Federal Court  Cour fédérale

20120511

Docket: T-2300-05

Citation: 2012 FC 559

Ottawa, Ontario, May 11, 2012

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

APOTEX INC.

Plaintiff

and

ASTRAZENECA CANADA INC.

Defendant

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an action for the recovery of loss under the provisions of section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*NOC Regulations*). There has been a Reference ordered. Therefore this part of the proceeding is limited to addressing certain issues only with a Reference to follow if needed.

[2] The Plaintiff Apotex Inc. is an Ontario corporation and claims to be the largest Canadian-owned pharmaceutical manufacturer. It carries on business largely as a manufacturer and distributor of generic drugs; that is, copies of drugs made and developed by others. The Defendant AstraZeneca Canada Inc. is an Ontario corporation carrying on business in Canada as a distributor of drugs. These drugs include those developed by associated AstraZeneca corporations outside Canada. In the parlance of the trade, Apotex is a “generic” and AstraZeneca is a “brand” or “innovator”.

[3] The claim made by Apotex under section 8 of the *NOC Regulations* arises from the dismissal of an application for prohibition brought in this Court by AstraZeneca and a related company against Apotex under the provisions of those *Regulations*. That application, identified as T-2311-01, was commenced by a Notice of Application filed by AstraZeneca and a related company on December 31, 2001. By an Order dated 30th of December 2003, Justice O’Keefe dismissed that application. He provided reasons on the 2nd of March 2004, cited as 2004 FC 313. That decision is final.

[4] In general, the application T-2311-01 dealt with a drug known as omeprazole, sold by AstraZeneca in Canada under the brand name LOSEC and Canadian Patent No. 2,133,762 (the '762 patent) listed by AstraZeneca with the Minister of Health under the provisions of the *NOC Regulations*.

[5] The trial was divided into two parts. The first was an evidentiary part with argument addressing certain of the issues. The second part took place a few weeks later with argument

directed to AstraZeneca's challenges to the validity of section 8. This second part, on consent of all parties, was argued in common before me and Justice Snider who was seized with many of the same validity challenges in proceedings before her in cases numbered T-1161-07 and T-1357-09.

THE EVIDENCE

[6] The evidentiary portion of the trial of this action took place over five (5) days. In all, four (4) fact witnesses were called; two (2) for each party and, two (2) expert witnesses were called, one for each of Apotex and AstraZeneca. These experts were examined in a "hot tubbing" format after each had been examined and cross-examined by Counsel in the usual way. In addition, the parties filed an agreement stipulating that certain documents could be put in evidence without formal proof, without, however, any concession as to the truth of the contents of those documents.

[7] The Plaintiff Apotex provided the evidence of the following persons in its case in chief:

1. Dr. Bernard Sherman, a fact witness. He is the founder and Chairman of Apotex. He testified as to the efforts made by Apotex to obtain regulatory approval in Canada to make and sell its generic version (Apo-omeprazole) of AstraZeneca's omeprazole drug, LOSEC, in 20 mg capsule format. He testified as to events prior to, during and subsequent to receiving approval. He also testified as to manufacturing facilities of Apotex at sites known as Signet and Torpharm, and

the capacity of those facilities to manufacture this generic drug. I accept his evidence as credible.

2. Mr. Gordon Fahner, a fact witness. He is Vice President, business operations and finance, of Apotex. He provided particularization as to the ability of Apotex to manufacture the generic omeprazole drug at its Signet and Torpharm facilities. He provided data which he derived from Apotex business records kept in a computerized system known as SAP. I accept his evidence as credible.

3. Ms. Sue Wehner, an expert witness. She provided two reports marked as exhibits P-12 and P-13. After cross-examination as to her qualifications, Counsel for AstraZeneca agreed that Ms. Wehner could be qualified as an expert in the manner proposed by Apotex as follows:

> *Expert in regulatory affairs relating to the pharmaceutical industry, including the preparation and management of submissions to Health Canada, including new and abbreviated new drug submissions, supplemental new drug submissions and notifiable change submissions.*

I accept her evidence as credible.

[8] In addition, Apotex tendered portions of AstraZeneca's discovery and documents referred to; exhibits P-24 and P-25, and a bundle of documents submitted pursuant to the Agreement of Documents, exhibit P-23.

[9] The Defendant AstraZeneca provided the evidence of the following persons in its defence:

1. Dr. Sheila Garven, an expert witness. She provided a report marked as Exhibit D-26. After cross-examination as to qualifications, Counsel for Apotex agreed that she could be qualified as an expert on the basis of paragraph 18 of her report, modified as follows:

. . .

> *…as an expert in Canadian regulatory practice ("regulatory practice") (…) including regulatory practice as it relates to the filing of new drug submissions, supplemental new drug submissions and notifiable change submissions.*

I accept her evidence as credible.

2. Dr. Alison Ingham, a fact witness. She appeared pursuant to a subpoena from AstraZeneca. She is a senior advisor with the Bureau of Pharmaceutical Sciences at the Therapeutic Products Directorate of Health Canada. She testified generally as to certain practices at Health Canada relating to evaluation of new and abbreviated drug submissions and notifiable changes. I accept her evidence as credible.

3. Harvey Wasiuta, a fact witness. He testified pursuant to a subpoena from AstraZeneca. He is Director of Access to Information and Privacy for Health Canada. He is ultimately responsible for responses given by Health Canada to requests for Access to Information made to Health Canada. He testified as to the general practices

of Health Canada in respect of Access to Information (ATI) requests and gave specific evidence as to requests made, including by AstraZeneca, as to files relating to Apotex's omeprazole submissions to Health Canada. I accept his evidence as credible.

[10] At the end of the testimony of Ms Wehner and Dr Garven I conducted a "hot tubbing" examination in which each of them took the stand at the same time, remaining under oath. They answered questions put to them by me and responded to the answers given by each other. At the end of this process, each Counsel was invited to put follow-up questions to these witnesses. I will repeat part of the dialogue at the beginning (page 773) and at the end of the "hot tubbing" session (pages 779 - 780):

> *JUSTICE HUGHES: Where are you different, if at all, Ms. Wehner?*
>
> *MS. WEHNER: I think the primary difference is the interpretation of whether a notifiable change is part of the regulations or apart from the regulations. I think it really boils down to that.*
>
> *JUSTICE HUGHES: Dr. Garven, where do you say the two of you are apart?*
>
> *MS. GARVEN: From a regulatory practice perspective I believe that the difference is whether a notifiable change is required or not and would require approval from Health Canada prior to implementing the change*
>
> . . .
>
> *JUSTICE HUGHES: They would carry on manufacturing any way?*

MS. GARVEN: From a regulatory perspective I would say they shouldn't be manufacturing for sale until they received that letter of no objection.

JUSTICE HUGHES: Anything to add to that, Ms. Wehner?

MS. WEHNER: This is a bit of an unusual situation but, in my experience, Health Canada would tend to work with the company in order to expedite the change, especially in this situation there would be a lengthy patent hold. It may be a moot point. I've seen Health Canada on a number of occasions working in close association with the companies to work things out.

JUSTICE HUGHES: Dr. Garven, what do you say about that?

MS. GARVEN: They do tend to work with the companies to work things out, but they would want it worked out in the sense that they would have to file that notifiable change and get the letter of no objection.

JUSTICE HUGHES: Have we then discussed the areas in which you were apart? Any other areas you were significantly apart?

MS. WEHNER: I don't believe so.

MS. GARVEN: No, I don't believe so either.

[11] AstraZeneca filed as part of its evidence a bundle of documents submitted pursuant to the agreement as to documents, exhibit D-37, and read-ins and related documents from its discovery of Apotex exhibits D-38, D-39 and D-40. Additionally, Counsel for Apotex agreed to certain stipulations respecting the '762 patent (transcript page 872).

[12] In reply, Apotex filed certain other materials arising out of answers that it gave to certain undertakings made during discovery, exhibit P-41 as did AstraZeneca, exhibit D-42. It called no further witnesses.

[13] I have made a separate Order dated March 29, 2012 respecting the confidentiality of certain portions of the transcripts of evidence and certain trial exhibits.

ANSWERS GIVEN ON DISCOVERY

[14] During Apotex's examination for discovery conducted by AstraZeneca, Apotex, by its Counsel, undertook to provide answers to certain questions. Among these questions was Question 858, as follows:

> *To advise why Apotex was seeking approval to have Apo-omeprazole manufactured at the Etobicoke site.*

[15] On June 7, 2011, Counsel provided the following answer:

> *The technology for the manufacture of Apo-Omeprazole on a commercial scale was not available at the Signet site during the specified time period. The notifiable change for the Etobicoke site was approved in August, 2004.*

[16] On March 5, 2012 (two weeks before the trial began) Counsel for Apotex provided the following corrected answer:

> *Apotex corrects and replaces the preceding answer as follows. The Signet plant was capable of manufacturing Apo-Omeprazole capsules for commercial sale. It had the requisite technology. However, there was greater capacity to produce Apo-Omeprazole capsules at the Torpharm facility.*

[17] AstraZeneca, as part of its case in defence, filed only the first or "uncorrected" answer. In reply Apotex filed the corrected answer, plus portions of its further discovery conducted by AstraZeneca "without prejudice" subsequent to the delivery of the corrected answer and before the trial began.

[18] AstraZeneca argues that Apotex is attempting to withdraw an admission upon which AstraZeneca was relying in conducting its case and should not be permitted to do so. Apotex argues that Rule 245 of the *Federal Courts Rules*, SOR/98-106 obliges it to correct inaccurate or deficient answers given on discovery. Rule 248 would also preclude it from leading evidence on the point at trial if the answer were not corrected. Further, Apotex argues, AstraZeneca had further discovery and the opportunity to cross-examine the relevant witnesses, Dr. Sherman and Mr. Fahner, at trial.

[19] To resolve the issue as to whether the "corrected" answer is admissible and whether the evidence of Dr. Sherman and Mr. Fahner, which contradicts the earlier, uncorrected, answer, is admissible, I will start with considering the distinction between "formal" and "informal" admissions. Sopinka et al, *The Law of Evidence in Canada*, 3rd ed (Markham: LexisNexis, 2009) at 1263, discusses formal admissions which are made for the purpose of dispensing with proof at trial and are conclusive as to the matters admitted. The authors illustrate the manner in which formal admissions may be made in Canadian proceedings at section 19.2 of this book, which I repeat:

> *§19.2 A formal admission may be made: (1) by a statement in the pleadings or by failure to deliver pleadings, (2) by an agreed*

> *statement of facts filed at the trial, (3) by an oral statement made by counsel at trial, or even counsel's silence in the face of statements made to the trial judge by the opposing counsel with the intention that the statements be relied on by the judge, (4) by a letter written by a party's solicitor prior to trial; or (5) by a reply or failure to reply to a request to admit facts. A formal admission of fact, as distinct from an admission of law, cannot be withdrawn except with leave of the court or the consent of the party in whose favour it was made. An admission relating solely to a question of law, on the other hand, may be withdrawn at any time, even in the Court of Appeal. Leave to withdraw an admission should not be granted, however, unless: (1) the admission was made clearly without authority, by mistake or under duress; (2) there exists a triable issue concerning the admitted fact; and (3) there will be no prejudice to the party in whose favour it was made. An inadvertent statement of fact by counsel in opening may be withdrawn if retracted before it has been acted upon. The discretion of the court ought to be warily exercised and usually on terms.*

[20] It appears that this Court has extended the categories of the means by which "formal" admissions are made to certain kinds of admissions made by Counsel on discovery, as is illustrated by the decision of Justice Tremblay-Lamer in *Archambault v Ministre du Revenu National*, [1998] FCJ No 635, 189 FTR 37 (aff'd without discussion on the point: 264 NR 171). The reported reasons do not repeat what was actually said during the discovery, but what was said appears to have been said expressly for the purpose of trial if we take paragraph 6 of the reasons, which refer to another case, as being illustrative. At paragraph 5, Tremblay-Lamer J. states that, absent consent of the opposite party, a "formal" or "judicial" admission cannot be withdrawn without leave of the Court:

> *5 The case law is clear on the question of withdrawing admissions: a party may not withdraw a "formal admission" (or "judicial admission") without first obtaining leave of the Court or consent of the adverse party.*

[21] On the other hand, this Court has treated answers on discovery as “informal” admissions which can be qualified, enlarged upon or even contradicted upon notice to the opposite party. Prothonotary Lafreniere in *Apotex Inc v Wellcome Foundation Ltd,* [2009] FCJ No 177, 343 FTR 41 wrote at paragraph 37:

> *37 Although the answers provided by GSK's representative during examination for discovery are considered informal admissions, they can be qualified, enlarged upon, or even contradicted upon notice to the opposing party. The correction of inaccurate or deficient answers is specifically contemplated by Rule 245 which provides that a person who was examined for discovery and who discovers that the answer to a question in the examination is no longer correct or complete must provide the corrected or completed information in writing without delay.*

[22] The Ontario Court of Appeal in *Marchand v Public General Hospital Society of Chatham*, [2000] OJ No 4428, 51 OR (3d) 97 dealt precisely with the issue of correction of an answer given on discovery where the correction was made during the trial itself. The Court distinguished between answers given on discovery and “formal” admissions. Discovery answers could be corrected, leaving the impact of the correction to be determined by the trial judge. The entire discussion on the point in the decision written by the Court at paragraphs 70 to 86 is instructive. I repeat only paragraphs 77 and 80:

> *77 First, Dr. Asher's original discovery answer was not a formal admission. As such, it was always open to him to explain his discovery answer in his testimony. In Sopinka, Lederman and Bryant, The Law of Evidence in Canada, 3rd ed. (Toronto: Butterworths, 1999) at 1051-53, the authors distinguish between formal and informal admissions. A formal admission is conclusive as to the matter admitted, and cannot be withdrawn except by leave of the court or the consent of the party in whose favour it was*

> *made. The Law of Evidence states at 1051-52 that a formal admission may be made in the following ways:*
>
> > *1) by a statement in the pleadings or by failure to deliver pleadings;*
> >
> > *2) by an agreed statement of facts filed at the trial;*
> >
> > *3) by an oral statement made by counsel at trial, or even counsel's silence in the face of statements made to the trial judge by opposing counsel with the intention that the statements be relied on by the judge;*
> >
> > *4) by a letter written by a party's solicitor prior to trial; or*
> >
> > *5) by a reply or failure to reply to a request to admit facts.*
>
> *In contrast, an informal admission does not bind the party making it, if it is overcome by other evidence. That is, a party making an informal admission may later lead evidence to reveal the circumstances under which the admission was made in order to reduce its prejudicial effect.*
>
> . . .
>
> *80 Holmested and Watson, supra, describe at 31 Subsection 25 the obligation under rule 31.09 as an ongoing duty to correct and complete the answers given. In general, parties are entitled to correct their discovery answers. The impact of corrections is a matter to be decided by the trial judge, who is entitled to examine both the original and the amended answers: See Machado v. Pratt & Whitney Canada Inc. (1993), 17 C.P.C. (3d) 340 (Ont. Master); Capital Distributing Company v. Blakey (1997), 33 O.R. (3d) 58 (Gen. Div).*

[23] In the present case, Apotex "corrected" an earlier answer in respect of a critical fact. AstraZeneca had further discovery. Two Apotex witnesses testified on the point at trial and were cross-examined. AstraZeneca led no evidence of its own in respect of this fact. I will accept the corrected answer into evidence and weigh it along with the evidence of Dr. Sherman and Mr. Fahner.

THE ISSUES

[24] The principal issues are first whether Apotex is entitled to claim for loss under section 8 of the *NOC Regulations* and, if so, over what period and to what extent; and, second, is section 8 of the *NOC Regulations* valid legislation.

[25] Counsel for the parties have filed with the Court a document entitled "Joint List of Issues for Trial" setting out more specifically the issues that they wish the Court to address. All parties consented to this List. At trial, that List was amended and certain issues removed as a result of discussions between Counsel. As amended, that List of Issues is as follows:

> *1. Is section 8 of the Patented Medicines (Notice of Compliance) Regulations (the "PM (NOC) Regulations") invalid and of no force and effect as being:*
>
> *a. Unconstitutionally vague and ambiguous;*
> *b. Draconian, harsh and punitive;*
> *c. Invalid delegated legislation; and*
> *d. Inconsistent with and contrary to NAFTA and TRIPS?*
>
> *2. Has Apotex satisfied the conditions for engaging section 8 of the PM (NOC) Regulations, including that it is a "second person" within the meaning of section 8 of the PM (NOC) Regulations, or has Apotex failed to satisfy any relevant condition insofar as such failure has been expressly pleaded by AstraZeneca(It is noted that paragraphs 58 and 59 of the Defence have been dropped by AstraZeneca and that party now agrees that the Minister did certify that a Notice of Compliance would have been issued to Apotex on January 3, 2002 were it not for the proceedings T-2311-01).*
>
> *3. Does section 8 of the PM (NOC) Regulations require a second person to establish abuse by the first person to comply with TRIPS and NAFTA and is the remedy so limited?*

4. (Omitted)

5. Whether the alleged infringement of the '693 Patent is relevant in law, including whether it is relevant as a defence, to the section 8 claim of Apotex (including possible set-off of damages) (and if so, see para. 4 of Order of October 4, 2011)?

