Federal Court  Cour fédérale

Date: 20180215

Dockets: T-389-11
T-1668-10

Citation: 2018 FC 181

Ottawa, Ontario, February 15, 2018

PRESENT: The Honourable Mr. Justice Locke

Docket: T-389-11

BETWEEN:

APOTEX INC.

Plaintiff

and

ASTRAZENECA CANADA INC.

Defendant

Docket: T-1668-10

AND BETWEEN:

ASTRAZENECA AKTIEBOLAG,
ASTRAZENECA CANADA INC. and
ASTRAZENECA UK LIMITED

Plaintiffs/
Defendants by Counterclaim

and

APOTEX INC. and
APOTEX PHARMACHEM INC.

Defendants/
Plaintiffs by Counterclaim

JUDGMENT AND REASONS

I. Introduction

[1] This decision follows a trial that took place over a number of weeks in May and June 2017 in relation to two actions. Supplemental submissions were made in January 2018 following a decision of the Supreme Court of Canada which affected both actions.

[2] In the main action (Court File No. T-389-11), Apotex Inc. (Apotex) seeks damages under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (since amended) [the *Regulations*] for its losses suffered during the time it was kept off the market for its version of esomeprazole magnesium (40 mg and 20 mg tablets) by operation of the *Regulations*. Apotex's drug product is called Apo-Esomeprazole.

[3] In February 2007, Apotex initiated steps to obtain permission to market a generic version of the esomeprazole magnesium product marketed by AstraZeneca Canada Inc. (AstraZeneca) as Nexium by filing an Abbreviated New Drug Submission (ANDS). As part of this process, Apotex had to address 10 patents that AstraZeneca had identified on the patent list associated with its product under the *Regulations*. Apotex did this by serving AstraZeneca with seven notices dated January 17, 2008 alleging, for various reasons, that the listed patents should not impede Apotex from obtaining a notice of compliance (NOC) required for access to the market. In response to Apotex's notices of allegation (NOAs), AstraZeneca commenced seven separate applications under the *Regulations* on March 7, 2008 (Court File Nos. T-371-08, T-372-08, T-373-08, T-374-08, T-376-08, T-377-08, T-378-08), each seeking to prohibit the Minister of

Health from granting Apotex an NOC. By operation of the *Regulations*, the issuance of Apotex's NOC was stayed pending resolution of AstraZeneca's applications.

[4] These applications were all eventually discontinued or dismissed. More precisely, Court File Nos. T-374-10, T-376-10, T-377-10 and T-378-10 were discontinued on October 16, 2008, Court File No. T-373-10 was discontinued on February 17, 2009, Court File No. T-372-10 was dismissed on consent on May 25, 2010, and Court File No. T-371-08 was dismissed on June 16, 2010, by a decision of this Court (2010 FC 714). That decision ruled that Apotex's allegations of invalidity of Canadian Patent No. 2,139,653 (the 653 Patent) for lack of utility and for obviousness were justified. Apotex obtained its NOC on June 17, 2010.

[5] The delay period during which Apotex claims its losses (Delay Period) begins on December 11, 2009, the date that Health Canada certified that its examination of Apotex's ANDS was complete and it would withhold issuance of an NOC until the requirements of the *Regulations* were met. This is often referred to as the patent hold date. The Delay Period ends with the resolution of the last of the proceedings under the *Regulations*, on June 16, 2010.

[6] In its defence against Court File No. T-389-11 (the Section 8 Action), AstraZeneca asserts many reasons that Apotex should not be awarded any compensation, or that any award of compensation should be reduced. Among these reasons are allegations that, if Apotex had not been kept off the market during the Delay Period, any Apo-Esomeprazole product that it would have sold would have infringed the 653 Patent and Canadian Patent No. 2,193,994 (the 994 Patent). Apotex replies that these patents are invalid and therefore could not have been infringed.

Apotex also alleges that its product would not have come within the scope of the claims of the 994 Patent. Apotex does not dispute that its product would have come within the scope of the claims of the 653 Patent.

[7] With regard to the 994 Patent, the parties are now agreed that Apo-Esomeprazole product manufactured by a process that employs the titanium catalyst (the titanium process) falls within the scope of the claims of the 994 Patent, whereas Apo-Esomeprazole product manufactured by a process that employs the zirconium catalyst (the zirconium process) falls outside the scope. In addition, the validity of the 994 Patent is no longer disputed. It appears to be common ground that all Apo-Esomeprazole that was sold commercially in the real world was manufactured according to the non-infringing zirconium process.

[8] The story concerning the 653 Patent is more interesting and is explained beginning at para [11] below. It is sufficient here to state that there is no dispute that both the zirconium process and the titanium process result in the manufacture of Apo-Esomeprazole that falls within the scope of at least some of the claims of the 653 Patent.

[9] In the other action to be addressed in this decision (Court File No. T-1668-10), AstraZeneca, along with AstraZeneca Aktiebolag (AstraZeneca Sweden) and AstraZeneca UK Limited (AstraZeneca UK), seek damages and other remedies from Apotex, as well as from Apotex Pharmachem Inc. (Pharmachem), for infringement of the 653 and 994 Patents once Apotex obtained its NOC for Apo-Esomeprazole. Just as in the Section 8 Action, Apotex and Pharmachem allege in Court File No. T-1668-10 (the Infringement Action) that the 653 and 994

Patents are invalid, and that Apo-Esomeprazole did not come within the scope of the claims of the 994 Patent. Again, Apotex does not dispute that Apo-Esomeprazole comes within the scope of the claims of the 653 Patent.

[10] With regard to the 994 Patent, the parties have agreed on wording for a declaration of infringement whereby the only remaining issues in dispute are effectively (i) whether, and the extent to which, the experimental and regulatory use exemptions to infringement are applicable; and (ii) the amount of Apotex's and/or Pharmachem's liability, if any. These issues are to be addressed at a later hearing.

