

Federal Court



Cour fédérale

Date: 20120523

Docket: T-1169-01

Citation: 2012 FC 620

Ottawa, Ontario, May 23, 2012

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

APOTEX INC.

Plaintiff

and

**MERCK & CO., INC.,
MERCK FROSST CANADA LTD. AND
MERCK FROSST CANADA & CO.**

Defendants

AND BETWEEN:

**MERCK & CO., INC. AND
MERK FROSST CANADA & CO.**

**Plaintiffs by
Counterclaim**

and

**APOTEX INC. AND HER MAJESTY THE
QUEEN IN RIGHT OF CANADA AS
REPRESENTED BY THE ATTORNEY
GENERAL OF CANADA**

**Defendants by
Counterclaim**

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

[1] Apotex Inc. (Apotex), the Plaintiff in this action, seeks compensation from Merck & Co., Inc., Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. (collectively Merck) pursuant to s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*PM (NOC) Regulations* or *Regulations*). Apotex's claim relates to alleged losses incurred in the period that it was prevented from selling a generic version of the drug lovastatin because of the statutory stay imposed as a result of Merck's actions under s. 6(1) of the *Regulations*.

[2] In *Apotex Inc v Merck & Co*, 2010 FC 1264, 381 FTR 148 (the *Trial Decision*), I held that the 1993 version of the *PM (NOC) Regulations* applied to Apotex's claim for damages under s. 8 of the *Regulations*. On the basis of this conclusion, I found that Apotex was not entitled to any compensation under s. 8 of the *Regulations*. The Court of Appeal, in *Apotex Inc v Merck & Co*, 2011 FCA 364 at para 8, [2011] FCJ No 1865 (the *Appeal Decision*), told me that I was wrong, set aside the decision and remitted the matter to me "to determine the legal and factual issues necessary to quantify Merck's liability to Apotex under section 8 of the 1998 *Regulations*". Thus, my task is to determine whether, under the 1998 version of s. 8 of the *Regulations*, Apotex is entitled to compensation and, if so, for what period. The amount of compensation, if any, is to be determined in a subsequent phase of the trial. The text of s. 8 of the 1998 version of the *PM (NOC) Regulations* is set out in Appendix A to these Reasons.

II. Issues

[3] As the Court of Appeal explained in *Apotex Inc v Merck & Co*, 2011 FCA 329 at para 75, 425 NR 279, the assessment of s. 8 damages requires consideration of the following hypothetical question: What would have happened if Merck had not brought an application for prohibition? Put differently, I must determine what actions Apotex would have hypothetically taken in this “but for” world.

[4] For purposes of framing the issues for this re-consideration, I turn to the helpful directions provided by the Court of Appeal in the *Appeal Decision*, above at paragraphs 39 to 41:

[39] The conclusions that I have reached above leave many issues of law and fact to be decided before the amount of Apotex’ compensation can be quantified, including: the basis on which loss should be determined; the extent to which the *ex turpi causa* principle should be applied on these facts, if at all; and the starting date of the period during which the loss must have occurred under paragraph 8(1)(a).

[40] These issues were not considered by the Judge because of the basis on which she disposed of Apotex’ claim for compensation. In my view, it would not be appropriate for this Court to decide any of them in the first instance: they raised contested factual issues, involved difficult questions of law, and were not the subject of full argument in the appeal to this Court.

[41] Accordingly, I would return the matter to the Judge on the basis that: the 1998 version of section 8 applies; Merck is liable under subsection 8(1); and an *ex turpi causa* defence is capable of being raised under subsection 8(5) so as to reduce or eliminate the amount of loss otherwise recoverable. All other issues of fact and law relevant to the quantification of Merck’s liability to Apotex are to be decided by the Judge.

[5] In its judgment, the Court of Appeal explicitly directed that I consider the following two issues:

1. What is the period for which Merck is liable to Apotex for compensation under s. 8 of the *Regulations* (the Relevant Period)?
2. To what extent, if any, should the defence of *ex turpi causa* be applied to the facts before me to reduce compensation otherwise payable under s. 8 of the *Regulations*?

III. Background

[6] The background to this action is as follows:

1. As of all relevant dates, Merck held the rights to Canadian Patent No. 1,161,380 (the '380 Patent), a patent for the making of lovastatin by a particular process, referred to as AFI-1, using the *Aspergillus terreus* micro-organism as the basis of fermentation.
2. In 1993, Apotex applied to the Minister of Health (the Minister) for a Notice of Compliance (NOC) pursuant to the relevant provisions of the *PM (NOC) Regulations*, alleging that it would not infringe the '380 Patent, as it would use an

organism described as *Aspergillus flavipes* or *Aspergillus obscurus* rather than the patented AFI-1 process to produce lovastatin.

