Federal Court Cour fédérale

Date: 20131211

Docket: T-1786-08

Citation: 2013 FC 1237

BETWEEN:

APOTEX INC.

Plaintiff

and

TAKEDA CANADA INC.

Defendant

REASONS FOR JUDGMENT

PHELAN J.

I. INTRODUCTION

[1] This is a case under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [Regulations], concerning the calculation of loss for which Apotex is entitled to compensation under the Regulations.

[2] The liability for damages arises from a decision of Justice Gauthier, then of this Court, in *Solvay Pharma Inc v Apotex Inc*, 2008 FC 308, 323 FTR 1, which found that Apotex successfully addressed each of the patents in issue. Takeda's Notices of Application were dismissed by Justice

Gauthier on March 3, 2008 with public reasons on March 6, 2008. Apotex is entitled to compensation for the period it was prevented from entering the market with its drug, Apo-pantoprazole.

[3] The Court is not asked, at this time, to calculate the amount of the loss but to determine certain issues and from which determination the parties believe that they can arrive at the amount of compensation. Failing agreement, the Court may be required to settle the specific amount of compensation.

[4] The relevant provisions of the Regulations are:

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 (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of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*	(i) soit que la date attestée est devancée en raison de l'application de la *Loi*

the Food and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or

modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique), chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,

(ii) a date other than the 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.

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action en contrefaçon du brevet visé par la demande.

(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.

(4) Lorsque le tribunal enjoint à la première personne de verser à la seconde personne une indemnité pour la perte visée au paragraphe (1), il peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts à l'égard de

	cette perte.
(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).	(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).
(6) The Minister is not liable for damages under this section.	(6) Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

[5] The analytical framework for s 8 damages has been set out in *Sanofi-Aventis Canada Inc v Teva Canada Ltd*, 2012 FC 552, 410 FTR 1 [*Teva-Ramipril*] and *Apotex Inc v Merck Canada Inc*, 2012 FC 1235, 105 CPR (4th) 399 [*Alendronate 2012*].

I adopt that framework and the steps therein. Laid out below are the steps and the unsettled issues for resolution are emboldened.

[6] The steps and issues to be resolved are:

1. The burden of proof **(Issue 1)**;
2. The relevant period for determination of loss: the parties agree that the period is March 9, 2007 to March 5, 2008 [Relevant Period];
3. The size of the total pantoprazole market during the Relevant Period: the parties agree that the total pantoprazole market is the quantity of brand pantoprazole sold

during the Relevant Period which is 184,329,100 units of 40 mg tablets (including hospital sales) and 896,000 units of 20 mg tablets;

4. Size of the total generic segment of the pantoprazole market during the Relevant Period: the parties accept the real world experience of the generics entry; therefore, March 3, 2008 for the year to 2009 applied back one year to the Relevant Period is the basis for the size of the generic market within the whole of the pantoprazole market;

5. Apotex's share of the generic segment of pantoprazole market during the Relevant Period:

   a) Number and identity of generic market entrants **(Issue 2)**;

   b) If Apotex is alone in market: parties agree Apotex would have 100% of generic market;

   c) If Apotex is in competition – Apotex's percentage of market share **(Issue 3)**;

   d) Apotex's production capacity: parties agree;

   e) Timing of formulary listing: parties agree;

6. Apotex's lost revenue:

   a) Price **(Issue 4)**;

   b) Inventory adjustment **(Issue 5)**;

   c) Double ramp-up **(Issue 6)**.

7. Apotex's deduction from lost sales:

   a) Rebates **(Issue 7)**;

   b) Prompt payment discount: parties agree at 1.755% of Apotex's lost sales revenue;

c) Cost of sales: parties agree on $0.0745 per tablet;

d) Sales commission: parties agree on .22% of Apotex's lost sales revenues;

e) Freight and distribution: parties agree on $0.001 per tablet;

8. Interest **(Issue 8)**;

9. Discretion to reduce award based on Apotex's misconduct **(Issue 9)**.

II. GENERAL FACTS

[7] The brand drug at issue in this case sold by Takeda (formerly Nycomed Canada Inc.) is known as Pantoloc. Pantoloc is a protein pump inhibitor [PPI] that contains pantoprazole as its active ingredient and is available in 20 mg and 40 mg tablets.

[8] Pantoprazole was covered by five patents listed on the Patent Register maintained by the Minister of Health; Patent Nos. 2,109,697 [the 697 Patent], 2,310,585 [the 585 Patent], 2,092,694 [the 694 Patent], and 2,089,748 [the 748 Patent]. The fifth patent, No. 1,254,215 [the 215 Patent] was the substance patent for pantoprazole and expired May 16, 2006. Apotex did not challenge the 215 Patent and therefore the Notice of Compliance [NOC] to allow Apotex's version of pantoprazole on the market could not issue until after May 16, 2006.

[9] Apotex served three Notices of Allegation [NOAs] on October 26, 2005 for the 585 Patent; on January 18, 2006 for the 694 and 748 Patents; and on January 30, 2006 for the 697 Patent.

Apotex served two earlier NOAs on Takeda for the 694 and 748 Patents which were withdrawn.

[10] Takeda filed a Notice of Application against the January 18, 2006 NOA in regard to the 694 and 748 Patents (Court File T-427-06). Takeda did not commence Notices of Application against the other NOAs.

[11] The Minister of Health certified that the examination of Apo-pantoprazole was complete on March 9, 2007. By virtue of the Regulations, Apo-pantoprazole went on "patent hold" and would not receive its NOC until the conditions in the Regulations had been met.

[12] The parties have agreed that Apotex would have received its NOC on March 9, 2007 "in the absence of these Regulations" (paragraph 8(1)*(a)*). The Court accepts the parties' agreement on this matter as it does on all other matters where there is agreement.

[13] Justice Gauthier dismissed Takeda's Notice of Application on March 3, 2008, with public reasons on March 6, 2008. For purposes of calculating Apotex's loss, the parties have agreed that the end of the Relevant Period in this case is March 5, 2008.

[14] Reflecting Justice Snider's description of the task in assessing compensation to be awarded (see *Apotex Inc v Sanofi-Aventis*, 2012 FC 553, 410 FTR 78 [*Apo-Ramipril*] at paragraph 6 thereof), the question before this Court in this case is:

> "What would have happened if Takeda had not brought an application for prohibition?"

The task is complex, theoretic and akin to revising history by changing some facts and predicting the outcome – a "but for" form of analysis.

III. ANALYSIS

A. *Issue 1 – Burden*

[15] The parties have raised two aspects with respect to onus which are addressed differently. The first aspect is to determine which party bears the onus for which issue. For ease of reference, the Court has generally dealt with the onus matter at the beginning of each issue, on a case-by-case basis.

[16] The second aspect is to deal with the weight of the burden. In general, Apotex's argument is that a percentage weight may be appropriate – that the Court should consider a percentage probability and then apportion the deduction from damages according to that percentage.

[17] The percentage approach was referred to by Justice Hughes in *Alendronate 2012* at paragraphs 37 and 38 referring to the Supreme Court of Canada decision in *Athey v Leonati*, [1996] 3 SCR 458:

> 37 Also, both parties have cited and relied upon the decision of the Supreme Court of Canada in *Athey v Leonati*, [1996] 3 SCR 458, at paragraphs 26 and 27, which I repeat:
>
> > 26 The respondents argued that the trial judge's assessment of probabilities in causation was similar to the assessment of probabilities routinely undertaken by courts in adjusting damages to reflect contingencies. This argument overlooks the fundamental distinction between the way in which courts deal with alleged past events and the way in which courts deal with potential future or hypothetical events.
> >
> > 27 Hypothetical events (such as how the plaintiff's life would have proceeded without the tortious injury) or future events need not be proven on a balance of probabilities. Instead, they are simply given weight according to their relative likelihood: *Mallett v. McMonagle*, [1970] A.C. 166 (H.L.); *Malec v. J. C. Hutton Proprietary Ltd.* (1990), 169 C.L.R.

> 638 (Aust. H.C.); *Janiak v. Ippolito*, [1985] 1 S.C.R. 146. For example, if there is a 30 percent chance that the plaintiff's injuries will worsen, then the damage award may be increased by 30 percent of the anticipated extra damages to reflect that risk. A future or hypothetical possibility will be taken into consideration as long as it is a real and substantial possibility and not mere speculation: *Schrump v. Koot* (1977), 18 O.R. (2d) 337 (C.A.); *Graham v. Rourke* (1990), 74 D.L.R. (4th) 1 (Ont. C.A.).
>
> 38 I emphasize the last sentence of that decision; the hypothetical possibility must be real and substantial not mere speculation. Put another way, the possibility must be realistic and not simply hopeful.

[18] Justice Hughes' comments arise in the context of pricing only. He did not apply the percentage approach in that case.

[19] Justice Gauthier, then of the Federal Court, rejected that percentage approach in *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at paras 760-761, aff'd 2010 FCA 240, because it was only useful in the evaluation of potential future or hypothetical events for the purposes of assessing quantum of damages in a personal injury case.