A. *Judicial History of the 653 Patent in the Infringement Action*

[11] I return now to the 653 Patent. In the Infringement Action, it was arranged that the following issues would be bifurcated: (i) any experimental and regulatory use exemption, (ii) the quantum of any damages or profits, and (iii) all issues pertaining to the 994 Patent. This left the parties to proceed to a first trial essentially on the 653 Patent alone. Since it was not disputed that Apo-Esomeprazole falls within the scope of the claims in issue of the 653 Patent, the only issues in dispute in the first trial in the Infringement Action concerned the validity of the 653 Patent.

[12] That trial was conducted before Justice Donald J. Rennie (then of this Court) from September to November 2013. The 653 Patent validity issues in dispute were (i) utility (or lack thereof), (ii) novelty (or anticipation), and (iii) inventiveness (or obviousness). Justice Rennie issued his decision (2014 FC 638) on July 2, 2014. He found that the 653 Patent had the required novelty and inventiveness, but that it was invalid because it lacked utility. The basis for the

finding of lack of utility was that the 653 Patent makes a promise of a certain therapeutic benefit that had not been demonstrated, and could not be soundly predicted, at the date the patent was filed.

[13] AstraZeneca and its affiliates appealed to the Federal Court of Appeal (FCA) arguing that Justice Rennie had misconstrued the promise in question. For their part, Apotex and Pharmachem argued that Justice Rennie had erred in finding that the 653 Patent was novel and inventive. On July 6, 2015, the FCA dismissed the appeal concerning lack of utility, and found it therefore unnecessary to consider the issues of novelty and inventiveness that Apotex had raised. This decision is cited as 2015 FCA 158. Accordingly, Justice Rennie's decision stood unaltered after the appeal.

[14] AstraZeneca and its affiliates then sought leave to appeal to the Supreme Court of Canada (SCC), which leave was granted. The appeal to the SCC was heard in November 2016. Its decision (2017 SCC 36, the SCC's Decision) was rendered on June 30, 2017. The SCC ruled that the Promise Doctrine that had been applied by Justice Rennie is not the correct approach to determine the utility of a patent. The SCC allowed the appeal, set aside the decisions of Justice Rennie and the FCA, and declared that the 653 Patent is not invalid for lack of utility.

B. *2017 Trial of the Present Actions*

[15] With the issues pertaining to the 994 Patent largely resolved, the trial before me concerned mainly the Section 8 Action.

[16] During the trial in May and June 2017, the SCC's Decision had not yet been rendered. Accordingly, the 653 Patent was considered invalid, albeit with the understanding that the SCC would speak to the issue. Without the 653 Patent, AstraZeneca's defences in the Section 8 Action were limited. Most of the time at trial was devoted to evidence concerning what amount of compensation (if any) should be awarded to Apotex, including what would have happened in the hypothetical world (sometimes called the but-for world) in which AstraZeneca never commenced proceedings against Apotex under the *Regulations* (prohibition applications), what sales of Apo-Esomeprazole Apotex would have made during the Delay Period, and Apotex's costs associated with such sales.

[17] The SCC's Decision profoundly changed the complexion of the Section 8 Action. In its supplemental submissions, AstraZeneca argues that the 653 Patent has now been found valid. AstraZeneca argues that, in light of this and the fact that infringement was never disputed, any sales of Apo-Esomeprazole that Apotex would have enjoyed in the but-for world would have infringed AstraZeneca's 653 patent, and that Apotex should therefore be denied any compensation under s. 8 of the *Regulations*.

[18] Apotex disagrees. Firstly, Apotex notes that the SCC's Decision did not declare the 653 Patent valid, but simply that it is not invalid for lack of utility. Apotex argues that the 653 Patent actually remains invalid, but on other grounds. Secondly, Apotex notes that, even if there had been a declaration that the 653 Patent is valid, it would be of limited relevance because the Section 8 Action must focus on the but-for world rather than the real world. Apotex argues that there is no evidence that, in the but-for world, (i) AstraZeneca would have sued Apotex for

patent infringement, (ii) the parties would not have settled the matter before a trial, (iii) the SCC would have granted leave to appeal, or (iv) the SCC would have decided such an appeal the same way.

[19] Perhaps most importantly, Apotex argues that the SCC's Decision provides reason to believe that the "mischief" of the unmet promise in the 653 Patent remains a basis for invalidity on grounds other than lack of utility. Apotex argues that additional evidence is called for with regard to these other grounds of invalidity and that it is premature to rule on the Section 8 Action until such additional evidence has been received. Further, Apotex notes that it amended its Reply in October 2017 to allege that in the but-for world it would have found an alternative to avoid infringement of the 653 Patent (a non-infringing alternative or NIA). It argues that additional evidence is required on this issue as well. Apotex requests that it be given the opportunity to adduce further evidence before I render a decision.

II. Preliminary Issue: Should the parties be given the opportunity to introduce additional evidence?

[20] Apotex's request to adduce further evidence should be considered first because, if further evidence is to be received, then it is indeed premature to issue this decision. On the other hand, if no further evidence will be introduced, then there is no reason to delay my decision.

A. *Can Apotex Still Mount a Meritorious Attack on the Validity of the 653 Patent?*

[21] If 653 Patent validity remains in issue, then it may be relevant to permit additional evidence to be introduced. On the other hand, if the effect of the SCC's Decision was to close the

door to further attacks on the validity of the 653 Patent, then it follows that infringement (at least by Apotex's real-world Apo-Esomeprazole) has been established and no additional evidence is needed or appropriate. Therefore, I must determine the effect of the SCC's Decision.

[22] At para 2 of the SCC's Decision, Justice Malcolm Rowe (on behalf of a unanimous Court) summarized the matter before that Court as follows:

> The main issue in this appeal is whether AstraZeneca's patent is invalid for want of utility under s. 2 of the *Patent Act*, R.S.C. 1985, c. P-4, on the basis of the "promise of the patent" doctrine ("Promise Doctrine"). Unquestionably, a patent is invalid if it lacks utility. However, for the reasons that follow, I conclude the application of the Promise Doctrine is not the correct approach to determine whether a patent has sufficient utility. Had the trial judge not applied this doctrine, he would have been compelled to find that the '653 patent had sufficient utility, and upheld its validity. Accordingly, I would set aside the decisions of the Federal Court and the Federal Court of Appeal which held that the '653 patent was invalid for want of utility.

