141] Teva argues, based on Major's evidence, that in a BFW with the opportunity to be the sole source generic for a period of time, Ratiopharm would immediately do everything possible to secure the issuance of a NOC/c, which would be issued within two weeks. The two-week period was established as reasonable if Teva would have commenced the process in this BFW scenario.

[142] It was established that the patent hold date as represented by the patent hold letter is a key feature of the real world. Any generic with the knowledge that it will be held off of the market for two years, if it is serious about launching its products, wants that patent hold letter as soon as possible so that the stay will end as quickly as possible.

[143] Teva constructs a May 1 scenario which, with respect, might have been *possible*, but is entirely speculative and not consistent with relevant real world events.

[144] On April 19, 2010, Meany telephoned Ratiopharm to inform it that Health Canada was putting off processing Ratiopharm's ANDS submission due to matters related to Lyrica, the details of which were confidential.

[145] On June 30, 2010, Meany inquired into Ratiopharm's efforts to update its Product Monograph. It was not submitted until one month later, after which it needed small corrections and was eventually settled on August 25.

[146] In the final analysis, Ratiopharm took no steps in the real world to expedite the patent hold letter or even to inquire into its status, or to expedite its product monograph.

[147] Major was somewhat out of touch with the process; however, he acknowledges the importance of the patent hold letter, yet he did nothing to follow up on it. This failure to act expeditiously in the real world calls into question Teva's evidence that in the BFW, it would have acted expeditiously to obtain an NOC/c or some type of carve out of the product indications which would have allowed it to launch in this BFW.

[148] Teva's own expert Hilley was puzzled by Teva's failure to follow up on the patent hold letter. There is some suggestion that this may have been administrative error, although no solid evidence was led on this point. Even if it was, the failure to take action – to at the minimum inquire internally – is not consistent with the picture of a company anxious to enter the market as soon as possible.

[149] This evidence is more consistent with a company not able or reluctant to go forward with the considerable task of a product launch. The absence of documents, and plans, is also consistent with this general malaise of not pursuing the issuance of the patent hold letter with urgency. It is also relevant, although Teva led little evidence on conditions within Ratiopharm at

the time, that Ratiopharm's principal had died and the company was sold under auction to Teva. It is reasonable to conclude that in this interim regime from April to August 2010 there was some element of corporate upheaval pending the merger with Teva in August 2010.

[150] The actions and inactions of Ratiopharm were not adequately explained. In fact, Major had no explanation for the gaps in its conduct and for the gaps in the documentary evidence.

[151] Hilley, while confirming that a two-week period to obtain a NOC/c was reasonable, expressed puzzlement at Ratiopharm's failure to pursue the patent hold letter.

[152] Teva's construct of its BFW scenario with a May 1 start date also runs against the evidence from Health Canada's Meany. It is highly speculative whether Health Canada would have cooperated pending removal of conditions on Lyrica and it is questionable whether Health Canada would have issued a NOC until this matter was cleared up.

[153] While it is recognized that Ratiopharm was not prepared in the real world for a BFW sole source situation, taken as a whole the evidence does not persuade me to depart from the norm and find a start date other than August 26, 2010.

[154] Therefore, the Liability Period for calculation of damages is August 26, 2010 to February 14, 2013.

B. *Size of Pregabalin Market*

[155] The next issue to resolve is the total size of the Pregabalin market between August 26, 2010 and February 14, 2013.

[156] The Court is faced with the expert evidence of two well qualified individuals: Hollis (for Teva) and Cockburn (for Pfizer). The difference between them is largely on approach or methodology. On many matters, they are in agreement.

[157] The issue for the Court is which of the two methods or models should be used. The different methods impact not only the calculation of the total size of the Pregabalin market but also the generic share of the Pregabalin market and Teva's share of the generic Pregabalin market.

[158] To complicate the matter further, each expert used their respective methodologies on a number of different scenarios. The parties have agreed that none of the scenarios can be used without modification. This agreement not to use these scenarios affects particularly the BFW assumption of when other generics would have entered the market.

[159] Both experts are highly qualified and reputable, and they gave straightforward and balanced evidence. The choice between them is a difficult one but, as indicated earlier, the Court adopts Hollis' approach for reasons stated and elaborated on here.

[160] I do not ascribe much importance to Pfizer's suggestion that the Court should favour Cockburn because he had acted for both brand and generic companies on several occasions while Hollis had acted primarily for generics and has only once acted for a brand. There was no evidence of predisposition in either expert.

[161] The choice of expert rests more on the explanation and cohesiveness of their approach to the matter, as well as the explanations given in their reports and particularly the explanations given under cross-examination.

[162] The parties cannot agree on what aspects of the s 8 framework these experts agree. Teva suggests that the agreement is on size of the total market (Teva Memorandum at para 29), and Pfizer says agreement is on the generic share of the Pregabalin market (Pfizer Memorandum at para 275).

[163] While Hollis' economic model was clear, Cockburn's report contained inaccuracies and errors which required late amendments. For example, Cockburn excluded two comparator molecules from the competitive generic market but included generic competitors selling Pregabalin in markets where they have not sold Pregabalin.

There was no explanation for these exclusions and inclusions which had the effect of reducing Teva's BFW market.

[164] Cockburn had to make significant amendments to his report even with the omission of the two molecules referred to above – esomeprazole and quinapril without any further explanation.