[20] Like Justices Hughes and Gauthier, I will not adopt that approach. There were no arguments as to the scope of this approach; Apotex did not press this argument strongly. It adds a further and unnecessary level of speculative complexity to a process which is already speculative – where the question is "what would have happened if Apotex has not been prevented from entering the market?" This is also referred to as the "hypothetical world" from time to time here and in other cases.

[21] The better approach is to mirror as much as possible real world circumstances – to use history as the basis of the calculation of the hypothetical world. In this case the parties start from the premise that real world events post Apotex's NOC give the basis upon which to then work out what likely would have happened if Apotex had not been held back approximately one year.

[22] The evidentiary standard for any proposition asserted must be the civil standard of balance of probabilities that the proposition would be realized. Therefore, Apotex's approach on this aspect of the burden (to the extent that it continues to assert it) is rejected.

B. *Issue 2 - Number and identity of generic market entrants*

[23] This issue is directed at when and from whom Apotex would face competition from generic companies. It is Takeda who asserts that such generic competition would occur. Therefore, it is Takeda who bears the burden of establishing who the generic competition market entrants would have been and when they would have entered the market.

Justice Hughes in *Apotex Inc v AstraZeneca Canada*, 2012 FC 559, 410 FTR 559, at paragraph 35, neatly summarized the governing principle:

> 35 In brief, it may be said that the party who has led sufficient evidence to put an issue "in play", must, to succeed on that issue, put in sufficient evidence so that on the balance of probabilities, the relevant facts are accepted by the Court as having been proved. Thus Apotex must put in play and subsequently prove on the balance of probabilities the facts that it needs to establish its case for compensation. AstraZeneca must put in play and subsequently prove those facts that it asserts disqualifies Apotex or reduces or negates Apotex's claim for compensation.

[24] On this issue, The Court heard from a number of industry and party witnesses:

- Dr. Bernard Sherman, Chair, Apotex

- Gordon Fahner, Vice President, Business Operations and Finance, Apotex
- Peter Hardwick, Senior Vice President, Sales and Marketing, Apotex
- Frank Murphy, Vice-President, Finance IT Operations, Takeda
- Michel Robidoux, President and General Manager of Sandoz Canada Inc.
- William David Boughner, Director of Strategic Initiatives, Teva
- C. Benjamin Gray, Vice President, Legal and General Counsel, Mylan Pharmaceuticals
- James Erb, Entrepreneur, GRX Healthcare
- Ajay Vashisht, Vice-President of Commercial Operations, Ranbaxy

[25] Both parties advanced different scenarios for the Relevant Period in respect of the degree of competition:

- Apotex's Scenario 1 assumed Apotex was the sole generic for the Relevant Period.
- Apotex's Scenario 2 (also Takeda's Scenario 3), which was the "Common Scenario", had Apotex as the sole generic for three months at which point Ranbaxy entered. This was described as "Common" not because it was an agreed scenario but it is the only one both parties costed out fully.
- Takeda's Scenario 1 assumed Teva and Ranbaxy were the first entrants followed by the other generics six months later.
- Takeda's Scenario 2 had Apotex as the sole generic for one month after which Ranbaxy entered, followed by Teva two months later and a series of other generics three months later.

[26] As will be seen from these Reasons, the Court had to make its own determination rather than accepting one specific scenario. The use of multiple scenarios underscores the speculative nature of the parties' positions and generally are unhelpful.

[27] Takeda accepts that "but for" its application for prohibition, Apotex would have received an NOC for the Apo-pantoprazole 20 and 40 mg tablets on March 9, 2007 and that Apotex had and has available sufficient manufacturing capacity and motivation to enter the market.

[28] Takeda also takes the position that there would have been three non-related party generics in the market upon filing for their respective NOCs and the entry dates in the hypothetical world correspond to entry dates in the "real world". Therefore, Takeda says that the NOC dates for these generics would have been: Teva on September 1, 2006; Mylan on September 21, 2007 and Sandoz on October 19, 2007.

[29] With respect to Takeda's authorized generic [AG] Ranbaxy, Takeda contends that Takeda would have consented to Ranbaxy being in the market and that Ranbaxy would have entered the market at the same time as Teva.

[30] Takeda arrives at this position, at least in part, by concluding that the Regulations are removed from consideration in the hypothetical world in respect of all potential entrants. Takeda interprets the words "… would have been issued in the absence of these Regulations" in paragraph 8(1)*(a)* as applying to any generic who had applied for an NOC rather than applying only to the successful generic (in this case, Apotex).

[31] Takeda's position on the number and time of generics' entry into the market for pantoprazole is based on the following propositions:

- Ranbaxy would have entered the generic market and launched at the same time as the first entrant generic pantoprazole.
- Takeda would have received early warning of Apotex's imminent entry into the pantoprazole market.
- Given Takeda's interpretation of the Regulations, other generics are to be injected into the market in the hypothetical world on their patent hold dates.
- No permission from Takeda is required to enter the generic market in the hypothetical world.
- If this Court finds that permission is required, Takeda would have provided it on or after Apotex's launch.

[32] Apotex's position in summary is:

- Apotex would have entered the pantoprazole market on March 9, 2007 and Takeda would not have launched its AG (Ranbaxy in this instance) in the hypothetical world. This is based on the assumption that Apotex's 2007 launch would have been a surprise; Takeda would not have been in a position to launch an AG immediately and absent simultaneous launch of the AG with Apotex, Ranbaxy would not have entered the market.
- There are no other generics in the hypothetical world because Takeda would not have authorized other generics into the market. This requires a consideration of four scenarios developed by Takeda as to what would or could have happened.

[33] A critical consideration for this Issue 2 is how the Regulations are applied in the hypothetical world as it has impact on the entry of other generics. Either these other generics would be allowed to enter the market as of their patent hold date (a result favourable to Takeda) or they would be forced to litigate or be allowed into the market by Takeda (a result favourable to Apotex).

[34] In *Apo-Ramipril*, the Court held that in the hypothetical world, notice would not have been given. Underlying that conclusion is the premise that notice is part of a scheme of inter-related benefits that accrue to the first person under the Regulations; the other benefits being the right to file a prohibition application and the 24-month stay.

[35] The *Apo-Ramipril* decision is under appeal but until the Court of Appeal concludes otherwise, in constructing the hypothetical world, I conclude that Apotex would not have given notice of its NOA. The Court of Appeal's decision in *Apotex Inc v Merck & Co*, 2011 FCA 329, does not assist Takeda as that decision is distinguishable in that the case dealt with a prohibition application and preliminary application; not section 8 damages (see paragraphs 74-75 thereof).

[36] Although Apotex would not have given notice of its NOA on January 18, 2006 (which would suggest that Takeda would have been surprised by Apotex's market entry and would take some time to react to the competitive change), the situation is complicated by other NOAs in play.

[37] Firstly, Apotex submitted NOAs on August 15, 2005 relevant to the patents in issue as well as the 585 Patent and 697 Patent but withdrew them. It then filed the relevant NOAs again, which are the subject of Justice Gauthier's decision. As a consequence of *Apo-Ramipril*, those notices are

therefore not considered as part of the factual matrix of the hypothetical world. Takeda would not have had warning of Apotex's intent to enter the market on the basis of these NOAs.

[38] Furthermore, in the real world in the last quarter of 2006, Takeda's head office decided not to proceed with its AG despite both Apotex and Teva providing NOAs. Takeda was not prepared to launch its own AG in the face of warning that other generics were prepared to launch.

[39] On the facts surrounding these NOAs, I have concluded that while Takeda would not necessarily have been caught by complete surprise that Apotex entered the market, the real issue is whether Takeda was prepared or at least sufficiently prepared to compete with Apotex's generic drug and what strategy it would have employed.

[40] I conclude that in the hypothetical world, Apotex acts without the obligations and limitations of the Regulations. I also find that even with the warning of impending entry, Takeda did not decide to pursue an AG strategy prior to Apotex's launch and therefore would not have done so in a hypothetical world.

[41] The next matter to consider is whether Takeda would have launched an AG to meet Apotex after it had launched and when it would have done so.

[42] Takeda has summarized five factors to be addressed in this regard. While it is not an exhaustive or a minimal list, it is sufficient for purposes of this case:

1. the importance of the drug to the brand company – an important factor;

2. whether in fact an AG was authorized;

3. the brand company's financial consideration to introduce an AG;

4. the business arrangements under which the drug is sold and the financial viability of the AG; and

5. whether the brand company had contemplated the possibility of generic entry and possibility of a launch of an AG.

[43] I conclude that Pantoloc was very important to Takeda as it was virtually its only drug in the Canadian market representing 96-98% of its sales. As Frank Murphy, Vice-President, Finance IT Operations of Takeda explained, in around 2002 the brand company began to consider how to extend and defend this brand.

While the drug was important to Takeda in Canada, it appeared to be less so to the head office in Europe. There was not the same level of support from head office as the Canadian subsidiary seemed to require.

[44] With regard to the second factor, an AG – Ranbaxy – was ultimately authorized by Takeda. Apotex contends that it was a self-serving authorization to minimize section 8 damages. Even if that were so, the AG was authorized and was a real factor in the market. It was more than a "shell" or "stalking horse".