[23] Paragraph 64 of the SCC's Decision reads: "The appeal is allowed. The '653 patent is not invalid for want of utility. AstraZeneca will have its costs in this Court and the courts below."

[24] The SCC's judgment in this matter reads as follows:

> The appeal from the judgment of the Federal Court of Appeal, Number A-420-14, 2015 FCA 158, dated July 6, 2015, heard on November 8, 2016, is allowed with costs throughout. The appellants' 2,139,653 patent is not invalid for want of utility.

[25] The parties appear to be agreed that I must interpret what the SCC intended by its decision, and not vary it.

[26] Apotex argues that the SCC deliberately limited its judgment to the issue of utility, and that it was not ruling on validity as a whole. Apotex notes that, despite rejecting the Promise Doctrine (as it applied to patent utility), the SCC recognized overpromising in a patent to be a mischief (para 45), and stated that "[t]he scheme of the [Patent] Act treats the mischief of overpromising in multiple ways" (para 46). Later in the same paragraph, the SCC identified three specific grounds on which a patent might be held invalid for overpromising: (i) overbreadth of claims, (ii) insufficiency of disclosure, and (iii) unnecessary omission or addition to the specification wilfully made for the purpose of misleading.

[27] Apotex also notes that the SCC never addressed the issues of novelty (or anticipation) and inventiveness (or obviousness), which the FCA had found unnecessary to deal with. With the finding of lack of utility set aside, Apotex argues that these issues became relevant once more.

[28] Apotex also notes that much of the relief that AstraZeneca explicitly sought before the SCC was not granted in its judgment. This included a declaration of infringement, an award of damages or an accounting of profits as AstraZeneca may elect, and interest. Apotex argues that this indicates an intention by the SCC not to accept the 653 Patent as valid.

[29] It is important to note that Apotex made arguments similar to these before the SCC itself in a motion seeking (i) an amendment of the SCC's judgment to remand certain 653 Patent validity issues to the Federal Court and others to the FCA, and (ii) a re-hearing before the SCC. The SCC dismissed that motion without reasons.

[30] There appears to be no dispute that the matter that was heard by Justice Rennie was intended to address all issues of validity of the 653 Patent. It should also be understood that a patent is presumed to be valid: s. 43(2) of the *Patent Act*, RSC 1985, c P-4. The only ground of invalidity that Justice Rennie accepted was lack of utility based on the Promise Doctrine. That finding now having been set aside by the highest court in the land, that court having also explicitly refused to provide for any further consideration of other grounds of invalidity, I am satisfied that there remains no avenue for Apotex to challenge the validity of the 653 Patent.

[31] In my view, the SCC indicated its intent that the validity of the 653 Patent was finally decided in its decision by stating at para 2 that "[h]ad the trial judge not applied [the Promise Doctrine], he would have been compelled to find that the '653 patent had sufficient utility, and upheld its validity" (emphasis added).

[32] The fact that certain specific requests for relief that were included in AstraZeneca's submissions were not mentioned in the SCC's judgment does not change my view. I see no indication that the SCC intended to refuse a declaration of infringement, and every indication that it intended that such relief would be granted.

[33] As regards the references in paras 45 and 46 to overpromising as a mischief that can be addressed in other ways, I am not convinced that I should infer that the 653 Patent itself could be invalid on other grounds. If the SCC had intended that the validity of the 653 Patent remained in issue on other grounds, I would have expected the SCC to have said so.

[34] I also see no indication that the SCC intended to change the state of the law as concerns other grounds of patent invalidity. I agree with my colleague Justice Henry S. Brown who recently observed that, if the SCC wanted to state that the Promise Doctrine remains good law for other grounds of patent invalidity, it could have, but it did not: *Pfizer Canada Inc v Apotex Inc*, 2017 FC 774 at para 360.

[35] Apotex argues that Justice Brown and AstraZeneca misunderstand the change in the law that Apotex asserts. It appears to assert that it is not the law itself that has changed regarding the other grounds of validity mentioned in para 46 of the SCC's Decision, but rather that the application of overpromising to those grounds has changed. I must confess that I do not understand the distinction that Apotex attempts to draw here. Nevertheless, I am not convinced that other grounds of invalidity of the 653 Patent require further consideration.

[36] Finally, any doubt that might have remained about the SCC's intent in its decision concerning the validity of the 653 Patent was eliminated, in my view, by the dismissal of Apotex's motion before the SCC.

B. *Apotex's NIA argument*

[37] In its Third Amended Reply dated October 16, 2017, Apotex adds the following allegation at para 21:

> Apotex states that, in the hypothetical world and at all material times, it could have and would have supplied the Canadian pharmaceutical market with esomeprazole product that did not infringe the claims of the 653 Patent had it been enjoined from so doing by virtue of a finding of infringement. Specifically, Apotex

> could have readily made or had made esomeprazole magnesium salts with purity below those specified by the claims of the 653 Patent including, in the environs of 90% ee as taught in the prior art.

[38] This appears to be the allegation that supports Apotex's NIA argument.

[39] AstraZeneca notes that Apotex's entitlement to amend its Reply was due to AstraZeneca's amendment of its Defence to introduce new allegations related to the revived validity of the 653 Patent following the SCC's Decision. AstraZeneca argues that it was inappropriate for Apotex to introduce new allegations that go beyond the scope of the amendments made in AstraZeneca's Defence. AstraZeneca argues that Apotex should have made a motion to introduce such amendments and, in the absence of such a motion, Apotex's new NIA allegations should be ignored.

[40] Apotex responds that its amended allegations concerning an NIA are on record, and that the parties and the Court must address the pleadings as they stand. Apotex continues that, if AstraZeneca felt any of the new allegations in the Reply were inappropriate, it should have moved to strike them.

[41] I agree with Apotex that the parties and the Court must address the pleadings as they stand. Accordingly, Apotex has an NIA allegation that should be considered. However, this is a new allegation in respect of which Apotex bears the burden of proof. Just as I must address the pleadings as they stand, I must also consider the evidence as it has been adduced. It is not enough for Apotex to have made certain allegations without support from adequate evidence.