[165] It was not just that Cockburn had to make amendments to his report (Hollis did also), it was the nature of the amendments and the explanations given which causes the Court concern.

[166] Hollis' evidence was more balanced and fair.

[167] While both experts used econometric models, Hollis was less slavish in his acceptance of mathematical results from his model. Where the results seemed askew (as with the growth rate anticipated in Ontario and Saskatchewan), Hollis then applied his own judgment to adjust the numbers. Cockburn criticized this approach on the grounds of rigour, but to the contrary I find it to be a more balanced, real world expert viewpoint than simply "running the numbers". I am persuaded that the mathematic formulae take one only so far and expert judgment is then required to give real meaning to the results. This is what Hollis did.

[168] Therefore, the parties should use Hollis' model in determining the total Pregabalin market.

C. *Size of Generic Portion of Pregabalin Market*

[169] There is little disagreement between Hollis and Cockburn on the estimated generic share of the Pregabalin market in the BFW.

[170] Both experts used real world experience and adjusted the volumes based on assumed dates.

[171] For the reasons previously given, the Court prefers the evidence of Hollis and it is to be used in respect of the generic portion of the Pregabalin market.

D. *Teva's Share of the Generic Market*

(1) Experts

[172] Again, both Cockburn and Hollis ran scenarios and analyses of this issue. The two experts were very similar in their analyses in that they looked at other molecules to determine how a first entrant's market share changes over time as new competitors enter. Both then applied the results to Teva's share of the market in the BFW.

[173] Each expert's analysis is dependent on a plethora of assumptions – all of which are speculative, much like the construction of the BFW.

[174] Cockburn applied his analysis entrant by entrant according to his view of the relative strength of each in a BFW. That analysis makes more assumptions than Hollis' approach, which treats new entrants equally where the differences between entrants are more broadly based. Hollis' approach tended to lessen Teva's share because some of the competitors were weak.

[175] For reasons expressed earlier, in this case I find this broad approach more useful. I accept Hollis' analysis even though it benefits Pfizer by treating GenMed more favourably as a competitor than even Pfizer says is warranted (for example, Pfizer Memorandum at paras 293-294).

[176] There were immaterial differences in the molecules that formed their respective data sets. These differences had no real effect on the results or this Court's conclusion.

[177] The suggestion that Cockburn's model could be more easily applied to the factual findings of the Court cannot be a basis of acceptance where the Court finds Hollis' analysis and conclusions to be more persuasive.

(2) Competition

[178] There is no serious disagreement between the economists on what share of the Pregabalin market the generics would have obtained. For reasons stated earlier, the Court prefers Hollis' evidence.

[179] The resolution of the issue of Teva's share of the generic market depends on Teva's ability to enter the market and the timing of this entry, as well as the number and timing of the entry of other generics into the market.

Teva has modeled six scenarios that assume start dates of May 1, 2010 and August 26, 2010 with Teva alone in the market, in a competitive off-formulary interchangeability [OFI] market, and in a competitive full benefits market.

[180] The Court has rejected a May 1, 2010 start date. Therefore, the assumption, unless established otherwise by Pfizer, is that Teva would enter the Pregabalin market with Ratiopharm's Pregabalin product on or about August 26, 2010. Teva contends that it would then switch out the Ratiopharm product for Teva's own product in early 2011.

[181] Pfizer has alleged that Teva could not enter the market on or about August 26, even if it were authorized to do so, because of the impediments to the supply of the market. The alleged problem was the quality and quantity of the API.

[182] Pfizer has tried to inject into the analysis a consideration of pending prohibition proceedings in August 2010, which would have pushed the launch date past the proposed prohibition hearing date of March 2011.

[183] However, in constructing a BFW, the assumption is that there are no delays caused by these proceedings (although considerations of PMNOC proceedings are relevant for other generic competitors).

(3) Teva's Ability to Launch

[184] It was Pfizer's contention that Ratiopharm/Teva had problems which prevented its launch. It was for Pfizer to establish these impediments. The evidence established that Ratiopharm had the ability to supply ratio-Pregabalin, particularly at Ratiopharm's Mirabel facility. I accept D'Agostinis' belief that in the BFW, Ratiopharm could have produced approximately twice the entire Canadian generic Pregabalin market with the equipment in place, as contemplated by Hollis.

[185] This view was confirmed in part by Pfizer's Reider as to Ratiopharm's ability to manufacture.

[186] The essence of Pfizer's attack is that MSN could not meet Ratiopharm's particle size and specifications, and that its batch size of 55 kg could not satisfy the commercial market.

[187] Pfizer relied on Reider in respect of the ability to supply and of a secondary issue that the ingredient mannitol in Ratiopharm's formulation would make its Pregabalin unstable.

Reider's evidence was seriously undermined in cross-examination and did not withstand real world evidence of Ratiopharm's Pregabalin stability. His evidence was not realistic.

[188] With respect to batch size, Reider's evidence was speculative and was not founded on his experience or knowledge. The evidence is that MSN's equipment in 2010-2011 could produce 1,000 kg per month – this was sufficient for the market.

[189] The factual evidence is that MSN supplied over 1,100 kg of API to Ratiopharm using 55 kg size batches. This confirms that 55 kg batches were a workable size. Reider's opinion evidence is too speculative and is inconsistent with real world experience.

[190] The evidence from MSN was that it had the ability to scale up to large batch sizes if required. The Court accepts that evidence as what would have happened in the BFW.