6. Whether Apotex was in a position to market Apo-Omeprazole in the period January 3, 2002 to January 27, 2004, including any impact of Apotex's alleged lack of approvability to manufacture for sale at a commercial manufacturing site?

7. Whether the start date for any liability should be forward dated by reason of Apotex's alleged delay in serving a Notice of Allegation and/or Apotex's alleged lack of approvability to manufacture for sale at a commercial manufacturing site?

8. (Omitted)

9. Whether Apotex was under a duty to mitigate, and if so, whether Apotex failed to mitigate?

10. (Omitted)

11. (Omitted)

12. Whether, any of the subject of items 5-7 and 9-11 are relevant factors to consider pursuant to section 8(5)?

REFERENCE ORDER AND PRE-TRIAL ORDER OCTOBER 4, 2011

[26] The present trial dealt with only certain aspects of the disputes between the parties. There has been an Order in this action dated February 20, 2008 directing that a Reference be held, after the disposition of the matters presently before me, to deal with the quantification of damages and other matters. As it turns out, many of the matters dealt with in that Order are no longer relevant.

The relevant parts of that Order which remain, as agreed upon by Counsel at the trial before me, are:

> *THIS COURT ORDERS THAT:*
>
> 1. *Pursuant to Rule 107 of the Federal Courts Rules, this matter shall proceed to trial without requiring the parties to adduce evidence at trial, or to conduct discoveries, or make production on any issue of fact relating solely to:*
>
>   *(a) the quantum of any damages suffered by Apotex Inc. ("Apotex") as a consequence of any delay in issuance to Apotex of a Notice of Compliance ("NOC") for Apo-Omeprazole 20mg capsules by reason of the Patented Medicines (Notice of Compliance) Regulations ("Regulations");*
>
> . . .
>
> 2. *Subject to paragraph 3, a hearing under Rules 107 and/or 153 shall be conducted following trial, if it appears that any of the issues set out in paragraph 1 above require determination, including necessary documentary and oral discovery.*
>
> . . .
>
> 4. *Any party may apply to the Court at any time, on notice to all other parties, for an order varying this Order.*
>
> 5. *In the event of disagreement among the parties as to the interpretation of this Order, which the parties have been unable to resolve by negotiation, any party may apply to the Court, on notice to all other parties for: (a) a case conference to discuss the disagreement with the case manager with a view to resolution of the disagreement; or (b) an order or direction of the Court in respect of the subject of the disagreement.*

> 6. *There shall be no costs of the motion save as to the costs of the attendance on February 14, 2008, including disbursements associated with said attendance only, which shall be to the Moving Parties in the cause.*

[27] By way of example, as discussed with Counsel at trial, if I were to determine that Apotex could manufacture the product at issue in commercial quantities at one or other of its sites, I need not, at this time, make an apportionment as to which site could produce how much.

[28] Further, following a pre-trial conference, I issued an Order dated October 4, 2011. That Order made reference to another action in this Court, T-1409-04, in which AstraZeneca is suing Apotex for infringement of Canadian Patent No. 1,292,693 (the '693 patent, which is not the same patent as the '762 patent at issue here). Presently, that action is set down to be heard in April 2014. Paragraph 4 of my Order directs that, if I find that AstraZeneca's defences in this action respecting infringement are viable in law, then Judgment in this action shall be reserved until final disposition of action T-1409-04. Paragraph 4 of my Order states:

> *4. The trial in T-2300-05 will be heard on all issues and if the Court finds the defences raised in paragraph 60 of the Sixth Amended Statement of Defence and Counterclaim (Infringement Defences) are viable in law, then any Judgment in T-2300-05 finding liability will be reserved until the final disposition of T-1409-04, and in the event that Apotex is found to infringe a valid patent in T-1409-04, the parties will be given the opportunity to make further submissions to the Court as to the applicability and impact, if any, of the findings of infringement from T-1409-04 in the within action. The foregoing is without prejudice to Apotex's ability to proceed with a reference following the initial finding of liability in T-2300-05 or the ability of AstraZeneca to bring a motion to stay the Judgment in T-2300-05 or any subsequent appeal.*

[29] As discussed with Counsel at trial, if I find that AstraZeneca's defence as to infringement is not viable, there is no prohibition against giving Judgment in the present action right away.

BURDEN OF PROOF

[30] This action is based on section 8 of the *NOC Regulations*. The Federal Court of Appeal in *Apotex Inc v Merck & Co Inc*, 2011 FCA 364 has clearly set out the elements of a claim for loss under that section. It requires that (1) an application for prohibition be dismissed; (2) that a second person has suffered loss from a date certified by the Minister or another date found by the Court to be appropriate, and ending on the date of dismissal. The Court may determine in its discretion whether, and to what extent, a second person's claim for compensation should be reduced or eliminated.

[31] AstraZeneca argues that Apotex bears the burden of proof in respect of all those elements. I accept that Apotex has a burden in some respects but not others.

[32] Sopinka et al, *supra* provides a lengthy discussion as to allocation of burdens at sections 3.61 to 3.96. It cites the decision of the Supreme Court of Canada in *Rainbow Industrial Caterers v CNR Co*, [1991] 3 SCR 3 (QL) as modern authority on the point. That decision relates to facts similar to those at issue here in that the plaintiff claimed that it had been induced into entering into a contract with the defendant by misrepresentations of the defendant and had thereby suffered loss. The defendant argued that in the "hypothetical situation" where the plaintiff would have entered into a contract on different terms, the plaintiff was required to bear the burden of negating all the speculative hypotheses that the defendant put forward. The

majority of the Court disagreed. The defendant bears the burden of proving its hypothesis. Justice Sopinka for the majority wrote at paragraphs 23 and 24:

> *Once the loss occasioned by the transaction is established, the plaintiff has discharged the burden of proof with respect to damages. A defendant who alleges that a plaintiff would have entered into a transaction on different terms sets up a new issue. It is an issue that requires the court to speculate as to what would have happened in a hypothetical situation. It is an area in which it is usually impossible to adduce concrete evidence. In the absence of evidence to support a finding on this issue, should the plaintiff or defendant bear the risk of non-persuasion? Must the plaintiff negate all speculative hypotheses about his position if the defendant had not committed a tort or must the tortfeasor who sets up this hypothetical situation establish it?*
>
> *Although the legal burden generally rests with the plaintiff, it is not immutable. See National Trust Co. v. Wong Aviation Ltd., [1969] S.C.R. 481, and Snell v. Farrell, [1990] 2 S.C.R. 311. Valid policy reasons will be sufficient to reverse the ordinary incidence of proof. In my opinion, there is good reason for such reversal in this kind of case. The plaintiff is the innocent victim of a misrepresentation which has induced a change of position. It is just that the plaintiff should be entitled to say "but for the tortuous conduct of the defendant, I would not have changed my position". A tortfeasor who says "Yes, but you would have assumed a position other than the status quo ante", and thereby asks a court to find a transaction whose terms are hypothetical and speculative, should bear the burden of displacing the plaintiff's assertion of the status quo ante.*

[33] Thus, Apotex has the burden of proving the elements of its claim and AstraZeneca has the burden of proving those matters which it raises in arguing that no claim exists or that the claim should be reduced or eliminated.

[34] In stating that a party has the burden of proof, that burden is a two-fold burden. The first burden is to put sufficient evidence in the record such that the issue is "in play". The second burden is that of proving, in this case, on a balance of probabilities, that the issue is to be resolved in favour of the party asserting or challenging the issue. In this respect, I refer again to Sopinka et al, *supra*, at sections 3.6 and 3.7:

> *§3.6 As noted, the term "burden of proof" is ambiguous and it has sometimes been used to mean that there is evidence of a fact, while on other occasions it has been used to mean that a fact has been proved by the evidence. Since the term is applied without discriminating in which sense the term is being used, it is difficult to determine which burden a party has satisfied in a particular case.*
>
> *§3.7 The term "evidential burden" means that a party has the responsibility to insure that there is sufficient evidence of the existence or non-existence of a fact or of an issue on the record to pass the threshold test for that particular fact or issue. As Lord Devlin explained in Jayasena v. R., to satisfy an evidential burden a party is not required to prove anything:*
>
> > *Their Lordships do not understand what is meant by the phrase "evidential burden of proof"...It is doubtless permissible to describe the requirement as a burden, and it may be convenient to call it an evidential burden. But it is confusing to call it a burden of proof. Further, it is misleading to call it a burden of proof, whether described as legal or evidential or by any other adjective, when it can be discharged by the production of evidence that falls short of proof. The essence of the appellant's case is that he has not got to provide any sort of proof that he was acting in private defence. So it is a misnomer to call whatever it is that he has to provide a burden of proof...[emphasis added]*
>
> *In contrast, the term "persuasive (legal) burden" means that a party has an obligation to prove or disprove a fact or issue to the criminal or civil standard. The failure to convince the trier of fact to the appropriate standard means that party will lose on that issue. Because the evidential burden and the persuasive burden*

> *will on occasion be distributed between the parties, it is essential that the issues to be tried, and the underlying facts in support of the issues, be clearly identified.*

[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.

FACTUAL BACKGROUND

[36] Omeprazole is the active ingredient in the drug sold by AstraZeneca in Canada under the brand name LOSEC and by a related company in the United States under the brand name PRILOSEC. The drug is sold in varying strengths including 20 mg and 40 mg, and in capsule form and tablet form. Here we are concerned with a capsule form containing 20 mg of the drug. In this form, the omeprazole itself is mixed with other materials, called excipients, and formed into very small pellets. These pellets are coated then placed into capsules. For our purposes, therefore, the manufacture of the 20 mg capsule consists of three steps; pellet forming, pellet coating, and encapsulation.

[37] In the 1990s, AstraZeneca was selling omeprazole in Canada in forms including 20 mg LOSEC capsules. At some point in the late 1990's or early 2000's, AstraZeneca switched from the capsule form to the tablet form, at least for the 20mg strength. However, a related company continued to sell the 20 mg drug in capsule form in the United States under the PRILOSEC

name. There is a suggestion that AstraZeneca may have made the 20 mg product available again in Canada in the capsule form, but I find on the record before me that there is no evidence to support that suggestion.

[38] In 1994, Apotex made an application to Health Canada for approval to sell a generic version of AstraZeneca's 20 mg LOSEC capsules in Canada. At that time, Apotex had a manufacturing facility located at Signet Drive in Weston, a suburb of Toronto, which Apotex indicated would be the site of the plant to be used to manufacture this drug. This site is variously referred to in the evidence as Weston or Apotex or Signet. I will call it Signet. Subsequently, Apotex developed or acquired another manufacturing facility located a few kilometres away from Signet, in Etobicoke, another suburb of Toronto. That site is variously referred to in the evidence as Etobicoke or Torpharm. I will call it Torpharm. I find, on the uncontradicted evidence of each of Dr. Sherman and Mr. Fahner, and giving due weight to the answers given on discovery as previously discussed, that each of the Signet and Torpharm sites were capable of manufacturing the 20 mg omeprazole capsule in commercial quantities. I find that the entire manufacturing could take place at one site or the other, or partially at one and partially at the other; for instance, pellet forming and coating could take place at Torpharm, and encapsulation at Signet. These findings apply throughout any period that may be relevant here.

SEEKING, OBTAINING AND MAINTINING APPROVAL TO SELL A DRUG IN CANADA

[39] The Minister of Health, particularly through a department known as Health Canada, is responsible for regulating the manufacture, distribution and sale of drugs in Canada. The

Minister grants approval to do so by issuing a Notice of Compliance (NOC) to the party seeking such approval.

[40] Such approval may be sought by a party in one of two ways. One is by filing a New Drug Submission (NDS), which requires a party to provide a great deal of information as to the safety and efficacy of the drug in question. The other is by filing an Abbreviated New Drug Submission (ANDS), which requires first that some other person has already been granted an NOC for the drug; and second, that the party seeking approval need not provide the voluminous material otherwise required in respect of safety and efficacy, provided that it can make certain satisfactory comparisons to the drug already approved. The ANDS procedure is one followed by many "generic" drug companies.

[41] In filing an NDS or an ANDS, the party seeking approval must provide certain information to Health Canada, including that as set out in subsection C.08.002 (2)(d) of the *Food and Drug Regulations*, CRC c 870, as amended (*FDA Regulations*):

(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:	*(2) La présentation de drogue nouvelle doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :*
. . .	. . .
(d) a description of the plant	*d) la description des installations et de*

and equipment to be used in the manufacture, preparation and packaging of the new drug;	*l'équipement à utiliser pour la fabrication, la préparation et l'emballage de la drogue nouvelle;*

[42] At trial, there was discussion as to the precise meaning of "plant and equipment" and whether it is the equivalent of the "site" of manufacture. For instance, if there is more than one "site" that uses substantially the same machinery and procedures for making a drug, can each site be considered the same "plant and equipment"? I do not need to resolve this debate other than to say that it gives rise to a reasonable debate.

[43] I now turn to the circumstances which arise *after* an NOC has been given to a party and that party makes changes after the grant. Subsection C.08.003(1) of the *FDA Regulations* provides that if there are "significantly different" changes made to, among other things as defined in subsection (2)(d), "plant and equipment", then the party must seek and obtain a "supplement" to its NDS or ANDS. That supplement is called a Supplementary New Drug Submission (SNDS) or "Supplementary Abbreviated New Drug Submission (SANDS), as the case may be. I repeat the relevant portions of subsections (1), (2) and (3):

> *(1) Despite section C.08.002, no person shall sell a new drug in respect of which a notice of compliance has been issued to the manufacturer of that new drug and has not been suspended under section C.08.006, if any of the matters specified in subsection (2) are significantly different from the information or material contained in the new drug submission, extraordinary use new drug submission, abbreviated new drug submission or abbreviated extraordinary use new drug submission, unless*
>
> > *(a) the manufacturer of the new drug has filed with the Minister a supplement to that submission;*

> *(b) the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the supplement;*
>
> *(c) the notice of compliance in respect of the supplement has not been suspended pursuant to section C.08.006; and*
>
> *(d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.*
>
> *(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:*
>
> *[...]*
>
> *(d) the plant and equipment used in manufacturing, preparation and packaging the new drug;*
>
> *[...]*
>
> *(3) A supplement to a submission referred to in subsection (1), with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.*
>
> *[...]*

[44] Apart from the provisions as set out in section C.08.003 of the *FDA Regulations*, there are no other provisions dealing with changes. However, Health Canada has, through a series of "Guidelines", introduced a procedure known as NC or Notifiable Change. This procedure has been the subject not only of "Guidelines", but also draft guidelines and policies originating from Health Canada. In publishing its guidelines, Health Canada is careful to point out that:

> *Guidance documents are administrative instruments not having the force of law, and, as such, allow for flexibility in approach.*

[45] Justice Evans of the Federal Court of Appeal in *Thamotharem v Canada (Minister of Manpower and Immigration)*, 2007 FCA 198, [2008] 1 FCR 385, at paragraphs 58 to 60, wrote about guidelines. They are “soft law” techniques forming part of the continuum of legal rules and discretion and, although not legally binding, they may validly influence a decision-maker’s conduct. He wrote:

> *58 Legal rules and discretion do not inhabit different universes, but are arrayed along a continuum. In our system of law and government, the exercise of even the broadest grant of statutory discretion which may adversely affect individuals is never absolute and beyond legal control: Roncarelli v. Duplessis, [1959] S.C.R. 121 at 140. (per Rand J.). Conversely, few, if any, legal rules admit of no element of discretion in their interpretation and application: Baker at para. 54.*
>
> *59 Although not legally binding on a decision-maker in the sense that it may be be an error of law to misinterpret or misapply them, guidelines may validly influence a decision-maker's conduct. Indeed, in Maple Lodge Farms Ltd. v. Canada, [1982] 2 S.C.R. 2, McIntyre J., writing for the Court, said (at 6):*
>
> > *The fact that the Minister in his policy guidelines issued in the Notice to Importers employed the words: "If Canadian product is not offered at the market price, a permit will normally be issued; ..." does not fetter the exercise of that discretion. [Emphasis added]*
>
> *The line between law and guideline was further blurred by Baker at para. 72, where, writing for a majority of the Court, L'Heureux-Dubé J. said that the fact that administrative action is contrary to a guideline "is of great help" in assessing whether it is unreasonable.*
>
> *60 The use of guidelines, and other "soft law" techniques, to achieve an acceptable level of consistency in administrative decisions is particularly important for tribunals exercising*

> *discretion, whether on procedural, evidential or substantive issues, in the performance of adjudicative functions. This is especially true for large tribunals, such as the Board, which sit in panels; in the case of the RPD, as already noted, a panel typically comprises a single member.*

[46] In the present action, I have been provided with the expert evidence of Ms. Wehner and Dr. Garven as to how those experienced in the Canadian drug regulatory world deal with such guidelines and interpretations given by Health Canada. They largely agree in this respect.