[42] Of course, the lack of evidence in support of its NIA allegations is a key reason that Apotex now seeks an opportunity to adduce additional evidence. Here, I am concerned that Apotex has not acted diligently in making this request.

[43] The January 11, 2018 hearing date for supplemental submissions in this matter in light of the SCC's Decision was set three months earlier, on October 10, 2017. Other than some general discussion during a trial management conference earlier that same day in October about the possible need for further evidence, Apotex never made any effort until the January hearing itself to introduce such evidence or to indicate that it would seek to delay supplemental submissions. This is so despite the fact that, during the intervening three months, Apotex made multiple written submissions in respect of the Section 8 Action and the Infringement Action.

[44] Moreover, my recollection is that the discussion on October 10, 2017 of the possible need for additional evidence was in the context of Apotex's motion before the SCC, which had not yet been decided. That motion concerned patent invalidity, not NIA. My understanding at that time was that, in the event that the SCC dismissed Apotex's motion, there would be no need for additional evidence.

[45] Despite Apotex's lack of diligence in requesting the opportunity to introduce additional evidence, I heard the parties' arguments on the request during the hearing of supplemental submissions. Here, my concern is that Apotex has given me little reason to believe that its NIA allegations have any reasonable chance of success. The only concrete effort by Apotex in this regard was a brief reference to a UK High Court decision in *Ranbaxy (UK) Limited v*

AstraZeneca AB, [2011] EWHC 1831, which discusses one of Apotex's competitors, Ranbaxy, and its apparent use of an NIA in the UK. This is far from sufficient. I accept that it might be unreasonable to expect Apotex to make its case on NIA on a balance of probabilities at this stage. But Apotex is asking me to exercise my discretion to reopen the trial to receive additional evidence. Before I exercise that discretion, I expect to be convinced that it will not be a waste of time. In my view, the burden is clearly on Apotex to convince me of that. It has not succeeded. For example, it has made no attempt to show how Ranbaxy's product in the UK (or a product made using a similar process) could have and would have been used in Canada by Apotex during the Delay Period instead of Apo-Esomeprazole made using either the titanium process or the zirconium process (as was shown in the evidence adduced during the trial).

[46] The brief and unconvincing nature of Apotex's oral submissions on this issue demonstrates that a formal motion to introduce additional evidence, accompanied by supporting evidence and written submissions, might have been preferable. Though I cannot say whether such a motion would have been any more convincing, it would at least have given the opportunity for more detailed evidence and a deeper discussion of the issue.

[47] Apotex argues that AstraZeneca would not be prejudiced by any delay caused by the introduction of additional evidence (since Apotex is the plaintiff in the Section 8 Action), and that Apotex should have its day in Court on the NIA issue. My concern with this argument is that January 11, 2018 was its day in Court. The absence of prejudice does not alter that fact.

[48] In view of Apotex's lack of diligence in making its case on NIA or in seeking the opportunity to introduce additional evidence, I conclude that Apotex is not serious about its NIA allegations.

C. *Conclusion on the Preliminary Issue*

[49] For the foregoing reasons, I conclude that the parties should not be given an opportunity to introduce additional evidence. In deciding this matter on its merits, I have considered all of the allegations on record, but I have also considered the lack of evidence on certain issues.

III. Analysis in the Section 8 Action

[50] Having now heard the parties' supplemental submissions regarding the SCC's Decision and the 653 Patent, and having decided that there should be no opportunity to adduce additional evidence, I am now in a position to address the merits of Apotex's claim in the Section 8 Action.

[51] I should preface this analysis by noting that much of the evidence that was adduced at trial is no longer relevant to my decision because it goes to what Apotex would have and could have done in the but-for world and the quantum of Apotex's sales, expenses and profits in the but-for world. In view of my conclusions below, these issues are now largely irrelevant. For this reason, many impressions that I formed about the evidence pass without comment in this decision.

A. *Effect of the SCC's Decision*

[52] As indicated above, the SCC effectively determined that the 653 Patent is valid. Since it was never disputed that Apo-Esomeprazole, as it was manufactured and sold in the real world, falls within the scope of the claims of the 653 Patent, there is no issue on infringement, except the NIA issue raised in Apotex's recently-amended Reply.

B. *Legal Framework of Apotex's Section 8 Claim*

[53] The applicable version of section 8 of the *Regulations* is reproduced here:

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

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

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

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the

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

(ii) soit qu'une date autre que la date attestée est plus appropriée;

b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

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

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

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

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à

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).	cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).
(6) The Minister is not liable for damages under this section.	**(6)** Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

[54] As applied to the Section 8 Action, s. 8(1) provides that AstraZeneca is liable to Apotex for any loss suffered during the Delay Period. Subsection 8(2) provides for Apotex's action seeking compensation. Subsection 8(3) provides that I may award such compensation without regard to whether AstraZeneca has commenced its Infringement Action. Subsection 8(4) provides that, if I award such compensation, I may make an order for relief by way of damages that the circumstances require. Subsection 8(5) provides that, in assessing the amount of compensation, I must take into account all matters that I consider relevant. Subsection 8(6) is not relevant here.

[55] The parties disagree on the effect that patent infringement in the but-for world has on a claim under s. 8 of the *Regulations*. AstraZeneca takes the position that patent infringement in the but-for world gives rise to liability by Apotex to AstraZeneca such that any liability by AstraZeneca to Apotex under s. 8(1) is fully offset and Apotex's loss under s. 8(1) is effectively zero.

[56] For its part, Apotex argues that infringement is not relevant to the loss contemplated in s. 8(1), and is instead to be considered among the relevant matters to be taken into account in assessing the amount of compensation under s. 8(5).

[57] The position that a second person's patent infringement should operate to deny it compensation under s. 8(1) of the *Regulations* has often been identified by the Latin maxim *ex turpi causa non oritur actio* (from a dishonorable cause an action does not arise).

[58] The FCA had occasion to consider the relevance of patent infringement to a claim under s. 8 of the *Regulations* in *Apotex Inc v Merck & Co, Inc*, 2011 FCA 364 [*Lovastatin*]. There, the FCA identified two requirements for liability under s. 8(1): (i) that the first person's application under s. 6(1) was withdrawn, discontinued or dismissed, and (ii) that the second person suffered a loss during the Delay Period (paras 34-35). The FCA refused to read into s. 8(1) an exclusion where the second person's loss resulted from being prevented from infringing the first person's patent earlier. The FCA concluded that "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" (para 36). The FCA continued:

> [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.