[191] Reider's estimate of the time it would have taken Ratiopharm/Teva to come to market is not reliable, particularly with respect to "exhibition batches", validation batches, and building pre-launch inventory. His understanding of these features was shown to be faulty under cross-examination.

[192] Des Islet, on behalf of Teva, was a more knowledgeable and reliable witness. Des Islet gave clearer and unchallenged evidence on the batches at issue. His evidence is preferred over that of Reider.

[193] Even if there were problems with Teva's API after the merger of Teva and Ratiopharm, Teva would have been able, in a BFW, to have launched the Ratiopharm Pregabalin. I accept the evidence of Sommerville and Fishman in this regard. It would make no sense not to do so in a BFW and is consistent with real world experience where Teva initiated the scale up and validation of Ratiopharm Pregabalin. Pfizer does not seriously dispute this scenario.

[194] Again, Reider's evidence with respect to Teva's ability to supply the commercial market is rejected. His thesis rests principally on the assumption that Ratiopharm Pregabalin with mannitol was unstable; thus, Teva would not have used Ratiopharm Pregablin. As indicated earlier, Reider's opinion on this issue is unrealistic and unfounded. Mannitol is a commonly used excipient and is considered unreactive.

[195] The Court finds that as of August 26, 2010, Teva would have launched with the Ratiopharm Pregabalin product.

[196] In the worst case scenario, if Teva had continued to have API problems as alleged by Reider, Teva would have switched to MSN as its supplier in a BFW, as it did in the real world.

[197] Therefore, there would have been no real impediments in the BFW for Teva to launch Ratiopharm Pregabalin on or about August 26, 2010. Furthermore, there would have been no other generics who could have supplied the market at that time.

E. *Generic Entry - General*

[198] Pfizer constructs a BFW during the Liability Period where the competitive landscape bursts with competition from third party generics, authorized generics, and Pfizer's own generic GenMed. Often in the analysis one scenario detracts from the other: the stronger competitor one entity may be, the greater the adverse impact on the other entrants in the various scenarios. A very strong generic entrant tends to diminish or delay the entry of other generics.

[199] The issue is whether, when, and which generics would have entered the generic Pregabalin market during the Liability Period.

[200] Two starkly different BFWs were presented to the Court. For Pfizer the BFW would be populated with generic competition, such as the Pfizer owned GenMed, other authorized generics, or third party generics. For Teva, the BFW has Pfizer and Teva competing with weak if not nil authorized generic competition (including GenMed) and no independent generics during the Liability Period.

[201] The burden is on Pfizer to establish its competitive model. Real world behaviour is helpful in constructing the BFW, but its helpfulness is more limited in the case of competitive

behaviour. The market place is different in the BFW where the brand Pfizer and the generic Teva are in the market but all other competitors are faced with PMNOC proceedings and patent holds.

(1) Third Party Generics

[202] Pfizer contends that once one generic (in this case Teva) enters the marketplace, Pfizer would cease all opposition to market entry by other generics. The Federal Court of Appeal describes it as an "open season" methodology.

[203] This "open season" methodology was rejected by the Federal Court of Appeal in *Apotex Inc v Sanofi-Aventis*, 2014 FCA 68 at paras 156-159, [2015] 2 FCR 828, aff'd 2015 SCC 20 [the Ramipril decision], in which the Federal Court of Appeal agreed with the trial judge's reason for rejecting the open season methodology.

> [156] Sanofi points out that the combined effect of the decisions of the Trial Judge in this case and in the *Teva Liability Judgment* (FC) is that the hypothetical market for the period December 13, 2005 to August 1, 2006 (the overlapping portion of the section 8 liability periods for Apotex and Teva) exceeds the size of the actual generic ramipril market. As a result, according to Sanofi, its total liability to Apotex and Teva for section 8 damages is overstated. Sanofi argues that because this overstatement is the inevitable result of the methodology adopted by the Trial Judge for determining the characteristics of the hypothetical market, the methodology must be wrong in principle. Sanofi advocates a methodology in which each potential competitor is assumed to enter the hypothetical market free of the constraints of the *NOC Regulations* – I will refer to this as the "open season methodology".
>
> [157] The machinery of the *NOC Regulations* always takes time. She assumed that in the hypothetical world, the NOC Regulations exist and the competitors of a section 8 damages claimant would act as they did in the real world in relation to the *NOC Regulations*, except to the extent that there is evidence upon which the trier of fact can reasonably conclude that they would have acted

> differently. The open season methodology assumes the *NOC Regulations* away for the purpose of constructing the hypothetical market. For each claimant for section 8 damages, that would result in more competitors entering the hypothetical market at an earlier date than they could have done if the *NOC Regulations* were assumed to be in force. That would reduce the amount of the section 8 damages in every case in which the claimant has a potential competitor, and therefore it would reduce the aggregate liability of the first person (the innovator drug manufacturer, in this case Sanofi) in all such cases involving the same generic drug. That would undoubtedly be an advantage to the first person, but it could be unfairly prejudicial to a particular claimant because it is not possible to determine whether the open season methodology necessarily would result in reasonable compensation to each claimant or to all claimants collectively.
>
> [158] The Trial Judge rejected the open season methodology, largely because it is inconsistent with the requirement that each claim for section 8 damages must be determined on its own merits based on the evidence presented. She assumed that in the hypothetical world, the competitors of a section 8 damages claimant are bound by the *NOC Regulations*, and that those competitors would act as they did in the real world in relation to the *NOC Regulations* except to the extent that there is evidence upon which the trier of fact can reasonably conclude that they would have acted differently.