[45] It is with regard to the third factor that Takeda's case becomes troublesome (at least for Takeda). The financial considerations of Takeda to introduce an AG show problems in determining what strategy to apply and in obtaining corporate support from Takeda's head office.

[46] At a meeting in November 2005, Takeda executives presented to Takeda's head office a document entitled "Priorities". The document outlined three strategies: (1) defending the intellectual property; (2) launching Pantoloc M made with a new salt to extend the patent; and (3) launching an AG.

[47] Murphy testified that there was no hierarchy amongst these priorities but he did admit that they were listed in the order of greatest revenues.

[48] The document is critical evidence as it sets out the strategies considered to deal with Apotex's market entry. It shows that Apotex's entry was not a surprise but it also shows limited preparation to deal with generic competition. It also addresses the fifth factor that Takeda had contemplated an AG launch.

[49] The Court must determine whether Takeda would have launched an AG at all (and when) or would have pursued one of the other two strategies. Takeda's position that it would have launched an AG and done so immediately is weakened by head office's decision to shelve the AG concept pending resolution of the difficult transfer pricing problem. The position is further weakened by the absence of substantial explanation for abandoning the "priority one" strategy of defending the intellectual property and moving to "priority three".

[50] Takeda has established that the Canadian office had proceeded quite far down the road of creating an AG. Even in the face of head office opposition, the Canadian operation kept the AG strategy as a fall-back position to be able to launch when and if it could.

[51] The Canadian operation had taken several steps – a generic partner had been selected, heads of agreement and confidentiality agreements were in place. However, both Takeda and Ranbaxy needed their respective head office's approval.

[52] In the real world, Takeda received approval for an AG about one year later in the fall of 2007. In the hypothetical world, the issue is how quickly Takeda could move. Ranbaxy Canada required approval from both its US office and its India office; something that could proceed concurrently. There are no timelines advanced for these approvals. A cross-reference would have to be sought from Health Canada; a two to four week process.

[53] Even with a motive to move quickly on the part of Takeda, the evidence establishes that Takeda's head office did not fully endorse its Canadian strategy of an AG, that its Canadian executives were to some extent swimming against the head office current and that the resolution of transfer pricing issues was important and complex. However, the AG strategy seems to be the best option available.

[54] Takeda alleges it would have launched an AG to respond to Apotex's market entry on March 9, 2007, but Ranbaxy would not be up and running as quickly as Takeda alleges due to the

inherent corporate approvals, less than fulsome enthusiasm from Takeda's head office and related internal issues.

[55] As a consequence, I find that the most reasonable date for Ranbaxy's launch in the hypothetical world is three months (June 9, 2007) after Apotex's entry. This is the date estimated in the Third (or Common) Scenario the parties examined.

[56] With respect to the entry of other generics, the same type of factors are taken into consideration. As indicated earlier, the issue of whether in Apotex's hypothetical world the other generics are subject to the Regulations has been resolved in *Apo-Ramipril*. In considering Teva's and other generics' entry in the hypothetical world, they are subject to the Regulations and Takeda does not enjoy the benefit of claiming that because Apotex was successful, all other generics are, for purposes of hypothetical world analysis, free to enter the market.

[57] Takeda has also raised the issue that since other generics could make section 8 claims, there could be multiple recoveries against Takeda which exceed the total of real losses.

[58] There are several methods by which this problem may be alleviated but ultimately it is the loser's risk. Justice Snider in *Teva Ramapril* suggested that multiple recoveries could be accounted for by judicial discretion under subsection 8(5). Further, this Court attempts to have the same judge hear related section 8 damages claims; as was planned in respect of this drug (however, the other section 8 damages case was settled under a confidential agreement). The best resolution is for a

defendant to put forward a compelling hypothetical world which accurately reflects the results of other claims.

In the end, this Court need not resolve the problem of multiple recoveries as that is not the matter before it.

[59] In considering whether other generics would enter the market, Justice Hughes in *Alendronate 2012* outlined three factors to determine if a generic would enter the market:

- when the generic would have received its NOC;
- whether the generic had the capacity to manufacture or acquire the product in the relevant time; and
- whether the generic was motivated or dissuaded from entering the market during the relevant period.

[60] Takeda's principal position is that it would have given permission to the other generics Teva (then known as Novopharm), Sandoz, Mylan (then known as Genpharm) and Cobalt to enter the market on their patent hold date in the hypothetical world where Apotex entered as of March 9, 2007. Takeda goes so far as to say that it would have allowed Teva into the market in either September 1, 2006 or October 20, 2006 – six months ahead of Apotex.

[61] The date on which there would be generic competition to Apotex in the hypothetical world is important for a number of reasons. Not only does such competition influence the size and share of the generic market calculations but it impacts the price at which tablets are sold, particularly where Apotex would be the sole generic.

[62] Takeda relies on *Alendronate 2012* in support of its position that Teva should be included in the market from its patent hold date six months before Apotex's deemed entry. In that decision Justice Hughes injected Teva into the market on the date it would have been on patent hold.

[63] However, the facts in *Alendronate 2012* are quite different from those in this case. In *Alendronate 2012*, the parties let the generics on the market in the real world and therefore in the hypothetical world. In the present case, Takeda resisted the various generics at every turn, most particularly Teva.

[64] Takeda's actions in the real world belie its position that it would have consented to Teva's entry in a hypothetical world. In summary, when Takeda lost its monopoly, it continued to stifle other generics' entry into the market including prosecution of ongoing applications against Teva, Cobalt, Sandoz and Mylan, denying generic requests to be let into the market, fighting the generics' paragraph 6(5)*(a)* motions to have the prohibition applications dismissed and bringing a motion for reconsideration when Teva succeeded in defeating Takeda's application.

[65] There is no credible evidence that in a hypothetical world, Takeda would have allowed Teva on the market ahead of Apotex. In fact, the best evidence is that even after Apotex would be in the hypothetical market, Takeda would have fought Teva to the bitter end.

Therefore, in a hypothetical world, I find that Teva would have entered as of its NOC hearing date of September 2008.

[66] With respect to the other generics, Takeda negotiated to allow Cobalt, Mylan and Sandoz on the market in exchange for waiving section 8 damages. It says that it would have done the same in the hypothetical world because Apotex had unlocked the patent.

[67] While there would not, in a hypothetical world, have been any unlocking by Apotex because there would have been no prohibition proceeding, it is more likely than not that in respect of these smaller generics, Takeda would have permitted their entry as of their respective patent hold dates.

[68] In conclusion on this Issue 2, I have concluded that Ranbaxy would only have come into the market three months after Apotex. A third generic (Teva) would have entered on its NOC hearing date and other generics would have come in on their respective patent hold dates.

C. *Issue 3 - Apotex's Share of the Generic Market*

[69] This issue is an affirmative claim made by Apotex and therefore it has the onus to establish what its share of the generic market would have been in the hypothetical world.

[70] The issue is determined largely through the expert evidence commenting on various scenarios (earlier described) presented by the parties which assumed certain competition circumstances.

[71] The experts who testified on this issue were:

For Apotex:

Andrew Harington who was qualified as a chartered accountant, chartered business valuator and chartered financial analyst with expertise in investigative and forensic accounting, business valuation and loss quantification in commercial and intellectual property disputes.

Dr. Andrew Tepperman, an expert in industrial organization and economics with particular expertise in pharmaceutical markets and in competition in pharmaceutical markets.

For Takeda

Dr. Paul Grootendorst, an expert in economics with particular expertise in pharmaceutical markets.

[72] Both Grottendorst and Tepperman used econometric models in their calculations. Harington's evidence was based on data to which business judgment was applied to determine market shares.

[73] While there are differences in approach, methodology and results between the experts, each was well qualified, forthright, candid and credible. They fulfilled their obligations as experts. In preferring one expert over another, the Court does so because it finds their approach and results more compelling in the context of all the evidence, not because of any issues of integrity or candor.

[74] There are significant differences in the market shares calculated by Harington and Grootendorst:

- Harington concluded that Ranbaxy would gain market share in the first three months in the market before reaching "steady state" (conceptually a form of mature market position);
- Grootendorst suggested Ranbaxy would reach this steady state upon entry into the market;
- After three months, both experts reached similar conclusions with respect to Apotex's and Ranbaxy's market shares.

[75] Harington used sales data for five molecules including two PPIs, calculated average market share for all five molecules on a province-by-province and month-by-month basis. After performing these calculations, Harington applied business judgment to the calculations in order to determine market share values, discounting anomalous market share figures in certain provinces.

[76] Grootendorst engaged in an econometric analysis using data from 23 comparator molecules. His model then used the number of competitors, the number of months that Apotex preceded the second generic market entrant and the number of months the Apotex product was on the market as variables. Several other variables were used but the equation was never set out in the experts' report.

[77] I find that the first results of the three months of the hypothetical world scenario is the critical difference between these two experts and the remaining eight months' results which were modelled are essentially the same.

[78] The third expert, Tepperman, was called largely to rebut and criticize Grootendorst's econometric model. However, both parties were substantially comfortable with his approach which was used for the scenarios Takeda 1 and 2. Tepperman never analyzed the Common Scenario, the scenario largely accepted by the Court.