[47] It is important to begin with section C.08.003 of the *FDA Regulations* previously set out, as it requires that a party which already has an NOC advise the Minister (Health Canada) as to changes that are "significantly different". Thus, the initial interpretation in respect of any differences lies with the holder of the NOC, as they must consider whether a difference is "significant". I appreciate that inspectors from Health Canada do visit the NOC holders' facilities from time to time and they are expected to notice "differences", as well.

[48] In April 1994 and September 1994, Health Canada released publications described as "policy" documents. They never gained status as "guidelines". Nonetheless, the evidence is that these documents serve to inform the public as to what changes Health Canada may consider to be "significant" and what steps Health Canada expects an NOC holder to take. Four different "Levels" of changes are provided for with descending degrees of "significance" and descending degrees of expectations placed on an NOC holder. Both experts agree that while there is no "legal" requirement for an NOC holder to live up to these expectations, those holders regularly do endeavour to live up to those expectations.

[49] The practice with respect to a difference or change as to “plant and manufacturing equipment” under the practice established by Health Canada is considered a “Level 2” change. The relevant practice is set out in the “Policy Issues” document dated April 6, 1994, as follows:

> *LEVEL 2 – NOTIFIABLE CHANGE (Notice of Intention to Change)*
>
> *Level 2 changes are those considered to be notifiable. Changes identified in Level 2 require the preparation and filing of the same level and detail of information and scientific justification as is currently required in a supplemental new drug submission. This information and material must be filed prior to the institution of the change. Unless a written objection is received from the Branch within 90 days, the manufacturer may proceed with the change.*
>
> *Level 2 changes are those made:*
>
> . . .
>
> *3. subject to Level 1 (3) & (4), in the formulation, method of manufacture, equipment, process control, or production site of the drug product;*

[50] The experts advise that the practice is for Health Canada to review the changes set out in the notice (NC) provided by an NOC holder and to discuss with the holder what modifications, if any, ought to be made so as to satisfy Health Canada. Once Health Canada is satisfied, it sends out a letter described as a “No Objection” or NO letter which puts an end to the matter from Health Canada’s perspective.

[51] There is some overlap as to what kind of a change would be treated under the Notice of Change (NC) regime as opposed to one that would be required to be processed through the more

formal Supplementary New Drug Submission (SNDS) or Supplementary New Drug Submission (SANDS) process. I largely accept Dr. Garven's evidence as set out in paragraph 61 of her Report, exhibit P-14 that, from a regulatory perspective, the acceptance as a NC does not mean that the changes were insignificant; the level and detail of information and scientific justification which was required in a NC submission may be the same level as for an SNDS. Rather, from a policy perspective, Health Canada was prepared to treat the submission according to different timing review requirements and permit the change in one form or another.

[52] When I pressed Counsel for AstraZeneca in argument to provide me with any statutory penalty that could be imposed upon an NOC holder for failure to adhere to the *Food and Drug Act*, RSC 1985, c F-27 or the *FDA Regulations*, I was provided with section C.08.006 of the *FDA Regulations*. That section provides that the Minister may suspend an NOC if the new information is inadequate so as to assure and preserve the identity, strength, quality or purity of the new drug. I repeat subsections (1) and (2)(e):

> *C.08.006. (1) For the purposes of this section, evidence or new information obtained by the Minister includes any information or material filed by any person pursuant to Division 5 or section C.08.002, C.08.002.1, C.08.003, C.08.005 or C.08.005.1.*
>
> *(2) The Minister may, by notice to a manufacturer suspend, for a definite or indefinite period, a notice of compliance issued to that manufacturer in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission, if the Minister considers*
>
> . . .
>
> *(e) that, on the basis of new information obtained after the issuance of the notice of compliance, the methods, equipment, plant and controls used in the manufacturing,*

> *processing and packaging of the drug are inadequate to assure and preserve the identity, strength, quality or purity of the new drug; or*

[53] Neither of the experts could recall any instance when this had ever been done. They agreed in the "hot tubbing" session that, most likely, Health Canada personnel would work with the NOC holder so as to ensure that conformity with the necessary standards was achieved.

[54] It is important to note that in the circumstances of this case, Apotex has never been penalized or shut down by Health Canada.

NOC REGULATIONS – SECTION 8

[55] On many occasions, members of this Court have written that the *NOC Regulations* are poorly drafted and difficult to interpret and implement. I will once more lend my voice to that complaint and pass on.

[56] The purpose of the *NOC Regulations* has been discussed in many decisions of this and higher Courts. I will only briefly recap such purpose in general terms. The purpose is to provide a party who has already received an NOC to market its drug in Canada an opportunity to require another party who wishes to market the same drug and seeks an NOC, for instance, by way of the abbreviated ANDS route, to address a patent or patents that the NOC holder owns or in which it has an interest. Generally speaking, these persons are referred to as a "first person" for the NOC holder, and the other person as a "second person". The first person may list with the Minister of Health certain patents that it owns or in which it has an interest. The second person must send a

notice to the first person alleging whether it will simply await the expiry of the patent(s) or that the patent(s) are not infringed or invalid, and provide a factual and legal basis as to why. The first person may then, if it chooses, commence an application to prohibit the Minister from issuing an NOC to a second person until the patent(s) expire. The Minister would then put the second person's application on "patent hold" until the prohibition proceedings are resolved or for twenty four months, whichever comes first. In effect, the first person gets an injunction automatically for up to twenty-four months, which will prevent a second person from getting approval to sell its drug until the prohibition proceedings are resolved or the time period expires. Justice Iacobucci in the Supreme Court of Canada wrote in his decision in *Apotex Inc v Merck Frosst Canada Inc*, [1998] 2 SCR 193 at paragraph 33 that such a scheme was "draconian".

[57] As a counterweight to the "automatic injunction", section 8 of the *NOC Regulations* provides that the second person may seek recovery of any loss suffered during the period in which it was held off the market if it turns out that the prohibition application is withdrawn, discontinued or dismissed. The parties are agreed that the version of the *NOC Regulations* in force, October 1, 1999, is the version of those *Regulations* that is applicable to the present action. Section 8 in that version is as follows:

> *8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during that period*
>
> > *(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 is satisfied on the evidence that another date is more appropriate; and*
>
> *(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.*
>
> *(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).*
>
> *(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.*
>
> *(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).*
>
> *(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). [SOR/98-166, s. 8.]*

[58] I adopt the comments that I wrote in *Apotex Inc v Merck & Co Inc*, 2008 FC 1185 at paragraphs 54, 55 and 74 concerning section 8. A "first party" has choices: it may choose to list a patent with the Minister, or not; it may choose to institute prohibition proceedings, or not. Its basic patent rights, such as the right to institute an ordinary infringement action, are unaffected. In making a choice to list a patent and a choice to institute prohibition proceedings, that party must be mindful that, just as if it had given an undertaking in order to secure an interlocutory injunction, it must make good the losses suffered by the other party should it fail to secure the prohibition Order. I wrote:

54 In many respects, section 8 can be analogized to the undertaking usually required by a party seeking an interlocutory injunction from a Court. This Court (Rule 372(2)) and most other courts in this country require, unless otherwise ordered, that an undertaking as to damages be provided. An undertaking is a serious matter and the damages afforded may be substantial, although as stated by the Ontario Court of Appeal in Debrina Corporation v. Triolet Systems Inc. (2002), 17 C.P.R. (4th) 289 at paragraph 87, they must be reasonably foreseeable at the time of the granting of the interlocutory injunction and must be caused by ("naturally flow from") the injunction and not something else.

55 Merck characterizes section 8 as providing a civil remedy without a wrong having been committed. Merck argues that the simple institution of a section 6 application and being subsequently unsuccessful cannot be said to be a "wrong" for which liability is created. This is a mischaracterization of the circumstances. Merck and others in its position have choices, a patent may be listed or not, an application may be instituted or not. Just like the institution of proceedings and seeking an interlocutory injunction, choices are made. Section 8 is a consequence of such choices. Merck and any other patentee has available to it all the remedies afforded to any patentee under the Patent Act, it is deprived of nothing in that regard. In seeking the advantage of section 6, it must be presumed to have done so mindfully of section 8.

. . .

74 The PMNOC Regulations must be considered as a whole. Section 8 provides, just as in any ordinary court proceeding, a disincentive for seeking what is in effect an interlocutory injunction. It is like an undertaking given by a person seeking such injunction. It is part of a "balance" to use the words of the Supreme Court of Canada in Biolyse, supra, of the Regulations. It is a normal and expected balance having regard to undertakings given in Court proceedings such as those for patent infringement when interlocutory injunctions are sought. Subsection 55.2(4)(d) specifically provides for regulations respecting remedies and procedures in respect of disputes under subsection (c) as to when the NOC may issue. This includes the 24 month stay on any issuance of the NOC provided by section 7(1)(e) of the PMNOC Regulations and disincentives for seeking such a stay.

[59] I accept as appropriate the approach advocated by the Ontario Court of Appeal in respect of an undertaking given by a party who so readily receives an interlocutory injunction. It wrote in *Nelson Burns & Co v Gratham Industries Ltd*, [1987] OJ No 1100, 25 OAC 89, at paragraphs 10 and 11, that the undertaking should be honoured without quibble and the courts should generally be unsympathetic toward those who seek to resile from such an obligation:

> *Because of this change and because of the number of such injunctions that are sought it is appropriate to emphasize the serious nature of the undertaking to pay damages which is a condition of the issuance of the interlocutory injunction. In the ordinary course the unsuccessful plaintiff must understand that he is obliged to pay damages in accordance with his undertaking without quibble and courts generally will be unsympathetic towards those who seek to resile from such an obligation.*

TIMELINE OF EVENTS

[60] With the foregoing as background, I will set out a number of events, largely in chronological order, relevant to the matters at issue. An omission does not mean that I consider an event unimportant or have overlooked it:

- November 1994 – Apotex filed a new drug submission (NDS) for omeprazole capsules Including a bioequivalence study compared Apotex's product with LOSEC. It indicated that the site of manufacture was Signet

- May 1997 – Health Canada rejects Apotex's application and considers it withdrawn

- December 1997 – Apotex re-files the same application as an abbreviated new drug submission (ANDS) and includes further bioequivalence comparisons with LOSEC

- March 1999 – Apotex files further bioequivalence studies comparing the Apotex product to the United States product PRILOSEC, as LOSEC capsules are no longer available in Canada

- December 1999 – Health Canada rejects Apotex's application

- January 2000 – Apotex appeals, asserting that its application should be listed as an NDS, not an ANDS

- May 2000 – February 2001 – Apotex appeals within Health Canada at two levels. The appeals are denied

- March 2001 – Apotex files an application for judicial review in this Court (T-493-01) which is suspended pending reconsideration within Health Canada

- September 2001 – Health Canada reconsiders and allows Apotex's application to proceed as an NDS. The judicial review application is discontinued

- October 19, 2001 – Health Canada report recommends acceptance of Apotex's application, but without a declaration of equivalence

- November 2001 – Apotex serves AstraZeneca with a Notice of Allegation under the *NOC Regulations* addressing the '762 patent

- December 31, 2001 – AstraZeneca files an application to prohibit the issuance of an NOC to Apotex (T-2311-01) until the expiry of the ‘762 patent.

- January 3, 2002 – date certified by the Minister under section 8(1)(a) of the *NOC Regulations* as the date on which an NOC would have been granted to Apotex in the absence of the *NOC Regulations* if AstraZeneca had not started the prohibition application

- October/November 2003 – Apotex starts commercial manufacture of omeprazole capsules at its Torpharm facility for export to the United States and elsewhere

- December 30, 2003 – this Court dismisses AstraZeneca’s prohibition application

- January 24, 2004 – Health Canada issues an NOC to Apotex but does not put on that NOC any indication of equivalence to LOSEC or any other drug. Apotex commences manufacture of its omeprazole capsules for the Canadian market at Torpharm

- February 23, 2004 – Apotex files an application for judicial review (T-388-04) to require Health Canada to issue an NOC with an indication of equivalence to LOSEC

- May 14, 2004- Apotex files a Notifiable Change Level 2 submission with Health Canada indicating a change of site of manufacture from Signet to Torpharm.

- August 26, 2004-Health Canada issues a "No Objection" letter to Apotex respecting the change of manufacturing site.

- December 19, 2005 – Apotex discontinues its application T-388-04

- January 4, 2006 – Health Canada issues an NOC to Apotex which indicates an equivalence to LOSEC

[61] I will now turn to the Joint Issues for Trial as submitted by the Parties.

ISSUE #1 AND ISSUE #3

> *1. In section 8 of the Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations")invalid and of no force and effect as being:*
>
> *a. Unconstitutionally vague and ambiguous;*
> *b. Draconian, harsh and punitive;*
> *c. Invalid delegated legislation; and*
> *d. Inconsistent with and contrary to NAFTA and TRIPS?*
>
> . . .
>
> *3. Does section 8 of the PM (NOC) Regulations require a second person to establish abuse by the first person to comply with TRIPS and NAFTA and is the remedy so limited?*

These are the issues which were deferred on consent to the joint hearing before me and Justice Snider held April 30 and May 1, 2012.

[62] These issues have been raised by AstraZeneca as a defense to Apotex's claim. The constitutionality of section 8 was also raised by AstraZeneca by way of a counter-claim against the Minister. A few days before the hearing on these issues was scheduled to commence, AstraZeneca and the Minister settled their dispute, and the counter-claim was discontinued without costs, on consent. The Minister's representative did not appear at the hearing. A Notice of Constitutional Question had been served on the appropriate federal and provincial representatives, but none of them were represented at the hearing and none of them provided any written representations.

[63] What remains are the allegations made by AstraZeneca in its defense as to invalidity of section 8. I repeat those allegations and tie them in with the headings provided in the above Statement of Issues in bold type:

> ***Section 8 of the Patent Regulations is Invalid and of No Force or Effect***
>
> *50. Section 8 of the Patent Regulations is invalid and of no force or effect because:*
>
> *(a)* ▲
>
> *(b)* ▲
>
> *(c) Section 8 of the Patent Regulations is unconstitutionally vague and ambiguous. Section 8 exposes a first person to losses suffered during a*

defined period but which losses have no relationship to any activity of the first person. A vague regulation is unconstitutional because it forces the court to depart from its judicial role of interpreting legislation to that of legislator when the court attempts to give meaning to the legislation. ***[Unconstitutionally vague and ambiguous]***

(d) *Section 8 of the Patent Regulations is draconian, harsh and punitive because the first person has no control over the period of liability. The liability period is subject to manipulation by the second person. By its role in the regulatory process, the second person can affect the date when its drug submission is approvable by the Minister. In addition, the second person selects the date when a notice of allegation is made.* ***[Draconian, harsh and punitive]***

(e) *Section 8 is invalid legislation delegated by Parliament to the Governor General in Council because Parliament could never have contemplated a regulation which is unreasonable, uncertain, and arbitrary. Section 8 imposes an absolute liability and is penal and confiscatory if there is no requirement that fault be proven and an award under s. 8 can be granted even if the second person continues to infringe a valid patent. Thus, s. 8 can reward unlawful conduct.* ***[Invalid delegated legislation]***

(f) *Section 8 of the Patent Regulations is inoperative and of no force or effect because it is inconsistent with and contrary to Canada's treaty obligations under the North American Free Trade Agreement ("NAFTA") and the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") (Annex 1C to the Agreement Establishing the World Trade Organization) and the statutes implementing the treaties, the North American Free Trade Agreement Implementation Act, S.C. 1993, c. 44 (assented to June 23, 1993) and the World Trade Organization Agreement Implementation Act, S.C. 1994, c. 47 (assented to December 15, 1994). These statutes were implemented after the coming into*

> *force of s. 55.2(4) of the Patent Act, under which the patent Regulations were purportedly made. NAFTA and TRIPS require that Canada provide adequate and effective protection and enforcement of patent rights. Section 8 derogates from and is inconsistent with those requirements. In particular, while the Patent Regulations were enacted to prevent abuse of the regulatory use exception provided by s. 55.2(1) of the Patent Act, s. 8 imposes harsh remedies against a patentee, absent proof that the generic was improperly delayed market entry, namely, a finding that the patent is invalid and/or would not be infringed, so as to discourage reliance on the scheme provided by the Patent Regulations.* ***[Inconsistent with and contrary to NAFTA and TRIPS]***

[64] Issue #3 covers much the same ground as Issue #1(d). AstraZeneca pleads this issue at paragraph 56 of its Defence:

> ***No entitlement - no abuse***
>
> *56. In the alternative, if s. 8 is valid, in order to comply with Article 48.1 of TRIPS and Article 1715.2(f) of NAFTA, s. 8 should be interpreted ti (k) require a second person to prove that the first person abused enforcement procedures; and (ii) limit the second person's remedy to compensation for injury suffered because of such abuse. As Apotex has not alleged abuse by AstraZeneca, there can be no liability under s. 8.*

[65] I will start with the generally acknowledged principal that there is a presumption of constitutionality (e.g. *Nova Scotia Board of Censors v. McNeil*, [1987] 2 SCR 662 per Richie J for the majority at pages 687 to 688). The burden lies on AstraZeneca to displace this presumption.