[204] The Court of Appeal went on to explain that the BFW is one in which all potential market entrants (other than the s 8 claimant) are bound to navigate the PMNOC Regulations and, from the third party generics' perspective, the prohibition proceedings remain alive.

> [162] It follows that in the hypothetical market, the behaviour of competing generic drug manufacturers must be determined on the basis that the *NOC Regulations* exist, and each generic drug manufacturer will conduct itself accordingly.
>
> …
>
> [186] As explained above, I do not consider it correct to assume that there are no *NOC Regulations* in the hypothetical world, or that the *NOC Regulations* are not binding on the section 8 claimant (except for the purpose of determining the beginning of the section 8 liability period). Therefore, it appears to me that in the

> hypothetical world as well as in the real world, the prohibition applications against Apotex would have been dismissed just as they were in the real world. Each such dismissal gave Apotex a right to claim damages under section 8 of the *NOC Regulations*. But at the same time, each dismissal based on an invalidity allegation potentially put at risk any other Sanofi prohibition applications based on the same allegation, including the invalidity allegations made by Teva and Riva.

[205] I cannot accept Pfizer's assertion that it would have, in the BFW, consented to the market entry of third party generics upon dismissal of the prohibition proceedings against Teva. That dismissal does not occur in the BFW.

[206] Even accepting Noseworthy's testimony of Pfizer opening the market to all once even one generic succeeds in a PMNOC proceeding, that only occurs where there has been an invalidity finding against a brand such as Pfizer. There is no such finding in this BFW.

[207] Given the real world conduct of Pfizer to resist entry as it did in proceeding against Teva, I conclude that in a BFW Pfizer would have behaved in the same way.

[208] Although not argued as such, one reasonable construct of a BFW competitive market would be to apply the two-year hold period to each third party generic who filed for an NOC, assume that each would have succeeded in Federal Court on the same basis as Teva succeeded, and then assess when they could have actually come on the market. Even on that basis, the end of the period when Teva would have been the only generic would be approximately the same as the end of the Liability Period.

[209] It was clear from the evidence of those third party generics who gave evidence that price, market conditions, and significantly being “at risk” would have deterred them from earlier entry in a BFW.

[210] Even if one accepts that Pfizer would not have opposed market entry by third party generics, there is insufficient evidence that any of them would have done so.

[211] In that regard, Pfizer called representatives of Mylan, Sandoz, Ranbaxy, Pro Doc, and Riva. As indicated earlier, none would have entered the market immediately upon entry by Teva.

[212] It was a common theme that absent judicial approval or a finding of non infringement, they would not enter the market even where there were no NOC proceedings against Teva.

[213] The closest the evidence came to a possible entrant was Pharmascience. However, that evidence was subject to significant qualification surrounding the state of PMNOC proceedings. The suggestion that Pharmascience would have served its NOA earlier in a BFW does not align with the evidence.

[214] As conceded in cross-examination, Riva would not have entered the market on any basis but, if it did so, it would have been as a cross-reference to Pharmascience’s Pregabalin product, virtually exclusively in Quebec. The same situation applies to Pro Doc. This is too uncertain a basis upon which to suggest meaningful generic competition.

[215] In the real world, Shoppers Drug Mart secured for its Sanis drug line a cross reference for its Pregabalin product from Teva. As Sommerville outlined, once there were three competitors in the generic Pregabalin market in a BFW, a negotiation would have taken place to award one of the suppliers with a Pregabalin contract.

[216] In the real world, Pfizer/GenMed were unable to secure a Pregabalin supply arrangement with Sanis. Despite Pfizer/GenMed's contention that it could have done so, that hope must be rejected in the absence of confirmatory evidence from Sanis or Shoppers.

[217] In summary, there is insufficient evidence to establish that third party generics could and would have entered the Pregabalin market during the Liability Period. The questionable market conditions (even for a drug as significant as Pregabalin), the competitive battlefield, and the real or perceived legal and financial risks of launch appeared to have deterred any such entry.

(2) GenMed Entry

[218] Pfizer correctly points out that Pregabalin was a significant ("blockbuster") product for Pfizer and a critical molecule for the generic industry. Every major generic operating in Canada eventually developed or cross-licensed its own Pregabalin product. While generics might not be able to remain out of this market, the market conditions and the capability, and intent of generics to participate has to be established in this BFW during the Liability Period.

[219] Pfizer's position is that once Teva entered the market, Pfizer would have immediately commenced marketing a GenMed product. Having received Ratiopharm's NOA in July 2009,

Pfizer would have been planning to launch GenMed at the same time as Ratiopharm or Teva entered the market.

[220] GenMed was initially developed as part of Pfizer's broader LOE strategy in respect of other drugs such as Lipitor and Norvasc. The strategies for LOE included marketing actions (described as a "toolbox") which included GenMed. By 2013, upon genericization of the market, Pfizer launched GD-Pregabalin. These two real world events form the foundation of Pfizer's position that that which occurred in 2013 in the real world would have happened in the BFW in the Fall of 2011.

[221] With respect to this issue, Pfizer principally relies on evidence from Di Lullo and Cassar-Awe and, to a lesser extent, on Noseworthy. The Court's general views of those witnesses have already been discussed.