[79] Grootendorst's modelling suffered from using molecules with small sales which distorted their utility as comparators. The model used comparator molecules where the second generic entered the market more than ten months after the first generic and molecules that have simultaneous entry, thus distorting the timing element of comparison. It also included scenarios with more than three market participants.

[80] I find that Grootendorst's analysis is not a reliable basis for predicting Apotex's market share because it is unnecessarily complicated and opaque compared to Harington or Tepperman; it reached an unreasonable conclusion that steady state would occur instantly, its comparators were flawed; no regard was given for the "first moves" advantage; the results contained numerous inconsistencies and prediction errors.

[81] The Harington analysis was not free from problems. Harington took a more conventional market analysis approach, relying on real numbers and applying business judgment – the very common features of opinion evidence. However, many of the calculations were subjective and not particularly well explained. As Tepperman noted, Harington did not say how he selected various percentages specifically.

[82] However, opinion evidence always contains subjective elements, educated choices even in a purely mathematical model. As between Harington and Grootendorst, the Court favours Harington because the approach is more realistic and accords more closely in the result to the other facts surrounding this case. The fact that Tepperman supported Harington's approach generally (despite some reservations) is significant. There is no magic nor necessarily any compelling reason to use an econometric model in the Common Scenario.

[83] Although Tepperman did not assess the Common Scenario, the Court notes that Tepperman was particularly persuasive in his evidence. His model used a large number of observations, it was objective, his approach was balanced, he was the least criticized witness and even Grootendorst acknowledged that it was a good model.

[84] In a "perfect world", Tepperman would have analyzed the Common Scenario. However, even though Apotex suggested that the Court order Tepperman to determine Apotex's lost volumes and Tepperman acknowledged that mechanically speaking, it would be reasonably straightforward to do, he put in an important caveat:

> Q: Okay. And having modelled it for scenario 1, which involved Teva, Apotex, Ranbaxy and three other generics, so six, and scenario 2 and seeing your results, you used the term "economist inference". Is there any inference that you have on its applicability to scenario 3?

> A: Well, I wasn't asked to analyze scenario 3, so I haven't used it to analyze scenario 3. If I were asked to consider scenario 3 using an econometric model, I think there are a number of things that I would want to think about before I set out and mechanically apply this model to scenario 3. It's quite a different scenario. In scenario 3, Apotex is one of two, where the only other market participant is a much smaller authorized generic. And in scenarios 1 and 2, Apotex is one of six. It's a much different circumstance.
>
> (Trial Transcript at 855-856).

[85] The effect of sending the matter back to Tepperman is not simply some mathematical exercise but the creation of an entirely new and different expert's report with no advance knowledge or acceptance of the assumptions or other circumstances leading to the calculations.

[86] Absent the parties' consent to creating a new and independent expert's report, the Court must decide the matter on the basis of the best available evidence presented. In that regard, the Court must accept the Harington Report as the basis for calculating Apotex's share of the generic market in that hypothetical world accepted by the Court.

D. *Issue 4 – Apotex's Lost Revenue/Pricing*

[87] Apotex accepts that it is its burden to prove its lost sales and any deductions from those sales.

[88] The issue to be determined under this section is the price at which Apotex's Apo-pantoprazole would be sold under provincial formulary regimes. I concur with Apotex that its pricing depends on whether Apotex would have been in the market as the sole generic source or

with generic competition. The Court has already determined the period of time Apotex would have been the sole source generic.

[89] The principal spokesperson for Apotex in this regard is the Founder and Chair of Apotex, Dr. Bernard Sherman. He was backed up by Messrs. Fahner and Hardwick.

The Court also heard from the following provincial officers and the following expert witnesses:

- Brent Fraser, Director, Drug Program Services, Ontario Public Drug Programs Bureau, Ontario Ministry of Health and Long-Term Care;
- Lucie Robitaille, Vice President, Governance and Administration, Institut National d'Excellence en Santé et en Services Sociaux;
- Glenn Monteith, Chief Delivery Officer, Alberta Health;
- Neil Palmer, Takeda's expert witness – a pharmaceutical industry consultant with expertise in formulary listing and pricing regimes of the Canadian pharmaceutical industry; and
- Ross Hamilton, Apotex's expert witness – a chartered accountant with a specialist designation in investigative and forensic accounting and expertise in damages quantification in commercial and intellectual property disputes including in the Canadian pharmaceutical marketplace.

[90] It was Apotex's position that generic companies aggressively maximize profit when they are the sole source generic because price and hence profits are significantly lower in a competitive environment.

Apotex also contends that the generic has a strong motive to seek the highest price where it is faced with a potential claim for patent infringement from the brand (referred to as being "at risk").

[91] Sherman testified that Apotex would have sought as high a percentage of the brand's price as possible in all market scenarios and in all provinces while it was the sole generic in the market. Based on having received high prices in the past, Apotex asserted that its price would be 80-90% of the brand price during that sole generic period.

[92] In a generic competitive market, Apotex claimed that in Ontario, Quebec and Newfoundland the formulary price would drop to 50% of the brand price due to provincial regulation. In the rest of Canada absent provincial regulation, Sherman postulated that even with a second generic in place, both generics would keep the price as high as possible. In this regard Sherman's thesis was supported by a Sandoz representative who said that it would match Apotex. The generic competition would be fought out on the matter of rebates not price.

[93] Takeda's basic position was that Apotex would never be the sole source and that in a competitive market, Apotex's price would be approximately 63% of the brand. Takeda submits that in a sole source environment Apotex's price would be only 75% (not 90%) of the brand.

[94] Rather than repeat here the speculative and self-serving positions of the parties, the Court turns to and had the benefit of very credible fact witnesses from provincial formularies on which to rely. The witnesses, Fraser, Robitaille and Monteith, had no personal or professional stake in this case. They were knowledgeable and experienced and gave clear and convincing support for their

opinion of what likely would have happened in the hypothetical world. Even Palmer concurred that where his evidence was in conflict with them, the Court should rely on their evidence. Lastly, in total, the witnesses represented 80% of the Canadian market and in a real sense they were the customers and they knew what they were prepared to pay, backed by provincial regulation. The Court clearly prefers and accepts their evidence.

[95] Turning to Ontario, despite Apotex's claim that it would obtain prices at 90% of the brand, the province was governed by Bill 102 at the time Apotex would have theoretically entered the market. The legislation and regulations set a price floor of 50% of the brand price but did permit exceptions to be granted. Fraser acknowledged that it was "more likely than not" that some exceptions would be granted to Apotex initially.

[96] Fraser referred to his experience with different requests for exceptions where 40% of exceptions were priced at 76% of the brand price or greater and 30/35% of exceptions were priced between 50% and 75% of the brand price.

[97] For example, in the case of Apo-lansoprazole, a drug in the same therapeutic class (although a capsule not a tablet), that drug was listed at 75% of the brand price.

[98] Given the evidence with respect to Ontario's policies and practices, I find that in Ontario for the period Apotex was the sole generic source, it would have been granted an exception at 75% of the brand price.

[99] Although Apotex argued that Apo-pantoprazole was "at risk" when the sole generic source and that would have allowed for a higher price exemption, Fraser was clear that Ontario did not consider litigation risk. I accept his explanation despite evidence that the scope of exemptions available was broad enough to consider litigation risk.

[100] In Quebec, the province has a scheme known as "most favoured nation" [MFN] treatment. In practice, this means that Quebec pays to the generic the lowest price of the brand that has been negotiated anywhere in Canada.

[101] Because witnesses and counsel often referred to the generic price as 50% of the brand price, it must be made clear that in Quebec the MFN clause is based on price set for the brand not a percentage of brand price. Both Robitaille and Palmer testified to that effect and I accept that evidence as being the more objective credible evidence available.

[102] Robitaille testified that the maximum price available on a sole source generic basis is 60% of the brand subject to discretion in the Institut to increase the price. There are five factors to be examined in such an instance but being "at risk" is not one of them.

[103] Robitaille confirmed that it would be highly unlikely for Apotex to receive permission to price Apo-pantoprazole at 90% of the brand when it was the sole source generic. The attempts by Apotex to show that an exception to the usual 60% rule would have been warranted were not successful. There were instances of some drugs being granted exemption in the 70-80 or 90% range

but there was not enough evidence to counter Robitaille's opinion or to establish that an exception likely would have been granted.

[104] Therefore, for Quebec, during the sole source period, Apotex would be reimbursed at 60% of the brand price or if the price at 75% of the brand in Ontario was lower than this 60%, it would have been subject to MFN and received that lower price.

[105] Apotex argued that in the other provinces during the sole generic source period, it would have demanded and received 90% of the brand price. Other than Newfoundland which had a MFN scheme, the other provinces did not have a regulatory scheme like Ontario.

[106] As Monteith said in respect to Alberta, while Apotex might have tried to obtain approval for a 90% price, the Alberta government would not have agreed. Alberta had a policy of limiting the price, in this situation, to 75% of the brand. I accept that on a balance of probabilities, as Monteith explained, Apotex would have received a price of 75% of the brand in Alberta.