[66] Second, it must be noted that the decision of the Federal Court of Appeal in *Merck Frosst Canada Ltd v Apotex Inc*, 2009 FCA 187 (leave to appeal to SCC refused [2009 SCCA No. 347]) dealt with many issues respecting the validity of section 8 of the *NOC Regulations*.

[67] This decision is sometimes referred to by the parties in their arguments as the *Alendronate* decision. That decision, which is binding upon me, made several determinations as to section 8, including that section 8 of the *NOC Regulations* comes within the general grant of authority set out in subsection 55.2(4) of the *Patent Act*, RSC 1985, c P-4 and was thus validly promulgated. I repeat what Nöel JA, for the Court, wrote at paragraphs 58 to 61:

> *58 Section 8, by imposing on first persons a liability for the losses suffered by a second person, as a result of the operation of the automatic stay, when a prohibition application is withdrawn, discontinued or is ultimately unsuccessful, alleviates these concerns. As was noted in AB Hassle v. Canada (Minister of National health and Welfare), (2000), 7 C.P.R. (4th) 272 (FCA) (AB Hassle) (per Stone J.A. at para. 27), the ability of the Court to order payment of damages resulting from the operation of the automatic stay suggests that a first person no longer has an exclusive interest in delaying the progress of a section 6 prohibition proceeding.*
>
> *59 By the same logic, a first person no longer has an exclusive interest in triggering the operation of the automatic stay by reference to patents which are not properly listed (Ferring, supra; Hoffman-La Roche, supra; see also Apotex Inc. v. Canada (Minister of National Health and Welfare), (2000), 3 C.P.R. (4th) 1, at paras. 27 and 28) or to "evergreen" a patented drug in order to perpetuate the benefit which the PM(NOC) Regulations provide (AstraZeneca, supra, paras. 23 and 39; Biolyse, supra, para. 66). As a result of section 8, a first person must focus on the issue of infringement and consider the strength of its position before initiating a prohibition proceeding.*
>
> *60 This promotes the use of the PM(NOC) Regulations for the purpose for which they are intended: the prevention of*

> *infringement. Significantly, it does so in a manner which is consistent with maintaining the balance alluded to in Biolyse and in AstraZeneca. It is useful to repeat that both these cases were decided on the basis that the PM(NOC) Regulations should be construed in a manner which goes no further than is necessary in order to prevent infringement since overshooting this objective would upset the other part of the balance which section 55.2 of the Patent Act seeks to achieve, namely the timely entry of cheaper generic drugs on the market. The statutory authority of the Governor-in-Council to make regulations pursuant to subsection 55.2(4) of the Patent Act must be construed accordingly.*
>
> *61 I therefore find that section 8 of the PM(NOC) Regulations comes within the general grant of authority set out in subsection 55.2(4) of the Patent Act and that the Federal Court Judge came to the correct conclusion when he held that section 8 was validly promulgated.*

[68] Third, I refer to the principle that constitutional cases should not be decided without a clear factual foundation, and that the Court should not make a decision that goes any farther than it needs to, based on the factual circumstances of the case before it. I refer to what LeBel J wrote in *Kitkatla Band v British Columbia (Minister of Small Business, Tourism and Culture)*, 2002 SCC 31, at paragraph 46:

> *46 Constitutional questions should not be discussed in a factual vacuum. Even in a division of powers case, rights must be asserted and their factual underpinnings demonstrated. In this case, the appellants assert that the importance of the CMTs goes to the core of their cultural values and identity. This assertion grounds their claim that the impugned provisions of the Act impinge on a federal head of power. Because of this assertion, the nature and quality of the evidence offered will have to be assessed and discussed. Even if this case remains a division of powers case, the comments of McLachlin C.J. on evidentiary standards and problems in aboriginal law cases in Mitchell v. M.N.R., [2001] 1 S.C.R. 911, 2001 SCC 33, remain highly apposite. In such cases, oral evidence of aboriginal values, customs and practices is necessary and relevant. It should be assessed with understanding and sensitivity to the traditions of a civilization which remained an essentially*

> *oral one before and after the period of contact with Europeans who brought their own tradition of reliance on written legal and archival records. Nevertheless, this kind of evidence must be evaluated like any other. Claims must be established on a balance of probabilities, by persuasive evidence (Mitchell, at para. 39, per McLachlin C.J.). "Sparse, doubtful and equivocal evidence cannot serve as the foundation for a successful claim ..." (Mitchell, at para. 51, per McLachlin C.J.).*

[69] I also refer to what Sharpe JA of the Ontario Court of Appeal wrote in *Abou-Elmaati v Canada (Attorney General)*, 2011 ONCA 95 at paragraph 39:

> *39 It is not only unnecessary but also usually unwise to attempt to decide constitutional issues in the absence of a concrete factual situation. As this court stated in Clark v. Peterborough Utilities Commission (1998), 40 O.R. (3d) 409 at p. 413, citing Phillips v. Nova Scotia (Commission of Inquiry into the Westray Mine Tragedy), [1995] 2 S.C.R. 97 at p. 111, "courts should only rule on constitutional issues when it is necessary to do so".*

[70] As well, I refer to what the Chief Justice of the Supreme Court, Lamer CJ wrote in *Phillips v Nova Scotia*, [1995] SCJ No 36 (QL), at paragraph 6:

> *6 This Court has said on numerous occasions that it should not decide issues of law that are not necessary to a resolution of an appeal. This is particularly true with respect to constitutional issues and the principle applies with even greater emphasis in circumstances in which the foundation upon which the proceedings were launched has ceased to exist.*

[71] AstraZeneca has raised a number of factual scenarios in its argument, many of which have no relationship to the facts established in this case. It is important to keep in mind that in the present case:

- Apotex is not seeking to establish a date for the beginning of its recovery period any earlier than the date certified by the Minister;

- Apotex is seeking only damages suffered by it in respect of the delay in issuance to it of a Notice of Compliance for its 20 mg capsules by reason of the *NOC Regulations*; it is not seeking punitive or exemplary damages; it is not seeking damages beyond those provided for in the *NOC Regulations*;

- there will be a Reference conducted following this trial as to the nature and extent of those damages.

[72] With all of the foregoing in mind, I will turn to the specific issues raised.

[73] I have reviewed AstraZeneca's written arguments and heard its Counsel in oral argument. Some of that argument goes beyond what AstraZeneca pleaded. AstraZeneca urges that it is not required to plead law, and that its arguments are directed to the law; thus, do not need to be constrained by the pleadings. I do not subscribe to this argument. Rules 173 to 181 of this Court, which are similar to such rules as found in other Courts in this country, stipulate what pleadings shall contain. They shall contain a concise statement of the material facts, they may raise a point of law, and they shall contain sufficient particulars. Pleadings define the issues. Facts provide the framework for those issues. Law is argued in support of or against those issues when it comes to a trial or hearing. There is no unrestrained permission to present an argument simply because it is based only on law. The argument must relate to a pleaded issue.

[74] In the present case, AstraZeneca's arguments are not structured so as to conform with its pleadings. Furthermore, a few weeks before trial the parties, at the urging of the Court, produced a Statement of Issues designed to direct the Court to those matters that truly remained in controversy. That Statement, together with the pleadings, frames the issues. To the extent that the Notice of Constitutional Question appears to raise further issues I will ignore them for two reasons. First, as it turns out, there is no constitutional issue. Second, such a Notice is not a pleading; the opposite party has no opportunity to plead to it. The Notice is simply a document alerting possible interveners as to what might be raised. In this instance the Notice overstated those Issues and, to the extent it overstated them, it will be ignored. I repeat what Létourneau JA wrote for the Federal Court of Appeal in *Bekker v Canada,* 2004 FCA 186 at paragraph 9 that such a Notice is just that, a notice to the relevant Attorneys-General, it is no more than that:

> *9 The Notice serves a useful and essential purpose. The Attorney General, whether for Canada or for a province, bears the responsibility of enforcing legislation and defending the constitutionality of the laws enacted by Parliament or provincial Legislatures, as the case may be. The Notice enables them to discharge that duty: on the duty, see Thorson v. Canada (Attorney General), [1975] 1 S.C.R. 138, at page 146; Finlay v. Canada (Minister of Finance), [1986] 2 S.C.R. 607, at paragraph 28; Miron v. Trudel, [1995] 2 S.C.R. 418. It also alerts the provincial Attorneys General to challenges made to federal laws that may have an impact on their provinces although the duty to sustain the constitutionality of these laws is not theirs. This is why the Notice has to provide its recipients with adequate and sufficient information in terms of the material facts giving rise to the constitutional question and the legal basis for that question, otherwise it will be found insufficient and the Court will assume that there is no serious question to be addressed: see Gitxsan Treaty Society v. Hospital Employees Union et al., previously cited. Finally, it ensures that no injustice is created to the elected representatives who enacted the law and to the people that they represent: see Eaton v. Brant County Board of Education, [1997] 1 S.C.R. 241, at pages 264-65 per Sopinka J.*

[75] To the extent that any facts are recited in AstraZeneca's written and oral arguments, many are recited in the form of speculation and hypotheticals. Given this situation, I will address the issues as pleaded.

[76] In respect of the issues as pleaded, and those raised in argument by AstraZeneca, the following must be noted:

- There is no "constitutional" argument as such – no issue is raised that section 8 is *ultra vires* the jurisdiction of the federal Parliament;

- No *Charter* argument is raised.

ISSUE #1

a) Unconstitutionally Vague and Ambiguous

[77] I start with the remarks of Gonthier J in *Ontario v Canadian Pacific*, [1995] 2 SCR 1031, especially at paragraph 79, where he wrote that a law should only be declared unconstitutionally vague where it has concluded that interpretation is not possible; there is no need to consider hypothetical situations. He wrote:

> *79 Where a court is faced with a vagueness challenge under s. 7, the focus of the analysis is on the terms of the impugned law. The court must determine whether the law provides the basis for legal debate and coherent judicial interpretation. As I stated above, the first task of the court is to develop the full interpretive context surrounding the law, since vagueness should only be assessed after the court has exhausted its interpretive function. If judicial interpretation is possible, then an impugned law is not vague.*

> *A law should only be declared unconstitutionally vague where a court has embarked upon the interpretive process, but has concluded that interpretation is not possible. In a situation, such as the instant case, where a court has interpreted a legislative provision, and then has determined that the challenging party's own fact situation falls squarely within the scope of the provision, then that provision is obviously not vague. There is no need to consider hypothetical fact situations, since it is clear that the law provides the basis for legal debate and thereby satisfies the requirements of s. 7 of the Charter.*

[78] Here, AstraZeneca asserts in its pleadings that losses suffered by Apotex during a defined period have no relationship to the activity of AstraZeneca; thus, section 8 is unconstitutional for vagueness and ambiguity.

[79] It is difficult to find, outside of *Charter* cases, any situation where a Court has struck down legislation simply because it was vague or ambiguous. For instance, in *Canada v JTI-Macdonald Corp*, [2007], 2 SCR 610 at paragraphs 62 to 66, per McLachlin C J, the Court has held that where a reasonable interpretation can be afforded to legislation, the Court should not strike it down for vagueness.

[80] AstraZeneca's argument appears to be, with respect to subsection 8(1)(a)(ii) of the *NOC Regulations*, that the legislation does not "accord" with the enabling provisions of section 55.2 of the *Patent Act*; or that to afford the Court an opportunity to establish a "start date" earlier than the date certified by the Minister under subsection 8(1)(a), renders the provision unfair to a first person such as AstraZeneca. In either case, the provision is not "vague".

[81] AstraZeneca argues that, in order to be valid, the provisions of subsection 8(1)(a)(ii) must be "read down" so as to limit the Court's ability to provide for a different start date to a date *after* that certified by the Minister.

[82] Similarly, AstraZeneca argues that paragraph 8(1)(b) does not accord with the enabling provisions of section 55.2 of the *Patent Act* if it is construed so as to permit recovery of loss suffered after the date of withdrawal, discontinuance, dismissal or reversal of the proceedings.

[83] Both these arguments are not "vagueness" arguments. They are arguments relating to statutory or regulatory interpretation.

[84] In the present case, it is to be remembered that Apotex is *not* seeking that the Court establish a date for commencement of the recovery period under subsection 8(1)(a)(ii) of the *NOC Regulations* earlier than the date certified by the Minister under subsection 8(a). I am aware that my colleague, Justice Snider, is dealing with a situation where a generic, Teva, is seeking to establish an earlier date (*Sanofi-Aventis Canada Inc v Teva Canada Limited*, Court File No. T-1161-07). It may be that, whether in the Teva situation or some other situation, an earlier date is proper and justified. I leave that for Justice Snider or another Judge hearing another case. In the case before me, an argument "at large" that an earlier date is not supported by section 55.2 of the *Patent Act*, or is otherwise "unfair", is simply too speculative to address without a proper factual foundation.

[85] With respect to the end date for recovery as established by subsection 8(1)(b) of the *NOC Regulations,* I note two things. First, the Federal Court of Appeal in *Alendronate*, *supra*, has clearly interpreted this provision and observed that "the Governor-in-Council's *clearly expressed* intent" was that only losses during the relevant period (ie before the cut-off date) could be compensated. Nöel JA, for the Court, wrote at paragraphs 100 to 102:

> *100 When regard is had to the broad grant of authority conferred by subsection 55.2(4) of the Patent Act, it seems clear that the measure of the compensation which can be awarded under the PM(NOC) Regulations is a matter within the discretion of the Governor-in-Council. It is also clear that in keeping with the purpose of the PM(NOC) Regulations and the balance which the Patent Act seeks to achieve, a range of compensation was open to the Governor-in-Council in the exercise of this discretion.*
>
> *101 In this case, we have the advantage of knowing that in 1998 the Governor-in-Council focused on this very issue, and chose to limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of principle flows from this. The Governor-in-Council could have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.*
>
> *102 The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period. I therefore conclude that the appeal should be allowed on this limited point.*

[86] The second thing to note is that Apotex's claim for relief, previously recited in these reasons, does not purport to go beyond the relevant period as expressed by the Federal Court of

Appeal. If Apotex does intend at the Reference to claim for losses beyond that period, the matter can be addressed at that time keeping in mind what the Federal Court of Appeal has said. There is no "vagueness" and no basis for "reading down" subsection 8(1)(b) of the *NOC Regulations*.

ISSUE #1

b) Draconian, Harsh and Punitive

[87] In the absence of a *Charter* argument, there simply is no basis for striking down or reading down legislation or regulations simply because it is draconian, harsh or punitive. There is no *Charter* argument in this case.

[88] If a regulation falls within the enabling statutory provisions, then, simply because a party may view the effect of the regulation as being harsh in its particular circumstances, does not mean that the regulation is invalid.

[89] AstraZeneca urges that section 8 falls outside the scope of the enabling provisions of the *Patent Act*. That issue has already been determined by the Federal Court of Appeal in *Alendronate*, supra; section 8 is within the scope of the enabling provisions of the *Patent Act*. AstraZeneca argues, in a nuanced way, that perhaps certain arguments which were not put to the Court of Appeal may have persuaded it to make a different determination. I reject that argument. I accept what MacKinnon JA, for the majority, wrote *in R v Bell*, (1977), 15 OR (2d) 425, at page 430 (reversed on other grounds, [1979] 2 SCR 212):

> *It is a dangerous exercise to examine and rely on memoranda of law and fact or factums to determine how or whether certain*

> *arguments were made or whether all relevant authorities were cited to a Court. We are all aware how frequently cases are referred to in argument which are not cited in the memoranda nor referred to in the reasons, and how submissions in support of certain propositions vary markedly from the written ones. With respect, the approach taken by the Divisional Court could lead to chaotic results in the attempted application of stare decisis, and would increase the difficulty for those governed by the law to feel any certainty in the law. The binding effect of precedent, where the Court has made a clear statement of principle, cannot depend on whether, in the opinion of succeeding Courts on an examination of the available record, the case was properly argued or not.*

[90] Second, if the question of "harshness" is simply directed to the result that AstraZeneca may have to pay compensation of some amount to Apotex, then the obligation to pay has been established by the Federal Court of Appeal in *Alendronate*, *supra*, as being within the enabling legislation. The quantum will be established at the Reference.

ISSUE #1

c) Invalid delegated legislation

[91] This issue has been fully answered by the Federal Court of Appeal in *Alendronate*, *supra*. Section 8 of the *NOC Regulations* is validly delegated legislation. As discussed above, there is no basis, at least in this Court, for further argument on this point.

ISSUE #1

x) Balance

[92] AstraZeneca's Counsel in written argument and in oral argument spent considerable time in arguing that section 8 of the *NOC Regulations* failed to achieve an appropriate "balance"; thus,

was invalid. This issue was not clearly pleaded and for that reason, Apotex objected to it being raised. Nonetheless, Apotex addressed this argument, as will I, in the event of an appeal.