[222] There are several difficulties with Pfizer's position and these are summarized in the following paragraphs. As noted earlier, even Pfizer has acknowledged that GenMed was not a strong competitive force in 2010; however, it claims that its BFW strategy would be to divide the Pfizer Pregabalin market with its weaker generic, depress the revenues from this blockbuster drug, and undermine the brand in order to compete with Teva alone (while the other generics went through the PMNOC process), or that it would have just abandoned the market to generics generally including its own. It is difficult to envisage this strategy when another option could be, as also suggested by Pfizer, to compete vigorously with Teva (presumably on price and trade spend) while holding off other generics.

[223] Firstly, the evidence shows that GenMed was not a part of Pfizer's toolbox in 2010. Prior to May 1, 2010, Pfizer had not launched a single GenMed product into the retail market to compete with a generic upon LOE. The only prior attempt to launch a generic prior to 2010 (GD-Amlodipine) was abandoned.

[224] Pfizer did not generally launch a GenMed product upon LOE despite GenMed being in existence since 2004, although there is some evidence that Pfizer was contemplating expanding GenMed's role.

[225] A second difficulty is that the weight of the evidence establishes that Pfizer would not launch GD-Pregabalin into a sole source OFI market.

[226] This finding turns to some extent on answers given by Di Lullo, who admitted that Pfizer would not launch GenMed in an OFI situation. Pfizer suggested that she was confused in her responses between a situation in Quebec under the BAP15 (a full benefits regime – no price difference to the patient for generic or brand) and an OFI situation outside Quebec.

[227] Her answer is consistent with the fact that Pfizer refrained from launching GenMed into Quebec's BAP15 market because generic competition could "cannibalize" or erode the brand market.

[228] As mentioned earlier, it is also consistent with good sense that Pfizer would not launch GenMed into an OFI/non-formulary sole source market outside of Quebec because of potential price reduction and loss of market share.

[229] Therefore, Pfizer would not launch GD-Pregabalin into an OFI sole source market, as would have been the case in Ontario in 2010 in the BFW.

[230] The third difficulty with Pfizer's position is that Pfizer made no plans to launch GD-Pregabalin on LOE in the real world.

[231] Pfizer points to 2013 and following real world events to construct a BFW in 2011. However, Pfizer made no plans to launch GD-Pregabalin prior to the expected LOE in 2011. The difficulty with Pfizer's evidence is that it was incredibly speculative (more so than is inherent in the creation of a BFW), even in terms of real world planning for the eventual LOE on Lyrica.

[232] The fourth difficulty with Pfizer's position is its inconsistency in planning and response. It was admitted that Pfizer does not always launch a GenMed product on LOE and that it depended on the situation. A general "toolbox" – which was no more than a list of a number of potential competitive responses – does not establish that any or all would be used in response to conditions in 2010.

[233] To each example of the non-launch of a GenMed product in response to generic entry, Pfizer's witnesses had a thesis for distinguishing the example from what they contend would be

the BFW response. However, these examples undermine the credibility of Pfizer's BFW construct and show the inconsistencies in Pfizer's real world actions.

[234] In response to Noseworthy's thesis that upon one generic entering the market Pfizer would abandon all hope for the brand and permit unbridled generic competition, it must be noted that Cassar-Awe's 2011 business plan for GD-Aromasia was not to launch it until after a second generic entered the market.

[235] This inconsistency of response applied to other Pfizer products (see evidence on Lupitor), such that the only explanation is that "it depends" or "each situation is unique".

[236] Pfizer's contention that it would have launched GD-Pregabalin on LOE in 2010 because GenMed was part of its toolbox of competitive responses to LOE does not stand up as a general proposition in the face of its real world experience of not doing so.

[237] In order for Pfizer to establish that GenMed would have launched GD-Pregabalin, it must establish more than that GenMed was part of the toolbox.

[238] The fifth difficulty for Pfizer is that GenMed was not an effective competitor in the real world.

[239] As indicated earlier, Pfizer has acknowledged that it had this issue with GenMed. While it was in Pfizer's hands to address this weakness, it did not do so. It would be illogical to

conclude that its real world weakness, as shown in 2013 when it captured 1% of the market, would have been eliminated in the BFW.

[240] Di Lullo's evidence of the need to establish a commercial basis to launch GenMed shows that it was highly speculative to conclude that GenMed would be launched, despite Cassar-Awe's efforts to shore up the GenMed scenario.

[241] It is difficult to square Cassar-Awe's position that GenMed would not be launched into a highly genericized market because it could not compete with Pfizer's position that generics would enter the market along with GenMed and potentially an authorized generic.

[242] The position is even more difficult to square with Pfizer's actions in 2013 upon genericization, when it launched GenMed into a highly competitive market.

[243] The rationale for the 2013 GenMed launch is explained in part by Noseworthy as a way to limit s 8 damages. Since a s 8 damages claim by Teva would not be at issue in a BFW, that rationale for launching GenMed in the Liability Period cannot be made out.

[244] Therefore, Pfizer has not made out a case that GenMed would have been launched in 2010-2011 to compete with Teva in this BFW. Even if it were launched, it would not be an effective competitor.

(3) Authorized Generics

[245] The final matter in this analysis of the generics in the BFW is Pfizer's contention that it would have authorized at least one generic who would have entered the market at or about the time Teva entered.