> … 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.

[59] The FCA clearly favoured s. 8(5) over s. 8(1) as the context for taking into account the *ex turpi causa* principle.

[60] AstraZeneca argues that it is not asserting the *ex turpi causa* principle here. It argues that any profits that Apotex might have made from lost sales would have been fully offset by its liability to AstraZeneca for infringement of the 653 Patent, and thus the requirement in s. 8(1) that Apotex have suffered a loss is not met simply because that loss is nil. AstraZeneca asserts that the FCA did not exclude this argument.

[61] AstraZeneca's argument appears at first glance to find favour in the decision of my colleague Justice Robert L. Barnes in *AstraZeneca Canada Inc v Apotex Inc,* 2017 FC 726 [*Losec*]. In that case, it was found that lost sales by Apotex would have been infringing. At para 219, Justice Barnes stated that "Apotex is not entitled to recover under section 8 of the *NOC Regulations* because it suffered no loss by being kept out of the marketplace" (emphasis added). But other passages in *Losec* indicate that the "offset" of Apotex's infringement liability against its section 8 losses was actually made under the discretionary provision of s. 8(5). At para 214, Justice Barnes stated that he had discretion to take into account the infringement. Discretion applies in s. 8(5) but not in s. 8(1). Also, at para 218, Justice Barnes cited the view in *Lovastatin* that "it is unnecessary to apply the theory of illegality to resolve this issue", and indeed "the strict application of that principle could, in some cases, leave a party undercompensated."

[62] In my view, it is preferable, at least in this case, to take into account Apotex's infringement in the but-for world under s. 8(5) rather than s. 8(1). This approach permits the exercise of discretion and seems to be what the FCA had in mind in *Lovastatin*.

[63] Also, I note that the *Regulations* contemplate that I determine not the amount of loss but the amount of compensation (if any) that should be awarded to Apotex in respect of such loss. Though loss is a requirement under s. 8(1), its amount is secondary.

[64] In the end, it is of little importance in this case whether infringing sales by Apotex in the but-for world are taken into account in s. 8(1) or in s. 8(5). The important thing is that this factor be taken into account.

C. *What Would have Happened in the But-For World*

[65] As alluded to above, the assessment of compensation to be awarded in the Section 8 Action requires a determination of what would have happened in the but-for world.

[66] A key principle is that the real world informs the construction of the but-for world, and conduct in the real world is very important to what would have happened in the but-for world: *Apotex Inc v Merck & Co, Inc*, 2015 FCA 171 at para 90. All steps that were taken in the real world should be assumed to have been taken in the but-for world unless there is evidence upon which the trier of fact may reasonably conclude that different steps would have been taken: *Teva Canada Limited v Sanofi-Aventis Canada Inc*, 2014 FCA 67 at para 145.

[67] On the other hand, a look into what happened in the real world must not result in a hindsight bias as to what would have happened in the but-for world: *Airbus Helicopters, SAS v Bell Helicopter Textron Canada Limitée*, 2017 FC 170 at para 295.

[68] Apotex has the burden of proving the but-for world on the balance of probabilities: *Pfizer Canada Inc v Teva Canada Limited*, 2016 FCA 161 [*Venlafaxine*] at para 54.

[69] Construction of the but-for world is a factual inquiry which should use robust common sense: *Venlafaxine* at para 55.

[70] In constructing the but-for world, the Court must determine both what a party could have done and what it would have done if prohibition proceedings had not been commenced. As stated by the FCA in *Venlafaxine* at para 51:

> Both elements have to be present. "Could have" does not prove "would have"; "would have" does not prove "could have":
>
> - Evidence that a party would have done something does not prove that it could have done something. I might swear up and down that I would have run in a marathon in Toronto on April 1 aiming to complete it, but that says nothing about whether I could have completed it. Maybe I am not fit enough to complete it.
>
> - Evidence that a party could have done something does not prove that it would have done something. A trainer might testify that I was fit enough to complete a marathon race in Toronto on April 1, but that says nothing about whether I would have completed it. Perhaps on April 1 I would have skipped the marathon and gone to a baseball game instead.

[71] When constructing the but-for world, it is important to bear in mind that the SCC's Decision in the real world concerning the validity of the 653 Patent had not yet happened. That decision may have important implications for the amount of compensation to be awarded, but it does not affect prior events in the but-for world. Accordingly, the evidence of the but-for world that was adduced during the trial (before the SCC's Decision) remains as credible now as it was then.

[72] In closing arguments in June 2017 (prior to the SCC's Decision), Apotex's position was that, in the but-for world, it would have launched Apo-Esomeprazole manufactured by the zirconium process as of December 2009. It also acknowledged that it had conducted tests using Apo-Esomeprazole manufactured by the titanium process. It adduced no evidence concerning Apo-Esomeprazole manufactured by any other process.

[73] AstraZeneca's position in June 2017 was that Apotex's evidence was insufficient to establish that it would have launched Apo-Esomeprazole during the Delay Period. In the alternative, AstraZeneca argued that Apotex's sales of Apo-Esomeprazole during the Delay Period would have been less than Apotex claimed. AstraZeneca disputed whether Apotex could have obtained sufficient quantities of Apo-Esomeprazole manufactured by the zirconium process to meet its claimed sales.

[74] There is no evidence to support Apotex's assertion that it would have marketed Apo-Esomeprazole during the Delay Period that did not infringe the 653 Patent. In fact, Apotex's directing mind, Dr. Bernard Sherman, testified that the 653 Patent could not be avoided. Though

Apotex points out correctly that Dr. Sherman's view is not determinative on the question of infringement, it is very informative as to whether Apotex would have found (or even looked for) an NIA.

[75] I conclude therefore that it is more likely than not that, in the but-for world, Apotex would have launched its Apo-Esomeprazole product, and that such product would have infringed the 653 Patent. Because of my findings below, it is not necessary for me to decide when Apotex would have entered the market.