3. On June 1, 1993, Merck commenced an application for prohibition, arguing that Apotex's allegation of non-infringement was not justified, thereby triggering the statutory stay provided for in the *Regulations*.
4. In a decision rendered March 26, 1997, Justice Rothstein (then a judge with the Federal Court, Trial Division) refused to extend the time period or issue a prohibition order (*Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)* (1997), 128 FTR 210, 72 CPR (3d) 453 (FCTD) [*Merck FCTD 1997*]).
5. The Minister issued the NOC for lovastatin to Apotex on March 27, 1997.
6. In a judgment, delivered April 21, 1999, the Federal Court of Appeal dismissed the appeal of *Merck FCTD 1997*, on the basis that the question was moot (*Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)* (1999), 240 NR 195, [1999] FCJ No 555, (FCA), leave to appeal to SCC refused, [1999] SCCA No 313).

[7] In sum, Apotex was kept off the market, by operation of the *PM (NOC) Regulations*, until March 27, 1997, when the NOC issued. However, of considerable significance, no determination

was ever made under the *PM (NOC) Regulations* as to whether Apotex's allegations were justified.

[8] Faced with Apotex's entry into the lovastatin market, Merck commenced a patent infringement action (Court File No. T-1272-97) against Apotex and Apotex Fermentation Inc. (AFI), an affiliate of Apotex, for infringement of its '380 Patent. Apotex and AFI counterclaimed on the basis that the '380 Patent was invalid and, in any event, not infringed. In addition, Apotex commenced this action against Merck for compensation pursuant to s. 8 of the *Regulations* (Court File No. T-1169-01).

[9] Thirteen long years later, both Merck's claims in Court File No. T-1272-97 and Apotex's claim for s. 8 compensation came to trial. In *Merck & Co v Apotex Inc*, 2010 FC 1265, 381 FTR 162, aff'd 2011 FCA 363, [2011] FCJ No 1866 (the *Infringement Decision*), I held that the '380 Patent was valid and that some of the lovastatin tablets sold by Apotex after it came to market had been made by the infringing AFI-1 process. I also found that Merck had not proved that all of Apotex's lovastatin was infringing. Some of the product was made by another process – the AFI-4 process patented by Apotex and which used the *Coniotherium fuckelii* organism. This process did not infringe the '380 Patent. The *Trial Decision*, referred to above, was the result of Apotex's s. 8 claim.

IV. Relevant Period

[10] I turn to the first issue of establishing the beginning and end dates of the Relevant Period.

[11] As set out in s. 8(1) of the *Regulations*, a first person (Merck) is liable to a second person (Apotex) for any loss suffered during the period that, in most circumstances, commences on the date, as certified by the Minister, on which an NOC would have issued in the absence of the *Regulations* and which ends on the date of the withdrawal, the discontinuance, the dismissal or the reversal of the prohibition proceedings. In *Apotex Inc v Merck & Co*, 2008 FC 1185 at paras 106-116, [2009] 3 FCR 234, Justice Roger Hughes explained that s. 8(1)(a) gives the Court discretion to select a more appropriate date for the beginning of the liability period, although the presumptive period begins on the “patent hold” date, meaning the date on which an NOC would have issued, but for the proceedings under the *Regulations*.

[12] In this case, there is no dispute that the Relevant Period ended on March 26, 1997 with the decision in *Merck FCTD 1997*.

[13] The parties, however, disagree on the applicable commencement date. Apotex asserts that the appropriate date is April 30, 1996, the date on which it submits that the Minister would have issued an NOC to Apotex except for the *Regulations*. Merck submits that there is no proof of any date “certified by the Minister” on which Apotex would have received an NOC for the non-infringing AFI-4 process. In the alternative, Merck argues that the appropriate date is when

Apotex was notified that the Minister had “no objection” to Apotex’s Notice of Change switching to the AFI-4 process; specifically, that date was February 27, 1997.

[14] Apotex initially filed a New Drug Submission (NDS) for approval of Apo-lovastatin made by use of a micro-organism referred to as *Aspergillus flavipes* on December 21, 1994. Label drafts were submitted to Health Canada and apparently approved on April 30, 1996. On May 25, 1996, Apotex’s NDS was placed on “patent hold”, meaning that an NOC for Apo-lovastatin manufactured with *Aspergillus flavipes* would not issue until resolution of the prohibition proceedings or the expiry of the relevant patents (including the '380 Patent)

[15] Merck is correct that there is no Ministerial “certification” of May 25, 1996 as contemplated by s. 8(1)(a). However, I am satisfied that, but for the *Regulations*, Apotex would have received its NOC for Apo-lovastatin no later than May 25, 1996.

[16] Apotex submits that April 30, 1996 is the more appropriate date for the commencement of the Relevant Period. I agree with Apotex that its labels for Apo-lovastatin were approved on April 30, 1996. In spite of the testimony of Mr. Hems that NOCs normally follow label approval within a matter of days, I am not persuaded that this date is more appropriate than the “patent hold” date. There can be no doubt whatsoever that the application would have been approved on May 25, 1996, the date of the “patent hold” letter from Health Canada.

[17] In my view, the appropriate date, even though not certified by the Minister, would be the “patent hold” date of May 25, 1996.