[246] While the Court need not identify the particular authorized generic, in this case the likely authorized generic identified by Pfizer was Mylan. Pfizer also argued that there may have been other authorized generics.

[247] There were factors which would steer Pfizer toward an authorized generic, but there were also factors indicating otherwise.

[248] Despite the fact that in the real world Pfizer entered into an authorized generic agreement with Mylan to sell Pfizer's Pregabalin as a Mylan product in early 2014, the evidence indicates that this would not have happened in a BFW.

[249] Fahmy's evidence is to the effect that in the BFW Mylan would not have entered into the Pregabalin market as an authorized generic or as a third party.

[250] Fahmy testified that in 2010 it was proceeding with its own product on the assumption that its costs were satisfactory. In 2010, Mylan was not interested in an authorized generic arrangement. It was only in late 2011 or early 2012 that costs became an issue, and only then that

Mylan might have considered an authorized generic arrangement. At best, Fahmy's evidence is that Mylan might have considered an authorized generics arrangement in late 2012; this is too late to have any impact in the Liability Period.

[251] In addition, Fahmy's evidence points away from an authorized generics arrangement due to concerns for profitability. An authorized generic was not a favoured situation for Mylan. When it knew that it would not bring its own Pregabalin product to market in 2011, it did not seek out an arrangement with Pfizer.

[252] Pfizer has not established that, on a balance of probabilities, Mylan would have become an authorized generic during the Liability Period. The hard evidence points away from that scenario.

[253] The considerations of creating an authorized generic in 2013 to limit s 8 damages against Pfizer would have no application in a BFW.

[254] Teva's expectation of an authorized generic in the real world is not easily transported into a BFW scenario. The BFW would be a different landscape for a generic, as evidenced by Fahmy.

[255] As to the suggestion that if not Mylan then Pfizer would have found some other authorized generic, the evidence is thin and is not persuasive. For example, in the real world, Pfizer only spoke to Mylan about being an authorized generic; no other generic was approached by Pfizer or approached Pfizer.

[256] This issue of who would approach whom takes on some relevance since Pfizer's evidence is that Pfizer waits for a generic to approach it.

[257] Pfizer's reliance on the one example of entering into an authorized generic agreement upon LOE – the Atorvastatin situation – is not helpful, as that was a truly unique situation arising from a global litigation settlement.

[258] Pfizer has not shown that some other generic would have entered into an authorized generic agreement during the Liability Period. There is insufficient evidence to sustain Pfizer's position on this issue.

F. *Formulary Listing*

[259] The issue of formulary listing deals with the question of when Teva and its generic competitors (if any) would have been listed on provincial formularies. This issue is significantly affected by the Court's finding of lack of generic competition. In turn, the issue of formulary listing affects market share and price.

[260] There is substantial agreement between the parties on formulary listing dates in the various scenarios as the experts are of the view that they can model the dates based on the Court's factual findings. This covers off-formulary, interchangeability, and benefit listing matters.

[261] The parties also agreed that:

- Pregabalin would not have been listed as a benefit on the British Columbia, Alberta, or Manitoba formularies;
- Pregabalin would have been listed as a benefit on the Quebec formulary; and
- Teva and other generic manufacturers (if any) would have been motivated to apply for formulary listings. However, this assumes that other generics would or could have brought their Pregabalin product to market – a matter not established in this case.

[262] The principal issue in dispute is what would have happened in Ontario and, to a lesser extent, Saskatchewan and Atlantic Canada.

[263] The issues of Atlantic Canada and Saskatchewan can be resolved by reference to Palmer's evidence to the effect that these provinces would not commence the listing process until a generic other than Teva applied for a full benefits listing in those provinces.

[264] With respect to Ontario, Pregabalin was not listed as a full benefit on the Ontario formulary prior to the LOE in February 2013. Prior to that, Lyrica was only provided by the Ontario formulary pursuant to Ontario's Exceptional Access Program because its price was so high.

[265] It was generic entry in 2013 with its competitive forces on the brand and its pricing that caused Pregabalin to be classified as full benefits. The generics had applied for OFI.

[266] The key evidence on what happened and what would have likely happened in the BFW came from Fraser, the former Director of Pharmaceutical Services for the Ontario Drug Programs. While he was a fact witness, his knowledge, experience, and objectivity make him a virtual expert, and his evidence is given considerable weight.

[267] Fraser confirmed that Ontario would not put Pregabalin on full benefits if there were just one or two generics on the market (particularly Teva alone or Teva and GenMed). Fraser spoke in terms of requiring a cluster of generics on the market (somewhere between four and six) before he would consider moving Pregabalin to full benefits status.

[268] Given the Court's findings on the entry of generics during the Liability Period, in a BFW the only reasonable conclusion is that Pregabalin would not have moved to full benefits status in Ontario.

[269] Therefore, the Court concludes that in the BFW Pregabalin would have remained an off-formulary drug throughout the Liability Period outside of Quebec (where it would be listed).

[270] In so concluding, the Court does not find that provincial authorities had no resources to influence the price of Pregabalin and were slaves to generic pricing. While Pfizer had walked away from a "Product Listing Agreement" with Ontario, that was because Ontario would only agree to price Lyrica at a 40% discount. This was a discount that Pfizer refused to accept at that time.

[271] There was strong motivation on Ontario's part to list Pregabalin in order to assist physicians, patients, and Ontario's drug administrators.