[76] As mentioned above, Apotex argues that there is no evidence that any of the following would have happened in the but-for world: (i) AstraZeneca would have sued Apotex for patent infringement, (ii) the parties would not have settled the matter before a trial, (iii) the SCC would have granted leave to appeal, or (iv) the SCC would have decided such an appeal the same way. Accordingly, Apotex argues that, for the purposes of constructing the but-for world, the 653 Patent should be treated as invalid just as it was in the real world during the Delay Period.

[77] AstraZeneca disputes the relevance of such legal proceedings in the but-for world. It argues that we now know that the 653 Patent was valid during the Delay Period, and that it should be treated as such for the purposes of the assessment of compensation under s. 8 of the *Regulations*, regardless of whether it would have been found valid in the but-for world. Because of my findings below, it is not necessary for me to decide this issue. In the following paragraphs, I consider whether the events listed in the preceding paragraph would have happened in the but-for world.

[78] On the question of whether AstraZeneca would have sued Apotex for infringement of the 653 Patent, Apotex argues that I should draw a negative inference against AstraZeneca as a result of the absence of evidence since it had sole control of any evidence on the issue. In support of this argument, Apotex cites the following paragraph from *MacMaster (Litigation guardian of) v York (Regional Municipality)* (1997), 42 OTC 167, 42 MPLR (2d) 90 at para 28 (Ont Ct J, Gen Div):

> An adverse inference with varying weight attached to it may occur in circumstances where a party fails to call a material witness, and it is apparent from all of the other evidence in the case that the witness, who was particularly and uniquely available to that party, would have been able to help the court by giving evidence on a material issue.

[79] I decline to draw the inference Apotex seeks. To draw such an inference, I would expect to be persuaded that AstraZeneca was disinclined to introduce evidence on this issue because it was unfavourable. In my view, AstraZeneca's failure to adduce evidence that it would have sued Apotex for infringing the 653 Patent is likely because that fact seemed unimportant during the trial before the SCC had revived the 653 Patent from invalidity. I see no reason to believe that AstraZeneca was disinclined to introduce evidence on this issue because it was unfavourable.

[80] More importantly, Apotex's own Dr. Sherman testified that it was inconceivable that AstraZeneca would not have enforced its patent rights in the but-for world as it did in the real world. I see no reason to doubt this and every reason to accept it.

[81] Therefore, I conclude on a balance of probabilities that, in the but-for world, AstraZeneca would have sued Apotex for patent infringement shortly after Apotex's launch of Apo-

Esomeprazole, just as it did in the real world. Apotex suggests that, if AstraZeneca had sued in the but-for world, it would have done so roughly six months before it sued in the real world. This seems reasonable.

[82] I turn now to Apotex's argument that, even if AstraZeneca had sued for infringement of the 653 Patent in the but-for world, there is no evidence that the parties would not have reached a settlement before trial, such that the applicability of the Promise Doctrine would never have been debated. Again, I see no reason to doubt that what happened in the real world would have happened in the but-for world. I conclude that there would likely have been no settlement. Based on the roughly six-month difference in timing in the commencement of the action in the but-for world versus the real world, I conclude that the matter would most likely have progressed to trial about six months earlier than it did in the real world. I recognize that this difference in timing might have been more or less, but I have no reason to conclude definitively that it would have been either.

[83] Apotex argues, and I agree, that, in the but-for world, a judge other than Justice Rennie might have been assigned to rule on the validity of the 653 Patent at first instance. While it is possible that another judge might have found the 653 Patent invalid for anticipation (lack of novelty) and/or obviousness (lack of inventiveness), I am not convinced on a balance of probabilities that this would have happened. In my view, it is more likely than not that, in the but-for world, a judge of this Court (either Justice Rennie or another judge) would have found the 653 Patent invalid only for lack of utility (under the Promise Doctrine) about six months earlier than happened in the real world.

[84] Similarly, I see no reason to believe that the decision of the FCA dismissing Apotex's appeal would have been different in the but-for world, though it likely would have been about six months earlier.

[85] At the SCC, leave to appeal was granted in the real world in March 2016. In line with my reasoning above, I expect that the decision on leave would have been made about six months earlier in the but-for world (around September 2015). Apotex notes that the SCC denied a request for leave to appeal in April 2015 in another matter that would have addressed the Promise Doctrine (*Mylan Pharmaceuticals ULC v Pfizer Canada Inc*, SCC No 36228 dated April 23, 2015, 2015 CanLII 20820). This was only about five months before the but-for leave decision. Apotex argues that the SCC might have denied leave if AstraZeneca had requested it six months earlier in the but-for world, in which case the 653 Patent would have remained invalid. Apotex also points to statistics indicating that only about 10 percent of leave applications were granted by the SCC in 2015 and 2016.

[86] The SCC does not generally provide reasons for either granting or denying leaves to appeal. Therefore, it is difficult to have confidence as to whether the SCC, faced with a leave application in a matter concerning the Promise Doctrine at a time roughly midway between a denial in 2015 and a granting in 2016, would have granted leave. In my view, the balance is tipped in favour of a granting of leave in the but-for world. The leave application that was denied in April 2015 was on appeal from the FCA's decision in *Apotex Inc v Pfizer Canada Inc*, 2014 FCA 250. In that decision, the FCA refused to apply the Promise Doctrine, refused to find the patent in suit invalid, and it was the patent challengers who sought leave. Importantly, there is no

indication that the very existence of the Promise Doctrine was in dispute as it was in the present case. Rather, it appears that the key issue was, as Apotex states, "how the utility promised by the patent is to be identified and ascertained." That is not the same as a debate as to whether the Promise Doctrine is good law at all. In my view, this may well have contributed to the decision to deny leave in that case and grant it in the present case.

[87] On a balance of probabilities, I conclude that the SCC would have granted leave in the but-for world just as it did in the real world.

[88] A final question is whether the SCC, having granted leave in the but-for world, would have reached the same result as regards the Promise Doctrine if the matter had been heard six months earlier. Apotex notes that Justice Rowe, who wrote the SCC's Decision, was not a judge of the SCC at that time. Justice Thomas Albert Cromwell sat in his place.