[93] The argument can begin with a quote from the decision of Dickson CJ, for the majority, of the Supreme Court in *R v Big M Drug Mart Ltd*, [1985] 1 SCR 295 at paragraph 80:

> *80 I cannot agree. In my view, both purpose and effect are relevant in determining constitutionality; either an unconstitutional purpose or an unconstitutional effect can invalidate legislation. All legislation is animated by an object the legislature intends to achieve. This object is realized through the impact produced by the operation and application of the legislation. Purpose and effect respectively, in the sense of the legislation's object and its ultimate impact, are clearly linked, if not indivisible. Intended and actual effects have often been looked to for guidance in assessing the legislation's object and thus, its validity.*

[94] In discussing the "object" of the *NOC Regulations*, AstraZeneca relied on the concept of "balance" between the protection of patentee's rights on the one hand, and the desire to reduce health care costs, on the other. This concept originated with Binnie J in the Supreme Court in *Bristol-Myers Squibb Co v Canada*, 2005 SCC 26 ("*Biolyse*")at paragraphs 1 and 2:

> *Per McLachlin C.J. and Binnie, LeBel, Deschamps, Fish and Abella JJ.: The Minister was entitled to issue the NOC to Biolyse on the basis of its NDS without subjecting it to the statutory freeze. An interpretation of the NOC Regulations that confers on BMS a monopoly merely by demonstrating the presence of a public domain medicine like paclitaxel in its product would provide no value to the public in exchange for the monopoly BMS seeks. When the NOC Regulations are considered in their proper context, and in particular in light of the wording of the statutory power that authorized them, the NOC Regulations do not have the sweeping effect contended for by BMS. [para. 4] [para. 69]*

> *Parliament enacted the legislation in question in order to protect the rights of patentees by preventing generic manufacturers from marketing "copy-cat drugs" until the expiry of all relevant patents. Under the NOC Regulations the court hearing the prohibition application has no discretion to lift the stay even if it thinks the innovator's case for interim relief is weak. Nor does the court have a discretion to leave the contending parties to their remedies under the Patent Act. The "second person's" application for a NOC simply goes into deep-freeze until the statutory procedures have played themselves out. [para. 24] [paras. 45-46]*

[95] Binnie J, a year later in *AstraZeneca Canada Inc v Canada (Minister of Health)*, 2006 SCC 49, wrote at paragraph 3:

> *3 The response of Apotex is that the later patents have nothing to do with the version of Losec 20 it copied, which did not (and could not) have incorporated the 037 or 470 technology. The NOC Apotex received on January 27, 2004 does not approve the use by Apotex of that technology. Apotex copied the 1989 product and contends that in that respect all NOC regulatory requirements have been satisfied. Apotex argues that even if it had wanted to copy the 037 and 470 technology, it could not have done so "[to] demonstrat[e] bioequivalence" within the meaning of the NOC Regulations because AstraZeneca never produced a product incorporating the technology taught by the two subsequently issued and listed patents. Apotex could not copy a product that did not exist. Kelen J. accepted the argument of Apotex that the NOC Regulations were only concerned with patents [page565] relevant to the innovator product actually copied, and not with subsequently issued and listed patents from which, under the federal new drug approval process, a generic manufacturer could receive no benefit ((2004), 263 F.T.R. 161, 2004 FC 1277). He therefore dismissed AstraZeneca's application to quash the Apotex NOC. The Federal Court of Appeal reversed, Sharlow J.A. dissenting ([2006] 1 F.C.R. 297, 2005 FCA 189). In my view, Kelen J. and Sharlow J.A. reached the correct conclusion. I would allow the appeal. The procedural delays afforded AstraZeneca by the majority decision of the Federal Court of Appeal overshoot the provisions and purpose of the NOC Regulations. The NOC 9427-A1114-195 issued by the Minister on January 27, 2004 is valid.*

[96] The Federal Court of Appeal in *Alendronate*, *supra* picked on the theme of “balance”. That word is repeated several times in the reasons of the Court delivered by Nöel JA. I repeat what he wrote at paragraphs 36 and 60:

> *36 It is also useful to briefly consider what was decided by the Supreme Court in Biolyse and later in AstraZeneca. The issue in Biolyse was whether a "submission" for an NOC by a person who did not rely (i.e. piggy back) on a first person's drug came within the ambit of the PM(NOC) Regulations. Binnie J., writing for the majority, recognized that the word "submission" in subsection 5(1.1) was on the face of it unambiguous and all inclusive (Biolyse, para. 43). However, the PM(NOC) Regulations had to be construed having regard to the Patent Act read as a whole and the balance which it seeks to create between the effective enforcement of patent rights through the use of the PM(NOC) Regulations (subsection 55.2(4)) and the timely entry of lower price generic drugs through the use of the "early working" exception (subsection 55.2(1)) (Biolyse, supra, para. 50).*
>
> . . .
>
> *60 This promotes the use of the PM(NOC) Regulations for the purpose for which they are intended: the prevention of infringement. Significantly, it does so in a manner which is consistent with maintaining the balance alluded to in Biolyse and in AstraZeneca. It is useful to repeat that both these cases were decided on the basis that the PM(NOC) Regulations should be construed in a manner which goes no further than is necessary in order to prevent infringement since overshooting this objective would upset the other part of the balance which section 55.2 of the Patent Act seeks to achieve, namely the timely entry of cheaper generic drugs on the market. The statutory authority of the Governor-in-Council to make regulations pursuant to subsection 55.2(4) of the Patent Act must be construed accordingly.*

[97] Using this concept of “balance”, AstraZeneca’s Counsel enumerated a number of circumstances in which, it was argued, AstraZeneca was disadvantaged, or that a generic was disproportionately advantaged. One such instance, it was argued, was that a generic could wait, having been put on “patent hold”, to a time of its choosing, to serve a Notice of Allegation; thus triggering a patent holder to institute prohibition proceedings, or not at a time and with a delay of the generic’s choosing.

[98] In my view, the “balance” argument is wrongly based on an assumption that the *NOC Regulations* must be interpreted so as to achieve a perfect harmony; and that, certainly from AstraZeneca’s point of view, it should never be disproportionately disadvantaged. A “balance” in the sense as used in a legal context is not a perfect equilibrium. Lawyers and judges speak of the “balance of probabilities”, in which various pieces of evidence are weighed, and ultimately, one viewpoint or set of facts is preferred to another. *Black’s Law Dictionary* provides as one meaning of balance, “[t]o measure competing interests and offset them appropriately”.

[99] It is for Parliament to provide for the appropriate weighing or balancing of interests in enacting the *Patent Act,* and for the Governor-in-Council to do likewise in promulgating the *NOC Regulations*. There is no independent ground for arguing that section 8 of the *NOC Regulations* is invalid, simply because it was not “balanced” in the view of one of the interested parties.

[100] In any event, the Federal Court of Appeal has already held that section 8 is an appropriate part of a "comprehensive scheme" and that the Governor-in-Council recognized the competing interests. Rothstein JA (as he then was) for the Court, wrote in *Apotex Inc v Canada (Minister of National Health and Welfare)*, [1999] FCJ No 1978, 3 CPR (4th) 1 at paragraphs 27 and 28:

> *27 Paragraph 8(1)(a) specifically provides that a patent holder whose prohibition application is dismissed is liable for the loss suffered by a generic manufacturer for the delay incurred in the issuance of a Notice of Compliance to the generic by reason of the prohibition application. Under subsection 8(4), the Court has been given jurisdiction to make an award of damages or lost profits. Section 8 of the Regulations makes it apparent that the Governor in Council recognized that generic manufacturers could be subject to unjustified prohibition applications, including applications based upon ineligible patents on the Register and provided a remedy in the form of an award of damages or lost profits in such circumstances.*
>
> *28 In sum, there is a comprehensive scheme provided in the Regulations which specifically addresses ineligible patents on the Register and the costs, loss and damage suffered by generic manufacturers arising from such ineligible patents being included on the Register. Having regard to the scheme and its recognition that ineligible patents may be included on the Register, it follows that there is no unlawful refusal to exercise discretion by the Minister in not deleting such patents from the Register under subsection 3(1).*

[101] Therefore, even if "balancing" is a separate, if unpleaded, ground for invalidity, the Court of Appeal has already determined that section 8 is appropriately balanced.

ISSUE #1

d) Inconsistent with and contrary to NAFTA and TRIPS and

ISSUE #3

Inconsistent with and contrary to NAFTA and TRIPS

[102] I will deal with Issue #1(d) and Issue #3 together, since they cover much the same ground.

[103] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement signed by many countries. Canada became a party effective January 1, 1995. Among its objectives is:

> *"the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems."*

[104] There are a number of provisions dealing with enforcement of intellectual property rights. AstraZeneca makes particular reference to two of them: Article 48(1) and Article 50(7), which I set out as follows:

> *Article 48*
>
> *Indemnification of the Defendant*
>
> *1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.*
>
> . . .

SECTION 3: PROVISIONAL MEASURES

Article 50

. . .

> *7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.*

[105] The North American Free Trade Agreement (NAFTA) is a treaty entered into between Canada, the United States of America and Mexico. It came into force January 1, 1994. That treaty also contains a number of provisions respecting the enforcement of intellectual property rights. AstraZeneca particularly relies on two provisions: Article 1715(2)(f) and Article 1716(7). They provide:

> *Article 1715: Specific Procedural and Remedial Aspects of Civil and Administrative Procedures*
>
> . . .
>
> *(2) Each party shall provide that its judicial authorities shall have the authority*
>
> . . .
>
> > *(f) to order a party in a proceeding at whose request measures were taken and who has abused enforcement procedures to provide adequate compensation to any party wrongfully enjoined or restrained in the proceeding for the injury suffered because of such abuse and to pay that party's expenses, which may include appropriate attorney's fees.*

> *Article 1716: Provisional Measures*
>
> . . .
>
> *7. Each party shall provide that, where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where the judicial authorities subsequently find that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, on request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.*

[106] It is immediately apparent that these provisions of TRIPS and NAFTA are virtually identical. The first requires "abuse" on behalf of the party seeking enforcement before providing compensation. The second provides for compensation when provisional measures are resolved or they lapse due to any act or omission by the applicant. Both treaties were entered into after the *NOC Regulations* first were established, although, those *Regulations* have been amended several times since.

[107] Canada has enacted the *World Trade Organization Agreement Implementation Act*, SC 1994, c 47, which makes reference to several treaties, such as the General Agreement on Tariffs and Trade (GATT). Specific reference is made to the *Patent Act* in sections 141 and 142 neither of which has any bearing here.

[108] It is to be noted that Article 1(1) of TRIPS specifically provides for a great deal of latitude to a member country that wishes to implement the provisions of TRIPS into its national law:

Article 1

Nature and Scope of Obligations

> *1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*

[109] Canada has also enacted the *North American Free Trade Agreement Implementation Act*, SC 1993, c 44. Section 3 of that *Act* provides:

3. For greater certainty, this Act, any provision of an Act of Parliament enacted by Part II and any other federal law that implements a provision of the Agreement or fulfils an obligation of the Government of Canada under the Agreement shall be interpreted in a manner consistent with the Agreement	*3. Il est entendu que la présente loi, les dispositions d'une loi fédérale édictées par la partie II et tout autre texte législatif fédéral qui met en oeuvre une disposition de l'Accord ou vise à permettre au gouvernement du Canada d'exécuter une obligation contractée par lui aux termes de l'Accord s'interprètent d'une manière compatible avec celui-ci.*

[110] In this *Implementation Act*, a number of revisions of the *Patent Act* were implemented; but none directed to section 55.2, which is the section of interest in the present proceedings. Section 55.1 was amended by section 193 of the *Implementation Act*, but that is not relevant here. It states:

193. Section 55.1 of the said Act is repealed and the following substituted therefor:	***193. L'article 55.1 de la même loi est abrogé et remplacé par ce qui suit:***
55.1 In an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall, in the absence of proof to the contrary, be considered to have been produced by the patented process.	*55.1 Dans une action en contrefaçon d'un brevet accordé pur un procédé relatif à un nouveau produit, tout produit qui est identique au nouveau produit est, en l'absence de preuve contraire, réputé avoir été produit par le procédé breveté.*

[111] With respect to these two treaties, TRIPS and NAFTA, I repeat what Strayer JA wrote in *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158 at paragraph 25, that the *Implementation Acts* themselves do not give those treaties the force of an Act of Parliament, except that they may be used to assist in interpretation of domestic legislation. The treaty cannot override the clear words used in a statute. He wrote:

> *25 I do not accept this argument for two reasons. First, article 1709(8) is a provision of the NAFTA. The NAFTA has been approved by An Act to Implement the North American Free Trade Agreement, S.C. 1993, c. 44, s. 10. However, this does not give the provisions of the NAFTA themselves the force of an Act of Parliament. I accept that an international treaty may, where relevant, be used to assist in interpreting domestic legislation. See, for example, Baker v. Canada (Minister of Citizenship and Immigration), [1999] 2 S.C.R. 817, at paragraphs 69 and 70. However, the international treaty cannot be used to override the clear words used in a statute enacted by Parliament. Section 78.4 is plain and obvious. Petrolite, I think, is relying on article 1709(8) of the NAFTA to give a restricted meaning to section 78.4 which its words cannot bear.*

[112] In any event, the "paramouncy" clause provided in subsection 55.2(5) of the *Patent Act* resolves any doubt; the wording of the *Patent Act* and *NOC Regulations* is paramount:

55.2 (5) In the event of any inconsistency or conflict between *(a) this section or any regulations made under this section, and* *(b) any Act of Parliament or any regulations made thereunder,* *this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.*	*55.2 (5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.*

[113] AstraZeneca argues that, even though the relevant provisions of TRIPS and NAFTA were not directly implemented into Canadian legislation or regulations, they should "inform" the interpretation of the *Patent Act* and *NOC Regulations*. In so doing, they rely on *National Corn Growers Assn v Canada (Import Tribunal)*, [1990] 2 SCR 1324. Gonthier J for the majority wrote at page 1371:

> *The first comment I wish to make is that I share the appellants' view that in circumstances where the domestic legislation is unclear it is reasonable to examine any underlying international agreement. In interpreting legislation which has been enacted with a view towards implementing international obligations, as is the case here, it is reasonable for a tribunal to examine the domestic law in the context of the relevant agreement to clarify any uncertainty. Indeed where the text of the domestic law lends itself*

> *to it, one should also strive to expound an interpretation which is consonant with the relevant international obligations.*

[114] The legislation in question in *Corn Growers*, supra, was legislation specifically designed to implement certain of Canada's treaty obligations respecting subsidization of imported grain. The Supreme Court was not making a pronouncement of such general application that, wherever a treaty may be found, even if not implemented in domestic legislation, it can "inform" the interpretation of that legislation.

[115] In any event, even if one were to take the position that the TRIPS and NAFTA treaties are to "inform" section 55.2 of the *Patent Act*, and section 8 of the *NOC Regulations*, AstraZeneca has been less than clear in its argument as to what should be the result. At best, as discussed with its Counsel in oral argument, it seems to be that the obligation to pay under section 8(1) is only triggered if there is an "abuse". There is no jurisprudence to assist as to what TRIPS or NAFTA considers an "abuse" to be. AstraZeneca argues that only an abuse of process would trigger an obligation to pay and that simply to commence and follow through with an application for prohibition under section 6 of the *NOC Regulations* is not an "abuse".

[116] I reject this argument. The *Corn Growers* decision, even if applicable, states that reference to a treaty is only to be made if the legislation is unclear. Here, section 8(1) is not unclear. It does not include the word "abuse" or anything referencing an activity that could be considered abusive. AstraZeneca wants to read in a word that is not there and a word that would fundamentally change the meaning of that provision. There is no merit to the argument.

[117] The Federal Court of Appeal recently considered a similar argument in *Fraser v Janes Family Foods Inc*, 2012 FCA 99 in dealing with whether the obligation to post security for costs under Federal Courts Rule 416 was contrary to certain NAFTA and TRIPS provisions. The Court held that NAFTA cannot override the clear provisions of the Rule. Nöel J for the Court wrote at paragraphs 19 and 22:

> *19 In my view, "interpreting" Rule 416(1)(a) as not applying in these circumstances would amount to "overriding" its application. The proposition set out by Justice Cromwell in Merck is simply that where a legislative enactment is open to two constructions, one which is consistent with Canada's treaty obligation and one which is not, the former should be preferred. It does not put into question the conclusion reached in Baker Petrolite that the NAFTA cannot "override" a clear legislative enactment.*
>
> . . .
>
> *22 Again as was stated in Baker Petrolite and Pfizer, the fact that a treaty is approved by an Act of Parliament does not give the provisions of the treaty the force of law. The only way in which Rule 1.1(2) could assist the appellants is if they could show that Rule 416(1)(a) is inconsistent with the Implementing Acts themselves.*

[118] The only effect that TRIPS and NAFTA had respecting the *NOC Regulations* is that the compulsory licensing provisions relating to pharmaceuticals were repealed, and the present *NOC Regulations* were put in place. Binnie J wrote in *Biolyse, supra* at paragraph 10:

> *10 In a reversal of policy, Parliament in 1993 repealed the compulsory licence provisions of the Patent Act by what became known as Bill C-91 (S.C. 1993, c. 2) and extinguished all compulsory licences issued on or after December 20, 1991. In part, these changes flowed from international obligations accepted by Canada under the Agreement on Trade-Related Aspects of Intellectual Property Rights,*

> *1869 U.N.T.S. 299 ("TRIPS"). More immediately, perhaps, it was thought that Canada's compulsory licensing system would be declared incompatible with Canada's obligations under the North American Free Trade Agreement, Can. T.S. 1994 No. 2, in particular art. 1709(10), signed at the end of 1992.*

[119] Thus, I find that neither TRIPS nor NAFTA are of any assistance to AstraZeneca in this case.