[107] The evidence in respect of the other provinces (other than Ontario, Quebec and Alberta) was not particularly compelling for either side. However, I accept Palmer's evidence over that of Sherman. As Palmer explained, Newfoundland has the MFN rule and pays to the generic the lowest price of the brand that has been negotiated anywhere in Canada. He also explained that the other provinces had the former Ontario rule of 70/90 (sometimes called 70/63). This meant that the first generic received 70% and thereafter the price was 90% of the 70% (63%).

While all provinces were moving to the 50% rule, in the Relevant Period the 70/90 (70/63) rule was in place outside of Ontario, Quebec, Alberta and Newfoundland.

[108] In summary, for the sole generic period, Apotex would have had:

- a 75% listing in Ontario;
- a 60% listing in Quebec (unless the price in Ontario was less than 60% of the brand price in Quebec);
- 75% in Alberta; and
- 70% in the remaining provinces.

[109] Having found that the market would have gone multi-source, the Court finds that the prices thereafter would be:

- 50% in Ontario and Quebec (accepted by Apotex). Quebec could be slightly different because of MFN but the Court cannot determine that amount.
- 63% in Alberta and the other provinces except Newfoundland which, pursuant to MFN, would be the Ontario price.

E. *Issue 5 – Inventory Adjustment*

[110] Both parties agreed that a reporting system delay occurred. Remedying this delay requires an inventory adjustment (known as "pipefill"). The onus of establishing the pipefill rests with Apotex.

[111] The logistics and reporting system is as follows:

- a generic pharmaceutical manufacturer's sale is recorded in its accounting system. These sales are referred to as "ex-factory" sales;
- ex-factory sales are generally composed of (i) sales to a wholesaler who then distributes the product to smaller pharmacies, (ii) sales to a chain that may act as its own wholesaler, and (iii) sales directly to a retail pharmacy;
- inventory received by pharmacies is tracked by IMS and referred to as Canadian Drug and Hospital [CD&H] data;
- once a product is on the market, the ex-factory information approximates CD&H data subject to timing differences and systemic under-reporting by pharmacies because IMS does not receive data for all inventory sales made to pharmacies; and
- before a product is established, the ex-factory sales will exceed the amounts recorded in the CD&H data until the pharmacies have built up normalized inventory levels/reaching steady state.

In summary, CD&H data does not record the initial pipefill that occurred in the real world; therefore, an adjustment is made to account for this recording gap.

[112] The expert evidence in this regard came from Ross Hamilton and Andrew Harington whose qualifications have been previously described.

[113] These experts agree that the calculation of appropriate inventory adjustment requires an analysis of when "steady state" sales are achieved. This occurs when CD&H data shows "normalized" sales.

[114] The experts disagree as to when steady state was achieved. Takeda's expert Hamilton estimated steady state after approximately four months which required 0.9 months' inventory adjustment. Apotex's expert Harington estimated steady state in seven months which required an inventory adjustment of six weeks. In the end, there was a disagreement between the experts of two weeks' inventory adjustment.

[115] At the core of the dispute is the methodology employed by the experts. Harington treated all markets as equal in size and made his calculations on that basis. Hamilton, on the other hand, weighed the different markets recognizing that in smaller markets (BC/Manitoba), steady state was reached later than larger markets (Alberta, Ontario, Quebec). Hamilton applied judgment in his weighting exercise.

[116] The Court is no expert in this exercise and can only deal with it in the broadest terms – taking a "broad axe" to the issue as suggested by Apotex's counsel. It seems that recognizing different sizes of markets makes more sense than treating them as equal. Thus, Hamilton's methodology makes more sense.

[117] However, there is a problem with Hamilton's numbers – one which he recognized. He acknowledged that Quebec should have reached steady state at six months rather than his report's conclusion of four months. There were similar problems with Manitoba and BC.

[118] Having recognized that Hamilton's methodology makes more sense, the Court adopts Mr. Radomski's suggestion to resolve the problems with Hamilton's report. The Court finds in favour of

Hamilton's approach but directs that Takeda have Hamilton redo his analysis taking into account the correct calculations for Quebec, Manitoba and BC.

[119] The last point in this inventory adjustment issue is the calculation of the amount that would be in inventory. Hamilton concluded that based on the difference between Apotex's sales and IMS sales after steady state was reached, a 13.2% adjustment reduction had to be made to total sales leading to steady state.

[120] Harington took a less precise view but he approved of Hamilton's approach on this matter. It would seem that the adjustment would be in the 11-13% range and can be clarified in Hamilton's subsequent work.

F. *Issue 6 – Double Ramp Up*

[121] The issue of double ramp up relates to the income and expenses Apotex would experience when it commenced sale of Apo-pantoprazole. As such, the burden rests with Apotex.

[122] Ramp up is the initial period during which the generic drug has to be made or acquired, orders received from customers and the drugs shipped to those customers. It covers the period before Apo-pantoprazole achieves steady state sales.

[123] In the real world, Apotex experienced ramp up after it was successful in resisting Takeda's attempt to obtain a prohibition order which lasted until it reached steady state.

[124] In the hypothetical world, the calculation of Apotex's loss reflected this ramp up incurred or experienced in the Relevant Period.

[125] The effect of the calculation is that Apotex experiences the effect of ramp up in the hypothetical world resulting in a deduction from what would be steady state revenue and then in the real world it experiences the same ramp up consequences. This is double counting for the same circumstance; a disadvantage to Apotex and an advantage to Takeda.

[126] The evidence shows that when the generic is in patent hold and particularly in this case where Takeda (and its predecessor company) were aggressive and prepared to fight any generic entering the market, Apotex was precluded during the Relevant Period from taking steps to mitigate or reduce this ramp up. While it might be able to stockpile product, it cannot realistically take steps to get to steady state almost immediately after it receives its NOC.

[127] This ramp up is factored into the hypothetical world when assessing the Relevant Period. Apotex then experiences a second ramp up in the real world when it builds up to steady state which occurs outside the Relevant Period.

[128] The cases to date which address double ramp up focus on the 2nd ramp up consequences. They do not focus on the economic loss of not being able to ameliorate ramp up which occurs inside the Relevant Period.

[129] In this Court, based on the Court of Appeal's decision in *Apotex Inc. v Merck & Co.*, 2009 FCA 187, [2010] 2 FCR 389 [*Alendronate - FCA*], Justice Snider in *Ramipril* concluded that Apotex could not claim the loss of the ramp up after it received its NOC because it would be claiming for a form of lost revenue which "occurred" outside the period of the statutory stay.

[130] Justice Hughes in *Alendronate 2012* apparently felt that the Court of Appeal in *Alendronate – FCA* did not have the situation of double ramp up in mind when it precluded compensation for lost future revenue and market share outside that particular relevant period. Nevertheless, Justice Hughes "in the interests of comity and in the expectation of an inevitable appeal" adopted Justice Snider's view and did not allow compensation for double ramp up.

[131] With the greatest respect, I do not view the determination of "double ramp up" in the present case as resolvable under judicial comity nor a matter on which one can presume to be eventually resolved on appeal.

[132] The arguments before me have been developed since the matter was heard by Justice Snider. The considerations and factors which this Court must take into account are somewhat different than those before Justices Snider and Hughes.

[133] In resolving the conundrum presented by the double ramp up issue, it is helpful to return to some principal concepts. Section 8 of the Regulations is to be interpreted and applied in a manner consistent with section 11 of the *Interpretation Act*, RSC, 1985, c I-21 – to give it such fair and liberal interpretation as achieves its purpose.

11. The expression "shall" is to be construed as imperative and the expression "may" as permissive.	11. L'obligation s'exprime essentiellement par l'indicatif présent du verbe porteur de sens principal et, à l'occasion, par des verbes ou expressions comportant cette notion. L'octroi de pouvoirs, de droits, d'autorisations ou de facultés s'exprime essentiellement par le verbe « pouvoir » et, à l'occasion, par des expressions comportant ces notions.

[134] The *Patent Act*, and in particular section 8 of the Regulations, are not tools to penalize generic drug manufacturers where they have been successful against a brand company.

[135] Section 8 is a reflection of the normal rules in civil litigation governing the operation of interlocutory injunctions. The subsection 8(1) mandated stay is the equivalent of the injunction. The phrase "… the first person is liable to the second person for any loss suffered during the period …" (the stay period) is the equivalent of the undertaking given by the enjoining party to pay damages claimed for losses during the period of the injunction. The intent under the Regulations as under injunction law is to return the enjoined party to the position it would be in if the injunction/stay had not been granted (assuming the enjoined party is ultimately successful).

[136] In *Alendronate – FCA*, the Court of Appeal was dealing with a multi-faceted case covering constitutional issues and a claim for disgorgement of profits. On the more narrow issue referred to by Justices Snider and Hughes, the Court of Appeal was dealing with Apotex's claim for lost sales and market share well beyond the applicable Relevant Period. The learned trial judge described the claims as one for future losses.

[137] The difficulty with Apotex's claim for future loss was that it was the equivalent of present valuing future losses and shoehorning the amount into the stay period. It smacks of artificiality to suggest that those losses extended out over several years were "suffered" within the Relevant Period. It is this artificiality which appears to have caused the Court of Appeal to turn aside these future losses.