[272] As Fraser indicated, he had never seen a situation where, after the LOE, every generic refuses to move to the general benefit on the formulary. However, the BFW is not, in this regard, the real world. As previously found, other generics would not or could not have entered the BFW market during the Liability Period.

[273] To the extent that there are any issues with respect to the market division between various generics, as indicated earlier the Court would have favoured Hollis' model.

G. *Pricing*

[274] In the calculation of Teva's lost sales during the Liability Period, the parties have advanced different theories of what Teva's pricing would have been – that is, the percentage off of the Lyrica price.

[275] Teva (and Ratiopharm) claimed that it would have priced its product at 85% of Lyrica in a sole source OFI market.

[276] There is no doubt that in the sole source generic market the generic has the potential to set its price higher than in a generic competitive market. Pricing at 85% is at the highest end of the reasonable range. While examples from the real world can be helpful, and Teva did not price any product at 85% during the Liability Period, such examples are not determinative.

[277] The matter has to be examined from the perspective of a price which is not so high that it cannot penetrate the market because it is so close to the brand's price that other factors favouring the brand, such as the brand's relationship with competitors, reduce potential competitors. It must take into account the future – that competition will happen at some point. It must account for ongoing and future relations with those who have to reimburse drug expenses; one does not gouge the customer and expect good relations thereafter.

[278] Teva's documentary evidence to support pricing at 85% is weak or non-existent. While Teva tries to explain away the Risedronate example (where for that drug the price was 75% of that of the brand), that example is more consistent with the weight of the evidence in the instant case including:

- there was no pertinent time when Teva set a single source molecule price as high as 85% of brand; and
- Teva's highest price in Ontario for a single source molecule during the Liability Period was 75% of brand, with most examples in the lower 70%s.

[279] The Court concludes that, in the best estimate of price in circumstances where price would not be set by provincial formulary, Teva would have priced at 75% of the brand.

[280] To the extent that Teva (and/or Ratiopharm) would have been listed on provincial formularies, Palmer's revised Schedule D establishes an appropriate pricing regime.

H. *Trade Spend*

[281] The parties have multiple trade spend rates (that is, the discount to customer off of the price) depending on competitive market conditions.

[282] Teva claims that:

a) in a single source scenario Ratiopharm's rate would have been 15% and Teva's would have been 20%. Pfizer claims it would have been at least 30%;

b) in a dual source situation, the rate would have been 30%. Pfizer's position is that there never would be such a rate because there is no evidence of such a rate; and

c) in a multi source situation, the rate would have been 45%. To this, Pfizer claims a rate range of 60-65% trade spend.

[283] Given the Court's earlier findings regarding the competitive landscape, the single source trade spend is the most relevant consideration. The multi source scenario may inform the calculation of the single source to a limited extent and all in the context of the BFW.

[284] In this dispute on the trade spend, Teva's evidence is principally oral from its representations with the use of some limited number of examples. On the other hand, Pfizer's conclusion is based on an analysis of the records which Teva produced.

The Court finds the objective analysis of Pfizer to be more compelling than the subjective and optimistic predictions of Teva.

[285] The Court attaches little weight to Major's prediction that Ratiopharm would have had a trade spend of 15% because there is little, if any, credible evidence to support this figure. Major himself had little personal experience with trade spend.

However, given the timing of launch, only the Teva rate is important.

[286] Teva's 20% trade spend rate is based almost entirely on Sommerville's speculation. It is not supported by the records. It is too easy in this BFW analysis to take an overly generous and optimistic view of this constructed world.

[287] In Teva's case, Sommerville's speculation is not based on experience or records. Teva does not track trade spend by product, so Sommerville's evidence is at best a "guestimate".

[288] The best evidence of a parallel situation to that of single source Pregabalin, as admitted by Sommerville, is that of Risedronate. It was a single source molecule from January to July 2010. It was a strategic molecule and its circumstances were as close as one could get to Pregabalin.

[289] The trade spend rate in that period was 39% to 45%, averaged on volumes to be 40%.

[290] The trade spend numbers for Risedronate came from a document produced by Teva as "Teva 292". It was created by Teva's finance department by the Trade Spend Team in response to undertakings.

[291] Shortly before trial, Teva attempted to resile from this document on the basis that it was incorrect. Sommerville had no credible basis for so conveniently disassociating Teva from this obviously damaging evidence.

[292] However, Teva has not produced any corrected version of Teva 292. It has not shown how it was obviously a miscalculation or explained where it went awry, nor did it immediately resile from this document when it was first produced and relied upon even by Teva.

[293] The Court accepts that Teva 292 is the best and most objective evidence of trade spend numbers for a single source molecule.

[294] Teva 292 is an admission against interest. It is highly relevant and more objective and reliable than other records in this regard.

[295] Teva 292 is consistent with Steger's (Pfizer's accountant) evidence. His work was impacted by the absence of records produced, but he estimated Teva's overall single source trade spend rate to be 34% - 38%.

[296] In conclusion on this issue, Teva's 20% trade spend rate is not supportable. The weight of the evidence is that it is somewhere between 30% and 40%.

Given the exigencies of creating a BFW rate, I conclude that the appropriate trade spend rate is 35%.

[297] Unless requested by the parties, the Court will not comment upon either a dual source or multi source trade spent rate.