ISSUE #2

> *1. Has Apotex satisfied the conditions for engaging section 8 of the PM(NOC) Regulations, including that it is a "second person" within the meaning of section 8 of the PM(NOC) Regulations, or has Apotex failed to satisfy any relevant condition insofar as such failure has been expressly pleaded by AstraZeneca (apart from paragraphs 58 and 59 of AstraZeneca's defence).*

[120] The parties were asked to state their position briefly as to this and the other outstanding issues. Apotex says that it has satisfied the conditions for engaging section 8 of the *NOC Regulations*. AstraZeneca states that Apotex was not a "second person" within the meaning of section 8, as Apotex did not early work the patented invention and did not have a qualifying submission.

[121] The *NOC Regulations* applicable to this action, the 1999 version, describe a "second person" in the interpretation section, section 2, as a person referred to in subsections 5(1), or (1.1), as the case may be. Subsections 5(1) and 5(1.1) of that version read as follows:

> *5. (1) Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug, [SOR/98-166, s. 4(1); SOR/99-379, s. 2(1).]*
>
> . . .
>
> *5. (1.1) Subject to subsection (1.2), where subsection (1) does not apply and where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine found in another drug that has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent included on the register in respect of the other drug containing the medicine, where the drug has the same route of administration and a comparable strength and dosage form,*

[122] Subsection 5(1.1) was added to the *NOC Regulations* in 1999. The Regulatory Impact Analysis Statement (RIAS) said, in respect of this addition:

> *It has recently become apparent that a second or subsequent entry manufacturer may seek to obtain a NOC without triggering the application of the Regulations, even though a patent list for the innovator's drug has been filed with the Minister of Health.*
>
> *The present amendments are intended to clarify the law and reaffirm the application of the Regulations. This is accomplished by maintaining and clarifying the current subsection 5(1) while introducing a new subsection 5(1.1). The new subsection 5(1.1) is based on the proposed regulatory text published in the Canada Gazette, Part I, on July 31, 1999. As with the prepublished text, subsection 5(1.1) will address the cases where a second or subsequent entry manufacturer may seek to*

> *obtain a NOC without triggering the application of the Regulations under subsection 5(1).*
>
> *Subsection 5(1), as is currently the case, will apply where the second or subsequent entry manufacturer makes a comparison with, or a reference to, another drug that has been marketed in Canada and for which a patent list has been submitted to the Minister of Health. The words "wishes to" have been deleted to reflect the factual analysis that is done under these Regulations. The words "compare with, or make reference to" has been modified by the phrase: "for the purposes of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics" to clarify the intent that subsection 5(1) applies to a second or subsequent entry manufacturer who relies on a comparison with, or reference to, a previously approved innovator drug in order to obtain a NOC for its version of the innovator drug, which had, itself, been proven safe and efficacious through extensive clinical testing.*
>
> *Subsection 5(1.1) will apply where a second or subsequent entry manufacturer does not make such an explicit comparison or reference, but, in fact, seeks a NOC for another version of a drug that has previously been marketed in Canada by a first person who has filed a patent list with the Minister of Health. Specifically, subsection 5(1.1) will be triggered when the second or subsequent entry manufacturer's drug contains the same medicine, employs the same route of administration and has a comparable strength and dosage form as the drug listed on the patent register. In this context, "comparable" is intended to operate as it does within the context of the drug approval process. In the phrase "drug that contains a medicine found in another drug", "medicine" is intended to refer to both the substance that is the subject of the NOC issued for the innovator's drug and the substance that is the subject of a second or subsequent entry manufacturer's drug submission for a NOC.*

[123] Subsection 5(1.1) of the *NOC Regulations* was the subject of a decision of the Supreme Court of Canada in *Biolyse*, *supra*. In that case, Bristol-Myers had developed and patented an anti-cancer drug derived from a species of yew bush. It listed the patent on the list kept by the Minister under the *NOC Regulations*. Biolyse developed an anti-cancer drug from a different species of yew. The Federal Court and Federal Court of Appeal held that the Biolyse application,

which did not compare its product to that of Bristol-Myers for purposes of bioequivalence was, nonetheless, caught by the provisions of subsection 5(1.1) of the *NOC Regulations*. The Supreme Court allowed the appeal, holding that subsection 5(1.1) did not apply to innovative drugs, but only to generic copies of patented drugs. Justice Binnie, for the majority, wrote at paragraphs 29 and 69:

> *29 Biolyse also formed the opinion that paclitaxel was not only useful for treatment of refractory ovarian cancer (which was the use identified by the respondent BMS in its initial NDS to the Department of Health), but could also be useful in the treatment of non-small-cell lung cancer and forms of breast cancer. The officials at the Department of Health were concerned about the different botanical source of paclitaxel, and the claim of Biolyse for new and different uses for the medicine. The Department of Health therefore required independent clinical studies to be performed. In short, the officials at TPP regarded the Biolyse product as a substance "which has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada [its] safety and effectiveness", and was therefore a "new drug" within the meaning of s. C.08.001 of the FDA Regulations.*
>
> . . .
>
> *69 In my view, s. 5(1.1) does not apply to innovative drugs. It should be confined to applications for generic copies of patented drugs in the circumstances contemplated by the regulator, i.e. where a manufacturer makes a submission for a NOC for a drug which contains a medicine that it purports to copy from another generic but in fact copies from the innovator company that has filed the patent list. That is not this case. Where the applicant relies on bioequivalence, it will be caught by s. 5(1). On the facts here, neither s. 5(1) nor s. 5(1.1) applies. Accordingly, I conclude that the Minister was entitled to issue the NOC to the appellant Biolyse on the basis of its NDS without subjecting Biolyse to the statutory freeze.*

[124] This decision was commented upon by the Supreme Court in its subsequent decision in *Apotex Inc v AstraZeneca Canada Inc*, *supra,* which involved the same two parties as the present action and Apotex's generic omeprazole version of the LOSEC capsule, but was dealing with two different patents. The unanimous decision of the Court was delivered by Justice Binnie, who wrote at paragraph 19:

> *19 The Food and Drug Regulations and departmental policies require drug manufacturers to submit different types of new drug submission ("NDS") for different purposes. The two principal forms of submission are the NDS, filed by an innovative drug manufacturer for a new drug product, and the ANDS, filed by a generic manufacturer that claims its product is the "pharmaceutical equivalent" of a previously approved "Canadian reference product" (s. C.08.002.1(1)(a)). A SNDS may be submitted for substantive or for purely administrative reasons. Unlike the situation in Biolyse, the intention of the applicant Apotex from the outset was to produce a generic (i.e. copy-cat) version of the AstraZeneca product marketed as Losec 20 in 1989. In this case, Apotex makes no pretence of originality.*

[125] In 2006, the *NOC Regulations* were amended so as to repeal subsection 5(1.1) and to remove the requirement of comparison for "bioequivalence" from subsection 5(1). The accompanying RIAS said with respect to this change:

> *The amendments also repeal subsection 5(1.1). That provision was introduced in 1999, when it became apparent that a generic company could avoid compliance with the PM(NOC) Regulations by making an indirect comparison to an innovator's drug with patents on the register. However, a subsequent ruling from the Federal Court of Appeal established that the pre-existing triggering provision, subsection 5(1), was sufficiently broad to capture avoidance strategies founded on indirect reliance. Repeal of subsection 5(1.1) is also consistent with the Supreme Court of Canada's recent decision in the "Biolyse case", which confirmed that the PM(NOC) Regulations do not apply to second and*

> *subsequent entry drug submissions where the sponsor of the submission is required by the Minister to conduct independent clinical studies to establish the safety and efficacy of its product.*
>
> *Notwithstanding the repeal of subsection 5(1.1), amended section 5 will continue to feature two triggering provisions, in order to better mirror the structure of section 4. Subsection 5(1) will apply to a generic manufacturer that files an initial submission for a NOC for a generic version of an innovative drug. Subsection 5(2) will apply whenever the manufacturer files a supplement to that submission for a change in formulation, change in dosage form or a change in use of the medicinal ingredient. Distinguishing between the two types of submissions in this manner should also serve to accelerate the drug review process as the Minister will no longer be required to verify each and every supplement for compliance with the PM(NOC) Regulations.*

[126] AstraZeneca made an argument in the present action that Apotex was not a "second person" because the filing that it made with Health Canada was originally an NDS, then changed to an ANDS; then changed back to an NDS. AstraZeneca points out that, when Apotex got its first NOC in 2004, bioequivalence was expressly omitted and not inserted until the revised NOC was issued in 2006. In effect, it argues that Apotex did not engage the "early working" provisions of the *Patent Act*. Apotex says that AstraZeneca did not plead this point. I agree and for that reason alone the argument should be dismissed. Nonetheless, I will consider it.

[127] Notwithstanding the point that the matter was not properly pleaded, Apotex rebuts this argument essentially in three ways. First, as a matter of *res judicata*, it has been established that Apotex is, vis-à-vis AstraZeneca, a "second person". Second, AstraZeneca cannot "approbate and reprobate"; that is, it cannot take advantage of a twenty-four month injunction on the basis that Apotex was a second person, and then say that it was never a second person. Third, that it is irrelevant whether Apotex sought to compare its product to LOSEC for the purposes of

bioequivalence, since it was caught either by subsection 5(1) of the *NOC Regulations*, or by subsection 5(1.1).

[128] First, as to *res judicata*, Apotex argues that this Court, in proceedings T-812-02 between Apotex, the Minister of Health and AstraZeneca Canada, clearly determined that, as between the parties and Apotex's application to market a generic version of the LOSEC 20mg capsule, that Apotex was a second person and was required to address the '762 patent pursuant to the *NOC Regulations*. In his decision dated April 30, 2004, cited as 2004 FC 650 (appeal dismissed January 31, 2005 by the Federal Court of Appeal, A-291-04, without reasons) Justice O'Keefe characterized AstraZeneca's submissions at paragraphs 50 and 51 of his Reasons:

> *50 AstraZeneca submits that Apotex's arguments that it only compared Apo-Omeprazole to the 1996 version of Losec and that Losec was not marketed in Canada at any material time are flawed. It is submitted that there is no basis for Apotex's suggestion that it compared its proposed product to a different "new drug". It is submitted that Apotex compared its Apo-Omeprazole capsules to the omeprazole capsules of AstraZeneca, thereby triggering the obligation to make an allegation. Further, it is submitted that if this Court finds that it is a requirement that AstraZeneca has marketed pursuant to the 1999 submission to trigger an allegation by Apotex, AstraZeneca has done so beginning in May 2002. AstraZeneca submits that on the facts of these case, the NOC Regulations are clearly engaged and Apotex must address the '762 Patent.*
>
> *51 Finally, AstraZeneca submits that even if subsection 5(1) of the NOC Regulations is not triggered, subsection 5(1.1) clearly requires Apotex to make an allegation of non-infringement since it has filed a submission for a drug which contains a medicine found in another drug marketed in Canada pursuant to an NOC.*

[129] Apotex argued in that case that subsection 5(1) did not apply to it since LOSEC capsules were not marketed at the relevant time. Justice O'Keefe dismissed this argument and held that Apotex was obliged to address the '762 patent in a Notice of Allegation (NOA). In other words, Apotex was a "second person". He wrote at paragraphs 66 to 70:

> *66 Apotex argued that the marketing of the drug must take place after the issuance of the NOC associated with the patent list in order to have subsection 5(1) of the NOC Regulations apply. Apotex argued that if the '762 Patent was properly listed, it was only in relation to Supplemental New Drug Submission no059881. The NOC for this submission was granted on June 4, 1999. AstraZeneca discontinued the sale of its 20 mg Lozec capsules in 1996 and did not start to sell Lozec again until May 14, 2002. Apotex submits that subsection 5(1) of the NOC Regulations did not apply to it because the capsules were not marketed in Canada pursuant to the June 4, 1999 NOC for which a patent list had been submitted.*
>
> *67 The Minister submitted that subsection 5(1) of the NOC Regulations does not require that the marketing in Canada take place at any particular time as long as it occurred pursuant to an NOC and also that the marketing need not take place pursuant to the NOC in connection with which the patent list was submitted.*
>
> *68 Based on the facts of this case, I need not decide which of these interpretations is correct, as I believe that with either interpretation of subsection 5(1) of the NOC Regulations, subsection 5(1) will apply and require Apotex to address the '762 Patent.*
>
> *69 AstraZeneca filed a patent list on August 31, 2000, listing the '762 Patent and referencing Supplemental New Drug Submissions 14671, 17495 and 059881 for which NOCs were issued on June 30, 1993, July 15, 1994 and June 4, 1999 respectively.*
>
> *70 The '762 Patent was added to the patent register on September 1, 2000. As AstraZeneca did not cease marketing Losec in Canada until 1996, AstraZeneca did market Losec in Canada pursuant to NOCs associated with the patent list, namely, the NOCs issued June 30, 1993 and July 15, 1994. Subsection 5(1)*

> *was triggered, obliging Apotex to address the '762 Patent in an NOA.*

[130] The classic case on *res judicata* is the decision of the Supreme Court of Canada in *Angle v Minister of National Revenue*, [1975] 2 SCR 248 at page 254, where Dickson J wrote, citing the *Carl Zeiss* case:

> *Lord Guest in Carl Zeiss Stiftung v. Rayner & Keeler Ltd. (No. 2) [[1967] 1 A.C. 853.], at p. 935, defined the requirements of issue estoppel as:*
> *... (1) that the same question has been decided; (2) that the judicial decision which is said to create the estoppel was final; and, (3) that the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies.....*

[131] I refer also to the Supreme Court decision in *Danyluk v Ainsworth Technologies Inc,* [2001] 2 SCR 460 at paragraph 18, where Binnie J. wrote:

> *18 The law rightly seeks a finality to litigation. To advance that objective, it requires litigants to put their best foot forward to establish the truth of their allegations when first called upon to do so. A litigant, to use the vernacular, is only entitled to one bite at the cherry. The appellant chose the ESA as her forum. She lost. An issue, once decided, should not generally be re-litigated to the benefit of the losing party and the harassment of the winner. A person should only be vexed once in the same cause. Duplicative litigation, potential inconsistent results, undue costs, and inconclusive proceedings are to be avoided.*

[132] In the present action, and in T-812-02, the parties Apotex and AstraZeneca are the same, the issue is the same - Did Apotex have to address the '762 patent under the *NOC Regulations* as a “second person” - and the decision is final.

[133] AstraZeneca argues that *res judicata* was not pleaded by Apotex in respect of proceeding T-812-02, but only with respect to another proceeding, T-2311-01. While technically correct, this argument is misleading and disingenuous. Proceeding T-2311-01 was, in effect, the "parent" of T-812-02. Justice O'Keefe, in dealing with T-2311-01, decided that the listing of the '762 patent should be determined in a second proceeding; thus T-812-02 was "carved out" of T-2311-01 and dealt with separately. I repeat what Justice O'Keefe wrote in his decision, 2004 FC 313 in T-2311-01 at paragraphs 32 and 78:

> *32. Apotex alleges that the '762 patent does not qualify for listing on the patent register, or, alternatively that it does not apply to the Apo-Omeprazole product.*
>
> . . .
>
> *78 The patent listing issue will be dealt with separately.*

[134] I am concerned that Counsel for AstraZeneca were not frank and open with this Court in making this argument.

[135] I find that, on the basis of *res judicata*, AstraZeneca cannot raise the argument in this action that Apotex was not a "second person" within the *NOC Regulations* when it comes to addressing the '762 patent.

[136] Even if *res judicata* did not apply, I find that, whether one considers either subsection 5(1) or 5(1.1) of the *NOC Regulations* applicable at the time, it is immaterial whether Apotex filed an NDS or ANDS, or whether it addressed, or was successful in addressing bioequivalence with regard to LOSEC. Whether or not Apotex made a filing based on bioequivalence it is

caught either by 5(1) or 5(1.1); thus, in the result, Apotex had to address the '762 patent as a "second person" under the *NOC Regulations*.

[137] A further basis for rejecting AstraZeneca's submission as to "second person" rests with the doctrine of election or approbation and reprobation. As Lord Wilberforce wrote in *Johnson v Agnew,* [1980] AC 367 (HL) at page 398, in the end, the doctrine is based on simple considerations of common sense and equity.

[138] AstraZeneca commenced proceedings under the *NOC Regulations* against Apotex, which had the immediate effect of preventing Apotex from getting an NOC to market its generic omeprazole capsules for twenty-four months. Such relief would only be available if AstraZeneca treated Apotex as a second person. Certainly, AstraZeneca at no time raised the issue in that proceeding as to whether Apotex was a second person and thus need not bother with the *NOC Regulations* at all. Indeed, in another proceeding already dismissed, T-2311-01, the Court held that Apotex had to proceed under the *NOC Regulations* as a second person. In effect, AstraZeneca wants to approbate and reprobate – to have its cake and eat it, too. It simply offends common sense and equity.