[138] The facts of *Alendronate – FCA* are clearly different from those in the present case. In the present case, a loss of revenue is being double counted against the successful party. The offending party, Takeda, is permitted a windfall.

[139] I do not read the *Alendronate – FCA* decision as endorsing that section 8 damages calculations are to ignore double counting. While the *Alendronate – FCA* decision can be distinguished from the facts of this present case on that basis alone, I also see no principled conclusion in the Court of Appeal's decision which endorses double counting.

[140] I note that the expert evidence (particularly Apotex's Harington and Takeda's Hamilton) in this case effectively confirms that ramp up loss should only be counted once.

[141] In calculating "… the loss suffered during the period …", the Courts, through expert opinion, create a hypothetical world – an attempt to replicate what would have happened had there not been a stay and award damages on the basis of what the successful party would have otherwise

earned. However, this hypothetical world exercise is not mandated by law; it is a useful tool in trying to arrive at proper compensation. It is not a formula nor is it to be rigidly applied.

[142] Subsection 8(5) of the Regulations gives to the Court a wide discretion to "take into account all matters that it considers relevant to the assessment of the amount" of compensation.

8. (5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).	8. (5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

[143] The provision refers to all matters relevant to the assessment of compensation. It does not restrict the Court to matters of conduct of a party or similar matters.

[144] The discretion must, however, be exercised in a manner consistent with the purpose of section 8 and of the Regulations and consistent with the provision read as a whole.

[145] Whether a matter is double counted is relevant to assessing compensation. The purpose of section 8 is to provide proper compensation.

[146] There is nothing in law and certainly nothing in equity which requires the Court to ignore the factor of double counting and to adjust the compensation accordingly.

[147] Harington attempted to account for this double ramp up phenomenon and subject to such adjustments as may be necessary in a final accounting, his calculations are accepted.

[148] I conclude that it is a proper exercise of the Court's discretion to not include "ramp up" in the Relevant Period where "ramp up" was experienced in the real world.

G. *Issue 7 - Rebates*

[149] As noted earlier, competition in the distribution of pharmaceuticals not only revolves around price but also around the rebates that would be given to buyers to foster sales, both current and future. Justice Hughes in *Alendronate 2012* fairly described the rebate practice and issues:

> 94 The practice seems to be a murky one. There seems to be no established figure for the rebates; nor does one particular rebate necessarily, but not inevitably, apply to one particular product and another to another. The rebates seem to be applied collectively to a range of products and vary over time. Much seems to depend on the negotiating strength of the supplier, such as Apotex, and the purchaser, such as a pharmacy chain or purchasing group. Product exclusivity gives the supplier a stronger hand; non-exclusivity gives the purchaser a stronger hand. Even if there is exclusivity, a supplier may give a rebate in order to build goodwill or in expectation of favourable treatment in other areas. A purchaser who does not get a favourable rebate may seek to exact retribution elsewhere, or later. There is no science or exactitude that can be applied.

[150] It is basically Apotex's burden to show the rebate levels it would have paid since both parties acknowledged that the issue must be addressed. Aside from the experts Harington and Hamilton who touched on the rebate levels, Apotex's evidence was provided by Sherman, Fahrer (Vice President, Business Operations and Finance) and Hardwick (Senior Vice President, Sales and Marketing). Takeda relied on its expert and Virginia Cirocco, formerly of Shoppers Drug Mart, and Michael Blacker, a pharmacist from Windsor, Ontario.

[151] There are two issues in the rebates context. The first is what rebates would have been given in the single generic circumstance and in the multi-source environment. The second issue is what rebates would have been given to each type of purchaser – independent pharmacies, chain store pharmacies and "banners" (akin to a buying group).

[152] Apotex's basic position is that, like with pricing, during the sole source period it would have been concerned with its litigation risk and would have offered little or no rebates. Sherman said that he would not have authorized rebates.

[153] I consider his evidence on this and on pricing to be overstatement. The notion that Apotex would "squeeze" its ongoing customers for maximum price and offer them no rebate over a short period and knowing competition was coming, appears short-sighted and a counter productive - strategy. Given Apotex's success generally and Sherman's obvious business talents, I discount this self-serving evidence somewhat.

[154] Takeda's basic position was that rebates were always given by generics and that Apotex would have given the same level of rebates when it was the sole generic as it would have given in a multi-source market. Takeda also contends that the distinction between the three types of purchasers is irrelevant and Apotex's evidence, even from its expert Harington, is contradictory.

[155] The numbers advanced by the parties are in stark contrast. Apotex says its rebate level when it would be the sole generic is 0% and in a competitive market, it would be 44.7% rebate given to

chains and 0-10% rebate given to the independents' market (banners were considered to be, in effect, independents because rebates would be settled on a store by store basis).

Takeda's position is that Apotex's rebates throughout would be the same as those in the multi-source period - 44.7% because of Apotex's concern about forthcoming competition.

[156] In determining what the rebates would be, the situation surrounding different types of purchasers makes the analysis more difficult. The concept of a chain is a company where head office or headquarters makes decisions for pharmacies and negotiates rebates. Shoppers Drug Mart is an example. Independents are individually owned stores that negotiate with drug representatives for their business independently. Banners are like buying groups made up of independent organizations. It is often unclear whether a company is a chain or a banner because there may be parts of both descriptions of the two which may apply to the company. It is also unclear whether a banner would achieve rebates closer to a chain or to an independent.

[157] Turning to the evidence, Virginia Cirocco gave much the same evidence as she did in *Alendronate 2012* in which Justice Hughes found the witness to lack candor and to show a propensity to play games. However, before me, I saw none of those features and aside from being annoyed at having to appear and interrupt her holidays, her evidence was straightforward. However, it was not particularly helpful because her knowledge of Apotex's rebate rate was that of a blended rate across all products. She did not have knowledge of the rebate rate Apotex gave internally on a given product.

[158] With respect to Michael Blacker's evidence, he testified that he received a minimum 20% rebate on sole source products, that rebate rates fluctuated and that he received a 20% rate on Apo-pantoprazole in a competitive environment. His evidence was significantly local and anecdotal and it is difficult to draw general propositions regarding rebate levels from it.

[159] Apotex argues that Takeda should not be permitted to assert and rely on evidence to support the proposition that Apotex would have offered a 60% rebate. It complains that Takeda breached the rule in *Brown v Dunn* by not confronting Sherman or Hardwick with this evidence during cross-examination.

[160] The so-called rule in *Brown v Dunn* is not strictly a rule. It is a principle based on fairness and is open to exceptions and to court discretion. In the present case the evil of unfairness to which *Brown v Dunn* is directed, is completely ameliorated by Apotex's right as Plaintiff to call, in reply evidence, either or both of these witnesses to address the suggestion made by Takeda. Apotex did not do so. Takeda's evidence is admissible but not particularly persuasive.

[161] With respect to rebates in a single source market, I accept the evidence that the absence of competitive pressure and the "at risk" feature would keep the rate low. Harington's rate was 3.9% while Hamilton's was 28.3%; neither of which seems reasonable in the circumstances. The most persuasive evidence was the example of a molecule single sourced but "at risk" which attracted a rate of 8.9% (per Sherman).

[162] This rebate rate of 8.9% is neither *de minimus* nor is it approaching the competitive rate (per Hamilton). It is the most reasonable rebate rate advanced in this case in the sole generic circumstance.

[163] In the competitive or multi-source environment, the parties accept that rebate rates would be higher. Apotex advocates for a 44.7% rate which is based on real world competition where Apotex was competing against Teva across Canada and where the sales force of those two companies were large and competitive.

[164] In the circumstances, where Apotex is competing against Ranbaxy, the evidence shows Ranbaxy's sales force is considerably smaller (as is the company itself) than Apotex. I accept the logic that Ranbaxy would focus on the larger accounts, the chains, because of the efficiency of marketing to larger companies with large demand. Ranbaxy would, consequently, be less aggressive in pursuit of independents/banners.

[165] To make the calculation of the impact of rebates on Apotex's hypothetical world damages, it is necessary to determine the size of the market held by the various purchaser types. On this matter, the evidence is diverse and dispersed. The evidence showed a range of 55%-84% of the market was occupied by chains.

[166] However, the calculation of 55% market share for chains and 45% for independents/banners, advanced by Apotex, was an average that most witnesses, even some called by Takeda, supported.

[167] In a multi-source market, a 44.7% rebate rate applied to the chains (55% of the market) is reasonable. However, with respect to independents/banners, Apotex's suggestion of 0-10% is too low particularly given the 8.9% found to apply in a sole generic source situation. Blacker's 20% is too unsubstantial as a bench-mark to be applied across the market. A rate of 15% is more reasonable and, applying the "broad axe" approach, is the rate applicable to the damages calculation.

H. *Issue 8 – Prejudgment Interest*

[168] The issue concerns two related matters: the amount of interest and the date that interest begins to run. It is common ground that the Ontario *Courts of Justice Act*, RSO 1990 sc C43 s 127 should be applied.