I. *Miscellaneous Accounting and Cost Issues*

[298] Most of the accounting issues have been settled through agreement. For ease of reference, the Court will make its findings on the disputed matters as well as incorporate as findings those matters that have been agreed.

The disputed matters are:

- inspection costs of Ratiopharm products;
- cost of API;
- recipe cost error/quantity of API; and
- pipefill

(1) Inspection Costs

[299] Teva's position that no inspections would arise in the BFW is supported by the absence of inspections in the real world and the evidence of D'Agostinis.

[300] Pfizer's position that inspections might have occurred in the BFW is too speculative.

[301] Therefore, the Court finds that there would be no inspection costs.

(2) Cost of API

[302] The essence of the issue is whether pricing at [redacted] per kg should be included in the pricing over time of API. Given that the [redacted] per kg orders were never sent out and the evidence of Reddy is that [redacted] was not the real price in the market, I would eliminate that price of API during the Liability Period.

[303] I prefer the actual evidence from Reddy over the analysis by Pfizer's Steger, as his evidence on other matters (i.e. inspection costs) was strained and less credible.

[304] Therefore, the Court finds that [redacted] per kg is the appropriate price of API during the Liability Period.

(3) Recipe Costs and Quantity of API

[305] The parties agree that the API quantity in the recipe cards is incorrect. The issue is how to treat the "average" of the blend as compared to the number of capsules produced.

[306] In my view, this is a false issue. The best evidence is that of Morin in Operations Finance, who testified that any average would have been used to make more saleable product. Therefore, there is no wasted cost and thus no deduction from Teva's claimed amount of damages.

(4) Pipefill

[307] Pipefill sales represent a volume of sales initially made by the manufacturers to distributors in order to provide them with initial inventory.

[308] As explained by Cockburn from an economic perspective, a pipefill adjustment is not appropriate because that surge is offset by lower sales later on. From an economic perspective, there is no need for an adjustment; this is particularly true from the perspective of a "make whole" analysis. Essentially, the surge smooths out over time.

[309] However, in the Ramipril decision the Court of Appeal has made it clear that the s 8 damages regime is not a "make whole" analysis. It is restricted to what would occur in a BFW during the Liability Period, thus precluding double ramp-up compensation.

[310] Hollis correctly understood the judicial instructions that s 8 claimants could only recover those losses during the Liability Period.

[311] To the extent that pipefill or inventory adjustments represent sales lost in the BFW, they are appropriate. To the extent that they are a disguised method of compensating for double ramp-up, they are not.

[312] With that clarification, the Court accepts Hollis' adjustment as it was made on the basis of the instructions from the Court of Appeal.

V. AGREED UPON FINDINGS

[313] On the basis that the parties have agreed to the following matters, the Court adopts them as its findings.

a) Yield loss:

2010 (Ratiopharm)
Blending: 0%
Capsulation: 4%
Packaging: 1%

b) Ratiopharm manufacturing overheads:

2010 (Ratiopharm)
69.8% fixed; 30.2% variable

c) Distribution allowance:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
9.04%	2.78%	2.72%	2.77%

d) Prompt payment discounts:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
1.98%	1.79%	1.95%	1.92%

e) IMA fees:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
0.00%	1.30%	1.42%	1.39%

f) Free goods:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
0.00%	0.22%	0.33%	0.43%

g) Selling commission/bonuses:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
0.21%	0.13%	0.09%	0.10%

h) Insurance:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
0.07%	0.13%	0.07%	0.09%

i) Freight out:

2010 (Ratiopharm)	2011 (Teva)	2012 (Teva)	2013 (Teva)
0.52%	0.37%	0.57%	0.75%

VI. CONCLUSION

[314] The parties have asked for specific rulings and guidance in calculating Teva's s 8 damages. These findings are summarized as follows:

a) The duration of the Liability Period is August 26, 2010 to February 14, 2013, and Teva/Ratiopharm would have been able to launch in or about that date.

b) The overall size of the Pregabalin market is to be calculated based upon Hollis' reports.

c) The overall size of the generic portion of the Pregabalin market is likewise to be based upon Hollis' reports.

d) Teva's share of the generic market is, using Hollis' reports, to be based upon the Court's conclusions that:

   i. Pfizer would not have launched GenMed during the Liability Period.

   ii. Mylan would not be an authorized generic for Pfizer nor would any other generic be an authorized generic.

   iii. No other generic would have entered the Pregabalin market during the Liability Period.

e) Neither Ratiopharm nor Teva would have listed Pregabalin on any formulary outside Quebec during the Liability Period.

f) Pricing for Pregabalin outside Quebec would have been at 75% of the Lyrica price, except in Quebec where pricing would have been 60% of the Lyrica price.

g) Trade spend would have been at 35%.

h) With respect to accounting issues, there are no inspection costs, the cost of API would be [redacted] per kg, and there are no adjustments for recipe costs and API quantities.

i) Any pipefill adjustment will be in accordance with Hollis' report as clarified by the Court.

j) The agreed upon items in paragraph 313 of this judgment are to be findings of this Court.

[315] Teva's damages shall be calculated in accordance with these findings and any other agreed upon items.

[316] The Court will remain seized of this matter until the final damages calculations are agreed to or settled by this Court.

[317] Teva shall have its costs. The parties may speak to the matter of costs.

"Michael L. Phelan"
Judge

Ottawa, Ontario
March 30, 2017

FEDERAL COURT

SOLICITORS OF RECORD

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