[89] In my view, the SCC would likely have decided to reject the Promise Doctrine in the but-for world just as it did in the real world. The SCC's Decision in the real world was unanimous. Even though Justice Rowe was not on the Court in the but-for world to write the decision, another member of the Court would likely have written a decision reaching the same conclusion, which decision would have likely have gained the support of at least a majority of the members of the Court. Some of the reasons might have been different, but it is unlikely that the result would have been different.

[90] To summarize, it is my view that any sales of Apo-Esomeprazole that Apotex would have been able to make during the Delay Period in the but-for world would have been held to infringe the 653 Patent.

D. *Consideration of Discretionary Factors in 8(5)*

[91] For convenience, I reproduce here the text of s. 8(5) of the *Regulations*:

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

[92] As quoted in paragraph [58] above from *Lovastatin* at para 37, s. 8(5) "confers a broad discretion on the court when assessing the amount of compensation that the second person must pay." In exercising that discretion, I may decide whether, and to what extent, Apotex's claim for compensation should be reduced, or eliminated. I may consider Apotex's infringement of the 653 Patent in the but-for world, as well as arguments based on *ex turpi causa*.

[93] As indicated above, AstraZeneca argues that Apotex's infringement of the 653 Patent in the but-for world should fully offset any claim that Apotex may have in the Section 8 Action. Though AstraZeneca focuses this argument on s. 8(1) of the *Regulations*, it applies equally to s.

8(5). AstraZeneca cites Justice Barnes' recent decision in *Losec* as an example of patent infringement fully offsetting a claim under s. 8 of the *Regulations*.

[94] Apotex asserts several reasons for denying such offset in this case. For example, Apotex argues that I should take into account the fact that AstraZeneca commenced seven applications under s. 6 of the *Regulations* asserting 10 different patents in an effort to keep Apotex from bringing Apo-Esomeprazole to the market. All of these applications were either discontinued or dismissed.

[95] Apotex also notes that the Promise Doctrine was good law, and was generally accepted as such, until the SCC's Decision, and that all five judges of the Federal Court and the FCA who considered the validity of the 653 Patent found it invalid for lack of utility under the Promise Doctrine. Apotex also notes that AstraZeneca did not even challenge the existence of the Promise Doctrine before these courts. Apotex argues that the SCC's Decision to change the law and reject the Promise Doctrine was not foreseeable, and that this should be considered under s. 8(5).

[96] Even accepting all of the facts asserted in the preceding two paragraphs, the fact remains that the 653 Patent is, and always was, valid. This is the case in the real world even if I accept Apotex's allegations that the law on the Promise Doctrine would not have evolved in the but-for world as it did in the real world. Whether or not such allegations are justified, the fact is that Apotex claims compensation for loss as a result of being prevented from infringing AstraZeneca's valid patent.

[97] In my view, Apotex's patent infringement in the but-for world is an important consideration that outweighs those asserted by Apotex. To overlook this would allow Apotex to be compensated for profits it never could have rightly made.

[98] Apotex argues that, even if AstraZeneca had been successful in suing Apotex for patent infringement in the but-for world, we cannot know that Justice Rennie would have granted AstraZeneca the right to elect an accounting of Apotex's profits instead of AstraZeneca's damages. If AstraZeneca were not allowed to make such an election, then any award of damages it would receive might be less than Apotex's profits. In that event, Apotex might have been able to keep some its profits in the but-for world, and a full offset of Apotex's claim under s.8 would leave it undercompensated. Apotex notes that other cases in which patent infringement has offset a s. 8 claim happened after liability for patent infringement had been quantified. That has not happened yet in this case.

[99] Regardless of the legal merit of this argument, I find that it is not applicable in this case. Apotex has acknowledged in its December 11, 2017 responding submissions in this matter that the amount of damages (lost profits) that AstraZeneca would have suffered as a result of Apotex's patent infringement in the but-for world far outstrips the profits that Apotex could have made. Further support for this view can be found in the testimony of Dr. Sherman (May 18, 2017, p 1059) and an Apotex marketing document entitled "Launching Product in the New World – Adapting to Change" (Ex P-35). It follows that AstraZeneca's successful patent infringement action against Apotex in the but-for world would likely have resulted in an award at

least as high as Apotex's profits, regardless of whether it had been awarded the right to elect an accounting of profits.

[100] For these reasons, I conclude that any Apotex loss under s. 8(1) of the *Regulations* is fully offset by the costs of its infringement.

E. *The Balance the Regulations Seek to Preserve*

[101] Apotex argues that I should not exercise my discretion to offset patent infringement against its s. 8 loss. Doing so, it argues, would upset the balance that the *Regulations* are intended to strike between the protection of patent rights and the desire to reduce health care costs by permitting fair competition in the pharmaceutical market.

[102] Apotex notes that a patent rights holder's ability under the *Regulations* to impose an automatic delay to a generic's entry into the market before those rights have been evaluated has been analogized to an interlocutory injunction, and it follows that the rights holder must accept liability for the generic's losses if it turns out that the rights holder does not have the rights it asserts. Apotex argues that this requirement to compensate the generic is also useful to dissuade rights holders from asserting weak patents in order to delay proper competition.

[103] Apotex argues that the balance between the parties is upset if the rights holder can avoid liability under s. 8 of the *Regulations* simply as a result of a decision, in a later proceeding, that the patent that had been held invalid in the prohibition application was in fact valid. Apotex points out that, if the situation were reversed (if the patent in issue were found to be valid in the

prohibition application, but invalid in a subsequent proceeding), the subsequent decision would not give rise to liability by the rights holder under s. 8. The situation is therefore unbalanced. Apotex argues that if a subsequent decision cannot operate to impose liability under s. 8, it should not operate to eliminate such liability.

[104] AstraZeneca counters this argument by noting the broad discretion available to the Court under s. 8(5) to consider all relevant factors, and that patent infringement remains a consideration. It emphasizes that Apotex's argument would have it compensated for lost profits in the but-for world that would have been entirely subject to liability to AstraZeneca for patent infringement.