Section 127 reads:

127. (1) In this section and in sections 128 and 129,	127. (1) Les définitions qui suivent s'appliquent au présent article et aux articles 128 et 129.
"bank rate" means the bank rate established by the Bank of Canada as the minimum rate at which the Bank of Canada makes short-term advances to banks listed in Schedule I to the *Bank Act* (Canada); ("taux d'escompte")	«date de l'ordonnance» Date à laquelle est rendue l'ordonnance, même si elle n'est pas inscrite ou exécutoire ce jour-là, ou si elle est modifiée en appel, et dans le cas d'une ordonnance de renvoi, la date à laquelle le rapport sur le renvoi est confirmé. («date of the order»)
"date of the order" means the date the order is made, even if the order is not entered or enforceable on that date, or the order is varied on appeal, and in the case of an order directing a reference, the date the report on the reference is confirmed; ("date de l'ordonnance")	«taux d'escompte» Le taux minimal exigé par la Banque du Canada sur les prêts à court terme qu'elle accorde aux banques mentionnées à l'annexe I de la *Loi sur les*

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

"prejudgment interest rate" means the bank rate at the end of the first day of the last month of the quarter preceding the quarter in which the proceeding was commenced, rounded to the nearest tenth of a percentage point; ("taux d'intérêt antérieur au jugement")

"quarter" means the three-month period ending with the 31st day of March, 30th day of June, 30th day of September or 31st day of December. ("trimestre")

banques (Canada). («bank rate»)

«taux d'intérêt antérieur au jugement» Le taux d'escompte à la fin du premier jour du dernier mois du trimestre précédant le trimestre au cours duquel l'instance a été introduite, arrondi au dixième près d'un point de pourcentage. («prejudgment interest rate»)

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

«trimestre» Les périodes de trois mois se terminant respectivement le 31 mars, le 30 juin, le 30 septembre et le 31 décembre. («quarter»)

Calculation and publication of interest rates

(2) After the first day of the last month of each quarter, a person designated by the Deputy Attorney General shall forthwith,

(a) determine the prejudgment and postjudgment interest rate for the next quarter; and

(b) publish in the prescribed

Calcul et publication des taux d'intérêt

(2) Après le premier jour du dernier mois de chaque trimestre, la personne désignée par le sous-procureur général, sans délai :

a) établit les taux d'intérêt antérieur et postérieur au jugement pour le trimestre qui suit;

b) publie selon le mode

manner a table showing the rate determined under clause (a) for the next quarter and the rates determined under clause (a) or under a predecessor of that clause for all the previous quarters during the preceding 10 years.	prescrit un tableau des taux d'intérêt établis aux termes de l'alinéa a) pour le trimestre qui suit et des taux établis aux termes de l'alinéa a) ou d'une disposition qu'il remplace pour tous les trimestres des 10 dernières années.
Regulations	Règlements
(3) The Attorney General may, by regulation, prescribe the manner in which the table described in clause (2) (b) is to be published.	(3) Le procureur général peut, par règlement, prescrire le mode de publication du tableau décrit à l'alinéa (2) b).

[169] Apotex contends that prejudgment interest should run from the date it would have begun sales in the hypothetical world – March 3, 2007. Takeda argues that the prejudgment interest start date is the date Takeda's prohibition application was dismissed.

[170] Apotex argues for a 4.5% rate which was current in March 2007; Takeda says the rate is 3.3% based on the quarter preceding the date of Apotex's statement of claim.

[171] The definition of "prejudgment interest rate" is "the bank rate at the end of the first day of the last month of the quarter preceding the quarter in which the proceeding was commenced" (Court's underlining).

[172] Apotex's statement of claim was dated November 18, 2008. The quarter preceding November 18, 2008 ended September 30, 2008. The interest rate at that time was 3.3% and is the rate to be used in the present case.

[173] With respect to the date from which prejudgment interest runs, Takeda claims it begins when Justice Gauthier dismissed Takeda's prohibition application. However, subsection 128(1) refers to such interest "calculated from the date the cause of action arose to the date of the order" (Court's underlining) – not the date on which a party could have commenced an action.

[174] In my view, the cause of action arose when the period of liability commenced – Apotex's patent hold date. Justice Snider in *Ramipril* appears to have been of a similar view.

[175] Therefore, prejudgment interest is 3.3% calculated from the patent hold date.

I. *Issue 9 – Discretion to reduce damages*

[176] The issue rests on four pillars:

(1) that Apotex gave an undertaking to Justice Gauthier in the prohibition proceedings that it would not market or promote Apo-pantoprazole in combination with one or more *Helicobacter* inhibiting anti-microbial agents for the treatment of *H. pyloric* diseases [triple therapy] thereby shielding itself from the allegation that it would infringe the 748 Patent.

(2) that Justice Gauthier relied on this undertaking in arriving at her conclusion that Takeda had not made out a case of infringement.

(3) that Apotex acted in breach of this undertaking by marketing and promoting to pharmacists Apo-pantoprazole for use in triple therapy, which marketing and promotion would have occurred during and did occur after the Relevant Period.

(4) that this Court should exercise its discretion under subsection 8(5) of the Regulations to deny Apotex any damages to which it might otherwise be entitled.

[177] It is fair to say that given the gravity of the allegation, the parties went down every conceivable avenue of attack and defence. I agree that the allegation is grave – it amounts to a form of contempt; either a misleading of the Court or a violation of a term of the Court's disposition of the case.

[178] Apotex filed its NOA in January 2006. The NOA stated:

> Our sodium pantoprazole tablets will be made, used and sold in accordance with the indications and clinical uses and dosage regimens listed in our draft product monograph aforesaid.
>
> Each of the claims of the '748 Patent includes as an essential element a *Helicobacter*-inhibiting anti-microbial agent. Our sodium pantoprazole tablets shall not contain said agent, as that term is construed in accordance with the claims of the '748 Patent, nor shall our tablets be marketed or promoted to doctors, pharmacists or others to be used in combination with a *Helicobacter*-inhibiting anti-microbial agent or as part of a medicament package comprising said agent. As such, our tablets shall not infringe any of the claims of the '748 patent.
>
> In the event that the terms "regulation of a gastrointestinal disorder," "treating duodenal or gastric ulcer relapse," and "gastrointestinal disorder regulant," as they appear in the claims, are to be construed such that they are limited to those gastrointestinal disorders or

> duodenal or gastric ulcer relapses that are caused or exacerbated by a *Helicobacter* infection and secreted gastric acid, we allege that said claims shall not be infringed since our tablets shall not be marketed or promoted to doctors, pharmacists or others to be used in any way against a *Helicobacter* infection or a gastrointestinal disorder caused or exacerbated by a Helicobacter infection and secreted gastric acid.
>
> We further allege that the only pharmaceutical compositions containing sodium pantoprazole and a Helicobacter-inhibiting anti-microbial agent are subject of an approval issued by Health Canada are the following two triple therapy combinations:
>
> (i) sodium pantoprazole (40 mg) clarithromycin/amoxicillin; and
> (ii) sodium pantoprazole (40 mg)/clarithromycin/metroidazole,
>
> when used for the treatment of a *Helicobacter-pylori*-associated duodenal ulcer which includes the eradication of *Helicobacter pylori* bacteria. 20 mg tablets of sodium pantoprazole are not approved by Health Canada to be used as part of the aforesaid triple therapy combinations or for other uses when combined with a *Helicobacter*-inhibiting anti-microbial agent. Additionally, when said triple therapy combinations are used, sodium pantoprazole and the *Helicobacter*-inhibiting anti-microbial agents (clarithromycin, amoxicillin and metronidazole) are not administered more than 24 hours apart. As such, given that the indications and clinical uses and dosage regimens of our tablets, as set out in our draft product monograph [Apotex Document No 11], are distinct from the aforesaid triple therapy combinations, our 20mg or 40mg tablets shall not infringe any claim that does not include within its scope said approved triple therapy combinations or the approved use of said combinations. Nor could we possibly infringe any claim that includes the regulation of a gastrointestinal disorder or a gastrointestinal disorder regulant, since the terms regulation and regulant have a meaning other than elimination or eradication.

[179] At paragraph 156 of the NOA decision (*Solvay Pharma Inc v Apotex Inc*, 2008 FC 308, 323 FTR 1), Justice Gauthier summarizes her understanding of Apotex's position in its NOA:

> In this case, Apotex alleges in its NOA that it will not be making, using or selling its tablets of sodium pantoprazole as part of the triple therapy combination, the use of which is claimed in the '748 Patent. Apotex also alleges that claims 15 and 16 of the '748 Patent will not be infringed, since its Apo-pantoprazole tablets will not be marketed

> or promoted to doctors, pharmacists or others for use in combination with a HIAMA, or as part of a medicament package comprising said agent. Moreover, given that the indications, clinical uses and dosage regimens set out in Apotex' draft product monograph are distinct from those indicated with respect to pantoprazole triple therapy, its 20 mg and 40 mg tablets shall not infringe any of the claims of the '748 Patent.

[180] Later, in referring to the efforts Apotex made to "scrub clean" from its product monograph for Apo-pantoprazole any reference to *H. pylori* with antibiotics, the Court concluded that Takeda had not met its burden of establishing that the "allegations of non-infringement were unjustified" (the use of double negatives seems to be a curse of this type of litigation).