[139] I find, in respect of Issue #2, that Apotex is a "second person" within the *NOC Regulations* applicable to this case.

ISSUE #5

> *Whether the alleged infringement of the '693 Patent is relevant in law, including whether it is relevant as a defence, to the section 8 claim of Apotex (including possible set-off damages) (and if so, see para. 4 of Order of October 4, 2011)?*

[140] AstraZeneca's position is that the alleged infringement is relevant in law as a defence to section 8(1) (as well as section 8(5)), since the statutory stay would not have caused damages for infringing sales because Apotex would have been liable to AstraZeneca for damages for such sales. Therefore, there is no "loss suffered".

[141] Apotex's position is that the alleged infringement of the '693 patent is not relevant in law to Apotex's claim in any respect. AstraZeneca's new allegation at trial that the defence of infringement is relevant under subsection 8(5) was never pleaded and, in any event, was without foundation.

[142] The question as to whether infringement of a patent by a generic can provide a viable defence to a claim for compensation by that generic under section 8(5) of the *NOC Regulations* was considered very recently by the Federal Court of Appeal in *Apotex Inc v Merck & Co Inc*, 2011 FCA 364 (referred to in argument by Counsel as "*Lovastatin").* In that case, there had been a finding by a Trial Judge of this Court (*Merck & Co v Apotex Inc*, 2010 FC 1265) affirmed by the Court of Appeal (2011 FCA 363) in an action for infringement of a patent (Canadian Patent No. 1,161,380) that some but not all the Apotex product infringed that patent. In *Lovastatin supra,* Apotex was claiming compensation for loss under section 8(5) of the *NOC Regulations*. Merck asserted that the finding of infringement precluded that claim. The Federal Court of

Appeal found that there was no preclusion; however there may exist a basis for reducing compensation arising out of any *ex turpi causa* consideration. Evans JA for the Court wrote at paragraphs 36 to 38:

> *36 I do not accept Merck's submission that the Court should read into this provision limiting words to the effect, "unless the second person's claim is based on the loss that is has suffered by being prevented from infringing the first person's patent earlier." The presumption against reading words into a statutory text may be rebutted when demanded by context and legislative objective. In my view, it is not necessary to read an ex turpi causa exception into subsection 8(1) in order to prevent patent infringers from unjustly recovering compensation from a first person.*
>
> *37 This is because subsection 8(5) confers a broad discretion on the court when assessing the amount of compensation that the second person must pay. It provides that the court "shall take into account all matters that it considers relevant to the assessment of the amount," including any conduct by either party that contributed to the delay in the disposition of the first person's application for prohibition. In my view, this provision enables the Court to determine in its discretion whether, and to what extent, a second person's claim for compensation should be reduced, or eliminated.*
>
> *38 The Court's broad discretion under subsection 8(5) allows it, when considering arguments based on ex turpi causa, to have regard to the factual situation in its entirety, including its nuances. In the present case, one such nuance is that not all the tablets sold by Apotex were found in the infringement action to contain lovastatin made by the infringing process. A court is likely to find it easier to apply the ex turpi causa principle through an exercise of judicial discretion than through the definition of liability. Discretion enables the court to assess the appropriate amount of compensation payable (including nil) in a manner that properly takes account of all the relevant facts.*

[143] The question of *ex turpi causa* came before the United Kingdom High Court of Justice, Chancery Division, Patents Court in *Les Laboratoires Servier v Apotex Inc*, [2011] EWHC 730 (Pat), a decision given by Justice Arnold. In that case, Apotex had been prevented from selling perindopril in the United Kingdom by an interlocutory injunction given pending trial. Servier, who obtained the injunction, had given an undertaking as to damages. Apotex prevailed at trial and sought damages pursuant to the undertaking. Servier argued that Apotex could not have made and sold the product, in any event, since the product would have been made in Canada. The Federal Court of Canada (Snider J.,) had held that Apotex's product would infringe a valid Servier Canadian patent, hence it would be unlawful for Apotex to make and export the product from Canada (*Laboratoires Servier v Apotex Inc*, 2008 FC 825). Justice Arnold made an extensive review of the law of *ex turpi causa* and concluded that the unlawfulness as proven must be sufficiently serious before a person engages the *ex turpi causa* rule, and that such unlawfulness must be an activity personal to the claimant, not vicarious. He wrote at paragraphs 92 to 95:

> *92. The main conclusion which I draw from this survey of the cases cited to me is that they confirm that the application of the ex turpi causa rule depends on the circumstances of the case. Significant factors include the knowledge of the claimant at the relevant time, whether the illegality involved intentional or negligent conduct on the part of the claimant and whether the commission of the illegal act was induced by the defendant. It appears from dicta in a number of these cases that it may not be sufficient that the act was criminal if the offence was one of strict liability and the claimant was unaware of the relevant facts. Equally, mere negligence is unlikely to be enough in the circumstances of a claim for contribution or indemnity against another tortfeasor.*
>
> *93. In my judgment none of these authorities establishes that, in the case of acts which are tortious rather than criminal, the rule*

only applies if the acts involve dishonesty. Furthermore, I consider that such a limitation would not properly reflect the policy considerations which underlie the rule. I accept that there will be situations in which the tort is not sufficiently serious to engage the rule, but what degree of seriousness is sufficient will depend on the circumstances of the case. In my view the key factor in most cases is likely to be the claimant's state of knowledge at the time of committing the act in question. If the claimant knew the material facts, and particularly if he committed the act in question intentionally, then the rule is likely to apply.

94. In the present case it is important to bear in mind that I am concerned with the court's equitable jurisdiction to enforce a cross-undertaking in damages. I considered the general principles applicable to this jurisdiction in Lilly v 8PM at [8]-[21]. As explained there, the purpose of a cross-undertaking is to ensure that the parties affected by the grant of an interim injunction are compensated if it later turns out that the injunction was wrongly granted. Nevertheless, it is well established that the court has a discretion to refuse to order an inquiry under a cross-undertaking even if the injunction is discharged. In the present case an inquiry has already been ordered and undertaken, and Servier does not contend that an order for payment of the compensation Norris J found due should be refused on purely discretionary grounds. Nevertheless, the fact that the court has a discretion to refuse to order an inquiry casts lights on the nature of the jurisdiction. The court is concerned to do what is just having regard not only to the fact that the injunction was wrongly granted, but also to wider considerations.

95. In the light of the foregoing discussion, I conclude that the principle which I stated in Lilly v 8PM at [287] and which is quoted in paragraph 47 above requires qualification in at least one, and possibly two, ways. The first qualification is that the unlawfulness must be sufficiently serious to engage the ex turpi causa rule. What is sufficiently serious depends on the circumstances of the case, and in particular the state of knowledge of the claimant under the cross-undertaking at the relevant time; but the claimant's conduct must be assessed having regard to the fact that the claim is for compensation under a cross-undertaking. The second possible qualification is that the unlawfulness must be personal to the claimant, not vicarious; but it is not necessary to decide this for present purposes.

[144] Arnold J. considered the specific circumstances of the case before him and concluded that *ex turpi causa* did apply to Apotex. He wrote at paragraphs 96 to 100:

> *96. In my judgment, Apotex's claim in the present case involves sufficiently serious unlawfulness to engage the ex turpi causa rule for the following reasons. For convenience, I shall express these reasons in terms of what Apotex actually knew and did during the relevant period, although strictly speaking the question is what Apotex would have known and would have done in the hypothetical scenario postulated by Apotex in support of its claim.*
>
> *97. First, this is not a case where Apotex's illegal act (infringement of the Canadian Patent) was induced by Servier. Nor was Apotex misled by Servier in any way.*
>
> *98. Secondly, Apotex was aware of all the material facts. In particular, Apotex was fully aware of both (i) the existence of the Canadian Patent and (ii) the nature of the infringing acts. Indeed, Snider J found as a fact that Apotex knew that making perindopril erbumine would infringe the Canadian Patent if valid.*
>
> *99. Thirdly, it is clear that Apotex committed the infringing acts intentionally, which is not to say that it intended to infringe. Apotex adduced unchallenged evidence before me that it had been advised that it had a good chance of successfully defending the claim for infringement of the Canadian Patent on the basis that it had respectable arguments that the Canadian Patent was invalid. It follows that Apotex decided to take a commercial risk that its manufacture of perindopril erbumine in Canada would be held to infringe a valid patent.*
>
> *100. Fourthly and most importantly, there is a precise symmetry between Apotex's claim for compensation under the cross-undertakings and the illegality upon which Servier relies. Apotex's claim for compensation under the cross-undertakings is predicated on the basis that it was wrongly restrained by Mann J from infringing the European Patent and that, but for those injunctions, it would have continued to import into the United Kingdom and sell perindopril erbumine manufactured by it in Canada so as to make a profit. But the decisions of the Canadian courts establish that such manufacture of perindopril erbumine would have infringed the Canadian Patent. Why should Apotex be permitted to claim compensation for being wrongly prevented from infringing*

> *one patent on the basis that, but for the injunctions, it would have infringed another patent belonging to the group of companies? In such circumstances, the rationale for the ex turpi causa rule given by McLachlin CJ in Hall v Hebert indicates that the rule should apply.*

[145] The English Court of Appeal reversed this decision. Reasons were written by Etherton LJ, in which Laws LJ and Kitchen LJ concurred and are cited at *Les Laboratoires Servier v Apotex Inc*, [2012] EWCA, Civ 593. An important concession was made by Apotex's Counsel just before that appeal was to be heard; namely, that Apotex accepted in principle the point made in paragraph 26 of Servier's re-amended Defence. That paragraph is set out at paragraph 22 of Etherton LJ's reasons:

> *26. In the further alternative, the manufacture by the First Defendant in Canada of each unit of perindopril which was intended for sale in the UK would have given rise under the laws of Federation of Canada to a liability by way of damages or by way of an account of the profits accruing to ADIR and Servier Canada Inc. by reason of the said manufacture. This liability should be deducted as an additional cost of manufacture there by reducing any lost profit suffered by the Defendants as alleged in the Confidential Points of Claim. The precise amount of the said liability is a matter which needs to be assessed by reference to Canadian law, further particulars of which will be provided in due course."*

[146] Etherton LJ commented on this concession at paragraph 33:

> *33. Apotex has added one important argument to those which it advanced before the Judge for rejecting what the Judge called Servier's public policy point, but which I would prefer to call its illegality defence, which is based on what the Judge called the ex turpi causa rule but which I prefer to call the illegality principle. The day before the appeal was due to be heard Apotex's solicitors wrote to Servier's solicitors accepting in principle the point made*

> *in paragraph 26 of Servier's re-re-amended Points of Defence, that is to say that there should be deducted from the damages awarded by Norris J an amount equal to what the Canadian court would have ordered Apotex to pay Servier in Canada for infringement of the Canadian Patent in manufacturing and exporting products for sale in the United Kingdom market had there been no interlocutory injunctions preventing sales here ("the paragraph 26 concession").*

[147] This concession played a critical role in the reversal by the Court of Appeal and the award of damages on the undertaking to Apotex. The Court considered that, in awarding such damages, a Court assessing the quantum of such damages could arrive at a quantum that was not offensive to comity with Canada or interfere with English public policy. Etherton LJ wrote at paragraph 88:

> *88. Accordingly, fifthly, the effect of the paragraph 26 concession is to place Apotex in precisely the position in which it would have been had there been no interlocutory injunctions in the United Kingdom and without offending comity with Canada. The unlawfulness of the breach of the Canadian Patent by the assumed manufacture and export of goods in Canada for lawful importation and sale in the United Kingdom would be marked by deducting from Norris J's award an amount equal to Apotex's profits recoverable by Servier under Canadian law for such unlawful manufacture and export. That would reflect the remedy actually imposed in Canada for the manufacture and export by Apotex infringing the Canadian Patent in the period prior to the grant of the final injunction by Snider J and in the thirty day period allowed under Snider J's final order for the sale of infringing items. There would be consistency in the law by recognizing, in the inquiry as to damages, the illegality in Canada in the same way and to the same extent as the Canadian courts would in fact have done in respect of any unlawful manufacture and export in Canada during the relevant period. Expressed in a different way, if Apotex was left with some of the compensation ordered by Norris J even after deduction of an amount reflecting the paragraph 26 concession, what would be left is not something that the Canadian courts themselves would regard as properly recoverable under Canadian law for breach of the Canadian patent. The result, therefore, would*

> *neither be offensive to comity with Canada not any reason for interference on the ground of English public policy.*

[148] This solution accords with what may properly be done in the present situation. A Court hearing the pending infringement action, if it concludes that the patent is valid and has been infringed by Apotex in making the omeprazole drug that is the subject of these proceedings, can at that time craft a remedy that is appropriate, having in mind any compensation awarded in these proceedings. It would be unconscionable for the present proceedings to come to a halt or for this Court to refuse to award compensation simply because another action on another patent was pending. To do so would be simply to encourage such actions to be brought. The best way to deal with the matter is as I have set out above.

[149] Apotex raises two other points in respect of this issue. The first is an overly technical argument that AstraZeneca's pleading as to infringement is to be found under the wrong caption. Apotex was not misled, nor was I. I reject this argument. The second is that AstraZeneca did not plead *ex turpi causa*. This is correct; however, the law on the point has developed so recently that they cannot be faulted for not pleading it. However, as I have found, that law is inapplicable in the circumstances of this case.

[150] In the circumstances, paragraph 4 of my Order of October 4, 2011 does not apply, Judgment as to liability in this action will not be reserved.

ISSUE #6

> *Whether Apotex was in a position to market Apo-Omeprazole in the period January 3, 2002 to January 27, 2004, including any*

> *impact of Apotex's alleged lack of approvability to manufacture for sale at a commercial manufacturing site?*

[151] AstraZeneca's position is that Apotex did not have approval to market out of its commercial manufacturing site, Torpharm, during the asserted period of liability. Apotex only had approval for Signet, a non-commercial scale site.

[152] Apotex's position is that it was in a position to market its product throughout the relevant period. AstraZeneca's assertion of illegality/*ex turpi causa* was never pleaded and, in any event, is without merit.

[153] First, with respect to any assertion by AstraZeneca as to *ex tupri causa* or illegality in this respect, I agree with Apotex that it was never pleaded. This is different from the allegation of *ex turpi causa* discussed in the previous issue, in that it does not turn on any question of a finding or allegation of infringement; rather, it turns on whether Health Canada's approval was necessary for Apotex to manufacture at Torpharm. The pleading in respect of this issue is found at paragraph 63 of the Defence:

> ***No entitlement – not in a position to market***
>
> *63. In the further alternative, if there is a prima facie liability, AstraZeneca denies that Apotex suffered any compensable damages, including for the reasons set out below. In the period 3 January 2002 – 27 January 2004, Apotex was not in a position to market Apo-Omeprazole in Canada. Apotex must show on a balance of probabilities that it was prevented from entering the market because of the prohibition application in T-2311-01. At no time during the period asserted was Apotex's submission in condition for approval to manufacture Apo-Omeprazole at a site that had the technology required to manufacture Apo-Omeprazole*

> *on a commercial scale. This is also a relevant matter that the court should consider in assessing compensation, if any, pursuant to s. 8(5).*

[154] There is no clear or unequivocal allegation of illegality or *ex turpi causa*. An allegation as serious as that must be clearly pleaded. The facts were well known to AstraZeneca for some time; it had ample discovery disclosing the relevant circumstances.

[155] The argument boils down to a rather simple one for which, on the facts established in this case, there is a simple answer.

[156] AstraZeneca's argument is that, as of January 3, 2002, the date that the Minister certified that the NOC would have been granted to Apotex "but for" the prohibition proceedings, Apotex had made an application specific only to the Signet site for manufacture. I agree. Therefore, AstraZeneca argues, the "but for" NOC would have been granted specific to that site. I agree largely, but not entirely since, after the "but for" NOC had been granted, Apotex could have manufactured in commercial quantities (as I have found) at the Signet site. Apotex could have moved the site, in whole or in part, to the Torpharm site and have given notice of the move to Health Canada. Health Canada would not have shut the manufacturing operation down, rather it would have continued to work with Apotex so as to reach the "No Objection" point.

[157] The evidence in this case shows that:

- When Apotex did get an NOC in 2004, it did start manufacturing at Torpharm
- Apotex notified Health Canada that it was manufacturing at Torpharm
- Health Canada never prevented Apotex from manufacturing at Torpharm and ultimately sent Apotex a “No Objection” letter which, in effect, approved manufacture at Torpharm

The evidence also shows that:

- Apotex could have commenced manufacture in January 2002 at the Signet site
- The Signet site had reasonable capacity to manufacture the product at some level of commercial scale

[158] A Reference will take place, at which time the capacity of each of Signet and Torpharm will be more closely examined. At present, it appears that each plant had a reasonable capacity to manufacture omeprazole in commercial quantities in the period of 2002 through 2004.

[159] I find that if in the “but for” world Apotex started to manufacture the product at Torpharm in 2002; it would not have been shut down by Health Canada. I find, as happened in reality in 2004 and following, and as both experts concluded in the “hot tubbing” session, that

Apotex would continue to manufacture at Torpharm while working with Health Canada so as to receive, ultimately, a “No Objection” letter. All the while, Apotex would continue to manufacture at Torpharm.