[105] Apotex also argues that, in view of the close connection of prohibition applications and s. 8 actions, the discretion available to the Court under s. 8(5) should not permit consideration of arguments that were not raised in the prohibition application. Apotex argues that since AstraZeneca did not challenge the existence of the Promise Doctrine in the prohibition application, it should not be considered under s. 8(5). In support of its position, Apotex cites the following passage from the decision of Justice James W. O'Reilly in *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493 at para 22:

> It is clear that s 8(5) permits the judge to consider all relevant circumstances in determining the amount of damages. On its face, this provision gives the judge a broad discretion. However, given the relationship between ss 6 and 8, the judge hearing the s 8 action must, in my view, have regard to the issues put in play in the s 6 application. In my view, this means that entirely new allegations of non-infringement or invalidity are not "relevant" for purposes of s 8. The NOA defined the issues in the s 6 application and, in my view, continues to define the limits of what is relevant for purposes of s 8.

[106] In my view, Justice O'Reilly's statement is distinguishable from the facts of the present case on two grounds. Firstly, he was limiting the issues to the allegations made by the second person in the NOA. That is not the issue here. Secondly, though AstraZeneca did not challenge the very existence of the Promise Doctrine during the prohibition application, it did challenge the applicability of this doctrine to the 653 Patent. Accordingly, I am not convinced that AstraZeneca's reliance on the SCC's Decision constitutes an "entirely new allegation" of the kind contemplated by Justice O'Reilly.

[107] In the end, I side with AstraZeneca. While I have considered Apotex's argument concerning the balance in the *Regulations*, I have also considered Apotex's liability for patent infringement in the but-for world. I am not prepared to give Apotex's argument such weight as to award it compensation for being prevented from infringing the 653 Patent.

[108] Apotex also argues that denying it compensation in these circumstances would frustrate a rights holder's disincentive from commencing meritless prohibition applications in that it could rely on the hope that the law would eventually be changed. I do not accept this argument. While it may be reasonable to consider that the SCC's Decision effects a change in the law as regards the Promise Doctrine, it is not appropriate to conclude that AstraZeneca has somehow benefited from the windfall of an unexpected and unforeseeable change in the law. It repeatedly and consistently defended the utility of the 653 Patent, but was successful only once the question reached the SCC. More importantly, it is incorrect to assert that a rights holder could rely on the mere hope of a change in the law. Even if the SCC's Decision is cast as changing the law, AstraZeneca benefits from that change only because we now know that it was right all along. If it

had been wrong, it would have been liable. Therefore, I conclude that there does indeed remain a disincentive against a rights holder commencing a meritless prohibition application.

F. *Level of Compensation*

[109] For the reasons provided above, I conclude that Apotex's liability in the but-for world for patent infringement fully offsets its loss from being kept off the market.

IV. The Infringement Action

[110] The bulk of the time at trial concerned the Section 8 Action. The Infringement Action was mentioned only to the extent of explaining that the parties had settled all issues concerning the 994 Patent except whether, and the extent to which, the experimental and regulatory use exemptions to infringement are applicable, which issue is to be addressed at a later hearing.

[111] Further to the stipulation of the parties, the Court is prepared to declare as follows:

1. The making, using and selling by Apotex Pharmachem Inc., prior to the expiry of the 994 Patent, of esomeprazole magnesium made by a process that employs the titanium catalyst infringes the 994 Patent save and except for such making, using and selling that qualifies for the experimental and regulatory use exemptions to infringement, the latter to be determined by the Court at a further hearing.
2. The using by Apotex Inc., prior to the expiry of the 994 Patent, of esomeprazole magnesium made by a process that employs the titanium catalyst infringes the 994 Patent

save and except for such using that qualifies for the experimental and regulatory use exemptions to infringement, the latter to be determined by the Court at a further hearing.

V. Conclusion

[112] Pursuant to my conclusion above that Apotex's claim for compensation under s. 8 of the *Regulations* is fully offset, I conclude that the Section 8 Action should be dismissed.

[113] With regard to the Infringement Action, the declaration quoted above will be made.

[114] AstraZeneca should have its costs of the trial. If the parties are unable to agree on the quantum of costs, I will receive submissions from the parties as contemplated in the Judgment below.

JUDGMENT in T-389-11 and T-1668-10

THIS COURT'S JUDGMENT is that:

1. Apotex Inc.'s (Apotex's) claim in Court File No. T-389-11 is dismissed.

2. As regards Court File No. T-1668-10:

    a. The making, using and selling by Apotex Pharmachem Inc., prior to the expiry of Canadian Patent No. 2,193,994 (the 994 Patent), of esomeprazole magnesium made by a process that employs the titanium catalyst infringes the 994 Patent save and except for such making, using and selling that qualifies for the experimental and regulatory use exemptions to infringement, the latter to be determined by the Court at a further hearing; and

    b. The using by Apotex, prior to the expiry of the 994 Patent, of esomeprazole magnesium made by a process that employs the titanium catalyst infringes the 994 Patent save and except for such using that qualifies for the experimental and regulatory use exemptions to infringement, the latter to be determined by the Court at a further hearing.

3. Apotex shall pay AstraZeneca Canada Inc.'s (AstraZeneca's) costs of the trial. If the parties are unable to agree on the quantum of costs, AstraZeneca shall serve and file its costs submissions, of no more than 12 pages, within 30 days following the date of this decision. Apotex shall have 15 days following receipt of AstraZeneca's submissions to serve and file its responding costs submissions which shall be limited to 15 pages.

Thereafter, AstraZeneca may, within five (5) days following receipt of Apotex's responding submissions, serve and file reply costs submissions of no more than three (3) pages.

"George R. Locke"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-389-11 and T-1668-10
DOCKET:	T-389-11
STYLE OF CAUSE:	APOTEX INC. v ASTRAZENECA CANADA INC.
AND DOCKET:	T-1668-10
STYLE OF CAUSE:	ASTRAZENECA AKTIEBOLAG, ASTRAZENECA CANADA INC. AND ASTRAZENECA UK LIMITED v APOTEX INC. AND APOTEX PHARMACHEM INC.
PLACE OF HEARING:	TORONTO, ONTARIO
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JUDGMENT AND REASONS:	LOCKE J.
DATED:	FEBRUARY 15, 2018

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