> 200 In the end, the Court is not able to conclude from the evidence before it that Apotex intends to market its tablets for use as part of the triple therapy regimen. Altana has not otherwise established any causal link between Apotex' actions (and its proposed monograph) and the direct infringement the Court was asked to assume.
>
> 201 The court concludes that Altana has not met its burden of establishing that the allegations of non-infringement in respect of those claims are unjustified.

[181] The Court decided the case and dismissed the prohibition application on the basis of non-infringement:

> In view of the foregoing, the Court finds that the application must be dismissed with costs on the basis that Altana failed to establish that the allegations of non-infringement were not justified. (paragraph 229)

[182] While statements in an NOA may rise to the level of an undertaking to be relied on by a court, such statements must be clear and unequivocal undertakings specifically or by inference. An example of such statement is found in *Pfizer Canada Inc v Canada (Health)*, 2007 FC 642, 320 FTR 48 (a case relied on by Takeda) at paragraph 6:

> Apotex's NOA alleges that it would not infringe the 089 Patent because it would not make, use or sell Apo-Quinapril for the Patented Use — the treatment of cardiac or vascular hypertrophy and hyperplasia - and it undertakes that it will only make, use or sell the Apo-Quinapril for the treatment of hypertension. The NOA also alleged invalidity but that allegation has not been pressed and is treated as abandoned.

[183] Another example of a specific undertaking is found in *Apotex v Syntex Pharmaceuticals International Ltd* (1999), 166 FTR 161, 1 CPR (4th) 22 at paragraph 4:

> In June of 1993, Apotex filed a Notice of Allegation (the 1993 NOA) with respect to an application it was making to the Minister for a Notice of Compliance for its sustained release naproxen tablets. That Notice contained two assertions. The first was that "no claim for the medicine itself and no claim for the use of the medicine" would be infringed by Apotex making and selling its naproxen controlled release tablets, because the '671 patent, as a composition (formulation) patent, did not claim the medicine itself or the use of the medicine. The second assertion was an undertaking by Apotex that any tablets it produced and sold would not fall within the claims of the '671 patent:
>
> > ...Apotex Inc. hereby undertakes that any tablets produced and sold by Apotex will not fall within the scope of the claims of patent 1204671, so that no claim would be infringed.

[184] An undertaking may be inferred where it is clear as found in *Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193 at paragraph 14:

> Accordingly, Simpson J. allowed the application on the basis of the prematurity of the allegation. While the remaining issues were therefore not necessary to decide, Simpson J. proceeded to consider them in obiter. She indicated that she would not have rejected the NOA only on the basis that it failed to mention the statutory restrictions on Novopharm's compulsory licence, given that they were, in effect, disclosed in the NOA when it advised that the licence had not been cancelled. Further, she viewed Apotex's undertaking in the NOA to purchase Norfloxacin only under the licence as sufficient to constitute an undertaking to be bound by the restrictions thereon. She also indicated that she would have followed the decision of

> McGillis J. in Apotex #1, *supra*, to find that the supply agreement was not a sublicence. Finally, she would have found that there was no agency agreement in place whereby Novopharm was the agent of Apotex. In her view, at p. 489, Novopharm "remains the principal when it contracts under the Agreement with a third party for the manufacture of a licensed drug."

[185] In *Eli Lilly and Co v Apotex Inc*, 2004 FC 206, 247 FTR 202 at paragraph 4, the Court referred to an Apotex representation as an undertaking:

> In summary, the allegations of fact, which, as I have said, are not disputed are as follows. Nizatidine was the subject of two NOAs and two proceedings, one for prohibition, one for certiorari under the *Patented Medicines (Notice of Compliance) Regulations* (the *PMNOC Regulations*). Lilly alleges that in the case of the first NOA, Apotex represented that it would rely upon Novopharm's compulsory license to acquire only licensed nizatidine, thereby not infringing the plaintiffs' patent, and that contrary to its undertaking Apotex did not in fact sell licensed nizatidine.

[186] The case law does not support the proposition that a bare pleading in an NOA constitutes an enforceable undertaking. In my view, there must be more than just the allegation unless it is phrased as an undertaking. Takeda put forward no evidence that representatives of Apotex stated that the company undertook not to market or promote triple therapy. There is no evidence that at the time of the proceeding before Justice Gauthier, Apotex had intended to market and promote in a manner contrary to its pleading.

[187] If an undertaking was so clearly in Justice Gauthier's mind or if an undertaking was critical to her decision, she would have so stated it. I cannot believe that such a knowledgeable and experienced judge would not have stated an undertaking as the basis for the decision if that had been intended.

[188] Therefore, I find that Takeda has not made out the case for the instance of an enforceable undertaking not to market or promote Apo-pantoprazole for triple therapy.

J. *Breach of Undertaking*

[189] On the assumption that an undertaking was given, I turn to the issue of whether it was breached and what the consequences should be.

[190] In so doing, I note that many of the acts relied on to prove breach are acts which are consistent with the absence of an undertaking or at least Apotex's belief that it had not given such an undertaking. The activities of marketing and promoting were so visible, so open, so widespread within the buying community (pharmacists) that Apotex's actions are more consistent with those of a person who believed no undertaking had been given. There is nothing hidden, surreptitious or underhanded in the marketing and promotion. Whether Apotex is responsible is a different issue.

[191] Takeda alleges two actions which breached the "undertaking". The first was in promoting Apo-pantoprazole for *H. pylori* through a computer display platform called "iPharmacist". The second was in applying to be listed as interchangeable with Pantoloc and not differentiating the Apo-pantoprazole product.

[192] The iPharmacist platform (Pharmacist Business Solution) was a software platform containing a suite of computer run tools provided free to certain Canadian pharmacists. The tools provided included business development tools, operational effectiveness tools and pharmacy services tools.

[193] For purposes of this case, the relevant tool about which Takeda complains is the "app" known as "iPharmacist Mobile". It is a collection of 25 reference applications for pharmacists consolidated into a single application on the iPhone/iPad (it used to be on a PDA-Palm Pilot). The applications offered include clinical tools, clinical reference materials and drug reference materials.

[194] Fountainhead Mobile Solutions [FMS], along with a sister company, created, owns and maintains the iPharmacist Mobile software. Apotex provides access to the software to its customers as part of a customer loyalty program. FMS licensed the content of iPharmacist Mobile from third parties.

Apotex owns approximately 10% of FMS but does not exercise control.

[195] Within iPharmacist Mobile is a Drugs mobile which contains data on 3,000 different drugs available in North America. That data is provided to a third party drug information provider – Lexi-Comp.

[196] The evidence of breach of undertaking included a series of screenshots of pages for iPharmacist Mobile. By using the display a pharmacist would find that Apo-pantoprazole is listed for use in *Helicobacter Pylori* eradication with two other antibiotics – classic triple therapy. It is described as "unlabelled use" – use of a drug in a manner not approved by the health authorities.

[197] Apotex's involvement with iPharmacist was not simply as a small minority shareholder as an owner of passive drug listing. As early as 2002 Apotex was involved with FMS's predecessor in

the launch and supply of the iPharmacist platform; its software was developed in cooperation with Apotex; it owns the iPharmacist trade mark; it owns, maintains and controls the content of iPharmacist website. Apotex and iPharmacist websites are linked, Apotex is the only company listed as iPharmacist's resource centre and iPharmacist's concierge service is called "Apotex iPharmacist Concierge Service".

[198] Indication of the close association and the influence of Apotex is that Apotex controls the "key" or access code for the current version of iPharmacist available from Apple.

[199] The Apotex witnesses who tried to establish a considerable degree of separation of Apotex from iPharmacist and the contents of iPharmacist were not persuasive.

[200] While Apotex may have had little influence over Lexi-Comp information, Apotex took no steps (even if unsuccessful) to limit or prevent Apo-pantoprazole being identified with triple therapy. It gave no warning to its own people or to pharmacists even if it could not have a negative caveat inserted in its Product Monograph.

[201] Given Apotex's relationship with iPharmacist, the use to be made of the information on the platform by pharmacists, the intention to give it (particularly iPharmacist Mobile) to pharmacists as part of Apotex's customer loyalty program, and the identification of Apo-pantoprazole with triple therapy, I conclude that Apotex took no steps to prevent the marketing and promoting of Apo-pantoprazole for the treatment of *Helicobacter Pylori* in triple therapy.

[202] It would be highly speculative at this stage to conclude on how this Court would exercise its discretion. The parties have not really addressed the alternative circumstances as this Court has found them – that Apotex was reckless, wilfully blind to breach of an undertaking (the terms of which are not clear), and failed to take any steps to mitigate the impact of third party's content (even if it did not control such content).

However, it is important to note that this is an alternative conclusion. The main issue is that Apotex did not give the undertaking which Takeda said is breached.

[203] In addition to any issues of calculations of amounts of damages, the parties are free to ask for the opportunity to make submissions on this alternative finding.

"Michael L. Phelan"
Judge

Ottawa, Ontario
December 11, 2013

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1786-08
STYLE OF CAUSE:	APOTEX INC. v TAKEDA CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 18-22, FEBRUARY 25-28, MARCH 1, 4, 5 AND 7, MAY 21-23, 2013
REASONS FOR JUDGMENT:	PHELAN J.
DATED:	DECEMBER 11, 2013

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