[160] Therefore, in respect of Issue #6, I find that Apotex was in a position to manufacture commercially as of January 3, 2002, whether at the Signet or Torpharm site, or both.

ISSUE #7

> *Whether the start date for any liability should be forward dated by reason of Apotex’s alleged delay in serving a Notice of Allegation and/or Apotex’s alleged lack of approvability to manufacture for sale at a commercial manufacturing site?*

[161] AstraZeneca’s position is that the start date should be forward dated (i) by reason of Apotex’s delay in serving the NOA, to March 3, 2003 and (ii) by reason of Apotex’s lack of approvability to the end of the asserted period of liability, to December 30, 2003.

[162] Apotex’s position is that the start date should not be forward dated for any reason.

[163] Section 8(1)(a) of the *NOC Regulations* provides that the start date is the date so certified by the Minister unless the Court is satisfied on the evidence that another date is more appropriate. Here, it is agreed that the date certified by the Minister is January 3, 2002. Any party asserting that another date is more appropriate, for the reasons previously set out, bears the burden of producing sufficient evidence so as to persuade the Court that a different date is more

appropriate. Here, AstraZeneca is the party asserting a different date, either March 3, 2003 or December 30, 2003; thus, it bears the burden of proof.

[164] The first basis upon which AstraZeneca asserts that a later date, March 3, 2003 in this case, should be selected is that it argues that Apotex delayed in serving its Notice of Allegation (NOA) with the consequential delay in commencing and resolving the prohibition proceedings.

[165] I reviewed the issue as to "delay" in serving a Notice of Allegation at some length in *Apotex Inc v Merck & Co Inc*, 2008 FC 1185, particularly at paragraphs 103 to 116. I repeat paragraphs 109 and 113:

> *109 The discretion that I am given in respect of that period is only with respect to the first date, February 3, 2004, the date that, to use the vernacular, the Minister has written to the generic to say that its application for an NOC is approved subject to "patent hold". I can only exercise my discretion under subsection 8(4)(a) if I am satisfied on the evidence that another date is more appropriate.*
>
> . . .
>
> *113 Subsection 8(1)(a) requires that the Court look at the date that the Minister says that the generic's application is approved subject to any outstanding PMNOC Regulations matters such as, in this case, application T-884-03. Here the date of such a letter is February 3, 2004. I can consider some other date where the evidence persuades me that I should. There is absolutely no evidence before me that the Minister would have sent the letter of February 3, 2004 at some earlier or later date having regard to some event or some conduct of some person or otherwise.*

[166] In the present case, the evidence shows that for a considerable period of time prior to the date when it did serve its Notice of Allegation, Apotex was engaged in a debate with Health Canada as to whether it needed to address the '762 patent at all. Apotex argued that it did not. There is a bundle of correspondence between Apotex and Health Canada, including Health Canada's letter of November 16, 2001 (Exhibit D-2, Vol 2, Tabs 46 and 47), Apotex's letter of November 30, 2001 (Tab 54), and Health Canada's letter received January 4, 2002 (Tab 56) indicating that Health Canada was adamant that, notwithstanding Apotex's submissions to the contrary, Apotex had to address its '762 patent by serving a Notice of Allegation under the *NOC Regulations*. Apotex did, in fact, serve a Notice of Allegation in mid November 2001. I find that there was, under the circumstances, no delay on the part of Apotex in serving a Notice of Allegation. It was reasonable for Apotex to endeavour to pursue its attempts to persuade Health Canada that it did not need to address the '762 patent; but, when that avenue appeared not to be fruitful, to serve a Notice of Allegation.

[167] The second ground raised by AstraZeneca for moving the start date forward is that Apotex lacked "approvability" for manufacture at its Torpharm site. I have already dealt with this issue. Apotex could have manufactured in commercial quantities at Signet or at Torpharm without being precluded from doing so as of January 3, 2002.

[168] Therefore, as to Issue #7, I find no basis for finding a start date other than January 3, 2002.

ISSUE #9

Whether Apotex was under a duty to mitigate, and if so, whether Apotex failed to mitigate?

[169] AstraZeneca's position is that Apotex was under a duty to mitigate its damages by serving the Notice of Allegation at the earliest opportunity and that it failed to do so by delaying service until November 2001.

[170] Apotex's position is that it was not under a duty to mitigate its damages and, even if it was, it did not fail to do so.

[171] The Supreme Court of Canada in *Michaels v Red Deer College*, [1976] 2 SCR 324, at pages 331 and 332, has stated that the burden lies upon the party claiming that damages could have been mitigated to prove that point:

> *In the ordinary course of litigation respecting wrongful dismissal, a plaintiff, in offering proof of damages, would lead evidence respecting the loss he claims to have suffered by reason of the dismissal. He may have obtained other employment at a lesser or greater remuneration than before and this fact would have a bearing on his damages. He may not have obtained other employment, and the question whether he has stood idly or unreasonably by, or has tried without success to obtain other employment would be part of the case on damages. If it is the defendant's position that the plaintiff could reasonably have avoided some part of the loss claimed, it is for the defendant to carry the burden of that issue, subject to the defendant being content to allow the matter to be disposed of on the trial judge's assessment of the plaintiff's evidence on avoidable consequences. This is the way I read what is said on the matter in such leading textbooks on the subject as Cheshire and Fifoot's, Law of Contract, 8th ed. (1972), at p. 599, and Corbin, Contracts, vol. 5 (1964), at p. 248. The matter is put as follows in two passages from Williston on Contracts, vol. 11, 3rd ed. (1968), at pp. 302 and 312:*

> *The rule of avoidable consequences here finds frequent application. The consequence of this injury is the failure of the employee to receive the pay which he was promised but, on the other hand, his time is left at his own disposal. If the employee unavoidably remains idle, the loss of his pay is actually suffered without deduction. If, however, the employee can obtain other employment, he can avoid part at least of these damages. Therefore, in an action by the employee against the employer for a wrongful discharge, a deduction of the net amount of what the employee earned, or what he might reasonably have earned in other employment of like nature, from what he would have received had there been no breach, furnishes the ordinary measure of damages.*
>
> ...
>
> *It seems to be the generally accepted rule that the burden of proof is upon the defendant to show that the plaintiff either found, or, by the exercise of proper industry in the search, could have procured other employment of an approximately similar kind reasonably adapted to his abilities, and that in absence of such proof the plaintiff is entitled to recover the salary fixed by the contract.*

Cheshire and Fifoot, supra, expressed the position more tersely as follows:

> *But the burden which lies on the defendant of proving that the plaintiff has failed in his duty of mitigation is by no means a light one, for this is a case where a party already in breach of contract demands positive action from one who is often innocent of blame.*

In my opinion, the obiter statement of MacDonald J.A. in John East Iron Works, Ltd. v. Labour Relations Board of Saskatchewan [[1949] 3 D.L.R. 51.], at p. 57, that "the onus of proving that the employee took reasonable efforts to obtain other employment and failed to do so is upon the employee" does not state the law correctly. I contrast this observation with that in Yetton v. Eastwoods Froy Ltd. [[1967] 1 W.L.R. 104.], a wrongful dismissal case, where Blain J. said (at p. 115) "if he can minimise his loss by a reasonable course of conduct he should do so, though the onus is on the defaulting defendant to show that it could be or could have been done and is not being and has not been done".

[172] The argument raised by AstraZeneca in this respect is the same as in respect of Issue #8, alleged delay in serving a Notice of Allegation. The Federal Court of Appeal has written in *AB Hassle v Canada (Minister of National Health and Welfare)*, [2000] FCJ No 855, 7 CPR (4th) 272 at paragraph 19 that there is no obligation to serve a Notice of Allegation by some imposed deadline:

> *19 The detailed statement is not a pleading per se but represents a pivotal step in the process leading up to the issuance of an NOC. By taking that step the second person puts the patentee on notice of the grounds on which he or she considers that the making, constructing, using or selling of the drug will not infringe the second person's patent rights during the unexpired term of the patent. In theory, this procedure ought to enable the patentee to confidently decide within the 45 day time limit whether to resist the issuance of an NOC. It is to be noted that, subject to business exigencies, the second person had no obligation to make its allegation and provide its detailed statement by an imposed deadline. As much time as the second person deems necessary is available under the scheme of the Regulations.*

[173] In the present case, I have found in determining Issue #7 that Apotex did not delay in serving its Notice of Allegation. Therefore, as a factual matter, AstraZeneca has not established any basis for alleging failure to mitigate.

[174] Therefore, in respect of Issue #9, I find that AstraZeneca has not established that Apotex was under a duty to mitigate or that Apotex had failed in any duty to mitigate.

ISSUE # 12

> *Whether any of the matters are the subject of Issues 5 to 7 and 9 are relevant factors to consider pursuant to section 8(5) of the NOC Regulations?*

[175] AstraZeneca's position is that the following factors are relevant to the assessment of any compensation pursuant to s. 8(5):

> Issue #5 – Alleged infringement, insofar as it would be an unlawful activity.
>
> Issue #6 – Apotex did not have approval to market Apo-Omeprazole made at its commercial manufacturing site, Torpharm, during the asserted period of liability. Apotex never had an intention to market out of its approved Signet facility.
>
> Issue #7 – See Issues #6 and #9
>
> Issue #9 – Apotex's duty to mitigate its damages by serving the NOA at the earliest opportunity.

[176] Apotex's position is that with respect to Issue #5, AstraZeneca failed to plead that infringement has any relevance to subsection 8(5) of the *NOC Regulations*. With respect to Issues #6 and #7, to the extent that AstraZeneca is reliant on the principle of *ex turpi causa* to establish relevance to subsection 8(5) of the *NOC Regulations*, *ex turpi causa* was not pleaded. With respect to Issue #9, the position is as set out with respect to that Issue.

[177] Subsection 8(5) of the *NOC Regulations* permits the Court, in assessing the amount of compensation, to take into account "all matters that it considers relevant, including any conduct of the first or second person which contributed to the delay or disposition of the application".

[178] In dealing with Issues #5, #6, #7 and #9, I have made determinations that AstraZeneca has failed to make out a case in each instance. Should I, nonetheless, take into consideration any suggestion that AstraZeneca may have raised a sufficient argument that somehow Apotex's claim must be reduced or eliminated?

[179] Subsection 8(5) affords judicial discretion in awarding compensation for loss under subsection 8(1). Those matters relating to the exercise of such discretion which are specifically set out in subsection 8(5) relate to factors contributing to the delay or disposition of the matter. One can readily assume that if a party, by unwarranted procedural games or foot dragging, delayed the disposition of an application brought in this Court; that would clearly be a factor to be considered under subsection 8(5). Procedural games or foot dragging are not at issue here. Should discretion be more broadly defined? I adopt the point of view expressed by the late Tom (Lord) Bingham in his lecture originally given November 2006 at Cambridge and in Lord Bingham, "The Rule of Law" (2008) 8(1) JSIJ 121 at pages 127 and 128:

> *My second sub-rule is that questions of legal right and liability should ordinarily be resolved by application of the law and not the exercise of discretion. Most modern commentators would not share to the full Dicey's hostility to the exercise of official discretions. In the immigration field, for example, judges have routinely and gratefully invited the Secretary of State to exercise his discretion to grant leave to enter or remain to applicants who do not meet the tests for entry laid down in the*

> *immigration rules but whose personal history or circumstances demand sympathetic consideration. But the essential truth of Dicey's insight stands. The broader and more loosely-textured a discretion is, whether conferred on an official or a judge, the greater the scope for subjectivity and hence for arbitrariness, which is the antithesis of the rule of law. This sub-rule requires that a discretion should ordinarily be narrowly defined and its exercise capable of reasoned justification. These are requirements which our law, in my opinion, almost always satisfies, because discretion imports a choice between two possible decisions and orders, and usually the scope for choice is very restricted.*

[180] While subsection 8(5) of the *NOC Regulations* may not be restricted only to actions which contribute to the delay in proceedings, it is not so broad as to encompass any factor that a party or a judge chooses to raise. Here the factors raised by AstraZeneca in respect of Issues #5, #6, #7 and #9 have all been determined against it. Discretion does not afford some sort of consolation prize for having lost or for having given the matter a good try. Having lost on those issues, I will not permit AstraZeneca to have them considered as a matter of judicial discretion.

[181] Therefore, in answer to Issue #12, I find that none of the matters which are the subject of any of Issues #5, #6, #7 or #9 are relevant factors to consider pursuant to subsection 8(5) of the *NOC Regulations*.

SUMMARY OF CONCLUSIONS AND COSTS

[182] In summary, my findings with respect to the Joint Issues before the Court:

ISSUE #1

> *In section 8 of the Patented Medicines (Notice of Compliance) Regulations (the "PM (NOC) Regulations") invalid and of no force and effect as being:*

a. Unconstitutionally vague and ambiguous;
b. Draconian, harsh and punitive;
c. Invalid delegated legislation; and
d. Inconsistent with and contrary to NAFTA and TRIPS?

FINDING: The legislation is valid.

ISSUE #2

Has Apotex satisfied the conditions for engaging section 8 of the PM (NOC) Regulations, including that it is a "second person" within the meaning of section 8 of the PM (NOC) Regulations, or has Apotex failed to satisfy any relevant condition insofar as such failure has been expressly pleaded by AstraZeneca (It is noted that paragraphs 58 and 59 of the Defence have been dropped by AstraZeneca and that party now agrees that the Minister did certify that a Notice of Compliance would have been issued to Apotex on January 3, 2002 were it not for the proceedings T-2311-01).

FINDING: Apotex is a "second person" within the *NOC Regulations* applicable to this case.

ISSUE #3

Does section 8 of the PM (NOC) Regulations require a second person to establish abuse by the first person to comply with TRIPS and NAFTA and is the remedy so limited?

FINDING: No.

ISSUE #5

Whether the alleged infringement of the '693 Patent is relevant in law, including whether it is relevant as a defence, to the section 8 claim of Apotex (including possible set-off damages) (and if so, see para. 4 of Order of October 4, 2011)?

FINDING: In the circumstances of this case, the *ex turpi causa* rule is not engaged; the future possibility of a finding of infringement is insufficient to engage that rule. The infringement action is not material to a determination under subsection 8(1) in this case.

ISSUE #6

> *Whether Apotex was in a position to market Apo-Omeprazole in the period January 3, 2002 to January 27, 2004, including any impact of Apotex's alleged lack of approvability to manufacture for sale at a commercial manufacturing site?*

FINDING: Apotex was in a position to market commercially as of January 3, 2002, whether at the Signet or Torpharm site, or both.

ISSUE #7

> *Whether the start date for any liability should be forward dated by reason of Apotex's alleged delay in serving a Notice of Allegation and/or Apotex's alleged lack of approvability to manufacture for sale at a commercial manufacturing site?*

FINDING: There is no basis for finding a start date other than January 3, 2002.

ISSUE #9

> *Whether Apotex was under a duty to mitigate, and if so, whether Apotex failed to mitigate?*

FINDING: AstraZeneca has not established that Apotex was under a duty to mitigate or that Apotex has failed in any such duty.

ISSUE #12

Whether, any of the subject of items(Issues) 5-7 and 9-11 are relevant factors to consider pursuant to section 8(5)?

FINDING: None of the matters which are the subject of those issues are relevant factors to consider pursuant to subsection 8(5).

[183] In the result, therefore, I find that Apotex is entitled to be compensated for loss under the provisions of subsection 8(1) of the *NOC Regulations* for the period extending from January 3, 2002 until December 30, 2003. AstraZeneca has failed to establish that there are any factors upon which judicial discretion can be exercised so as to reduce or eliminate any loss so found. A Reference will be ordered in terms of the Order dated February 20, 2008, paragraphs 1(a) and 3. Paragraph 4 of my Order dated October 4, 2011 is not applicable, since I have found the defences referred to not to be viable.

[184] The parties are agreed that they may address costs by a simultaneous exchange of submissions not to exceed five (5) pages within fourteen (14) days of release of the Judgment herein; with a right to file reply submissions not exceeding three (3) pages within seven (7) days thereafter. Costs will be determined after receipt of all submissions.

JUDGMENT

FOR THE REASONS PROVIDED:

THIS COURT'S JUDGMENT is that:

1. Apotex is entitled to be compensated for loss suffered by it by reason of the proceedings taken by AstraZeneca in T-2311-01 for the period from January 3, 2002 until December 30, 2003 under the provisions of subsection 8(1) of the *NOC Regulations***;**

2. There is no basis for an exercise of judicial discretion under subsection 8(5) of the *NOC Regulations* to reduce or refuse an award of such compensation;

3. A Reference shall be conducted in accordance with the Order dated February 20, 2008 herein, paragraphs 1(a), 2, 4,5, and 6; and

4. Costs shall be addressed by the parties as set out in the reasons herein.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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STYLE OF CAUSE:	APOTEX INC. (Plaintiff) v ASTRAZENECA CANADA INC. (Defendant)
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	March 19, 20, 21, 22, 26, 28; April 30, May 1, 2012
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DATED:	May 11, 2012

APPEARANCES:

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