[18] Merck's most serious argument on the appropriate commencement date relies on its view that Apotex's Apo-lovastatin would have infringed the '380 Patent until February 27, 1997. As discussed below, this is an argument that is more appropriately considered in the context of judicial discretion under s. 8(5) of the *Regulations*.

[19] I conclude that the Relevant Period should begin on May 25, 1996 and end on March 26, 1997.

V. Defence of *ex turpi causa*

[20] Merck submits that Apotex should be precluded from claiming compensation on the basis that it has been shown to have infringed the '380 Patent. This, Merck submits, should be a factor to reduce or eliminate Apotex's compensation otherwise payable.

[21] In the *Appeal Decision*, above at paragraph 41, the Court of Appeal described this as an *ex turpi causa* argument that was "capable of being raised" under s. 8(5) of the *PM (NOC) Regulations*. I observe that the court did not go so far as to say that such a defence would succeed – only that it could be argued.

[22] Subsection 8(5) of the *PM (NOC) Regulations* provides that:

<p>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).</p>	<p>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).</p>
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[23] In the *Appeal Decision*, above at paragraph 37, the Court of Appeal held that s. 8(5) “confers a broad discretion on the court when assessing the amount of compensation”. Justice Evans explained that “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”. As noted by Justice Evans, at paragraph 38:

The Court’s broad discretion under subsection 8(5) allows [the trial judge], 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.

[24] My determination in the *Infringement Decision* was that some – but not all – of the lovastatin made by Apotex was made by the infringing AFI-1 process. I also concluded that much of the lovastatin produced and sold by Apotex was made by the non-infringing AFI-4 process. All of the infringing lovastatin was sold after March 26, 1997; that is, after the issuance

of the NOC. The question is this: During the Relevant Period (before the issuance of the NOC) would it have been more likely than not that Apotex would have made Apo-lovastatin by the infringing AFI-1 process?

[25] Because the '380 Patent was ultimately held to be valid, any lovastatin made using the AFI-1 process during the Relevant Period would have been made by an infringing process. It is important to remember that, on the unusual facts before me, there was never any determination of the merits of Merck's prohibition application. Even without the *Regulations*, Apotex could not, as a simple matter of patent law, have had the right to use the AFI-1 process to produce and sell lovastatin. Stated differently, in the complete absence of the *Regulations*, Apotex would have been infringing the '380 Patent if it were to manufacture and sell Apo-lovastatin made with the AFI-1 process.

[26] In my view, Apotex should not be able to recover damages for the hypothetical sale of any lovastatin that, more probably than not, would have been produced and sold illegally. Quite simply, the doctrine of *ex turpi causa* provides that a plaintiff should not profit from an illegal or wrongful act (see e.g. *Hall v Hebert*, [1993] 2 SCR 159, [1993] SCJ No 51). If it can be shown that Apotex would have likely used the infringing AFI-1 process during the Relevant Period, Merck's *ex turpi causa* defence will succeed and I will exercise my discretion under s. 8(5) of the *Regulations* to disallow recovery by Apotex of those amounts.

[27] The facts of Apotex's initial NDS filing are described above. As noted, absent the *Regulations*, Apotex would have been approved in May of 1996 for the manufacture and sale of

Apo-lovastatin made from *Aspergillus flavipes*. Apotex's regulatory submissions relied on the use of this particular organism up to the issuance of the NOC on March 27, 1997. That NOC included a Product Monograph which specified the originating micro-organism as *Aspergillus flavipes* or *Aspergillus obscurus*.

[28] As time passed, it became clear that *Aspergillus flavipes* and *Aspergillus obscurus* were, in fact, the same micro-organism as *Aspergillus terreus*, the micro-organism used in the patented AFI-1 process. Thus, the approval that Apotex would have received in the "but for" or hypothetical world would have been for Apo-lovastatin made with the infringing AFI-1 process.

[29] During his cross-examination, Dr. Sherman was very clear that, absent the *Regulations*, Apotex would have manufactured and sold Apo-lovastatin:

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

[30] I understand this comment – together with other remarks of Dr. Sherman – to mean that Apotex would have been prepared to take the litigation risk of producing and selling potentially infringing Apo-lovastatin. Critical to all of this is the fact that, at least until late 1995, Apotex did not believe that its use of *Aspergillus flavipes* and *Aspergillus obscurus* would infringe the '380 Patent. As reflected in the product monograph issued with its NOC, Apotex continued to claim that it would be making lovastatin with *Aspergillus flavipes* and *Aspergillus obscurus*, even though it knew, in 1995, that these were the same organism as *Aspergillus terreus*. This evidence supports a finding that Apotex would have been prepared to sell infringing lovastatin throughout the Relevant Period.

[31] In spite of this evidence, Apotex assures me that it would have taken the necessary regulatory and operational steps to be ready to put non-infringing lovastatin on the market as of the commencement of the Relevant Period. I must accordingly determine whether Apotex would have been able to produce Apo-lovastatin by a non-infringing process at any point during the Relevant Period.

[32] I turn first to the regulatory approvals necessary to produce non-infringing AFI-4 lovastatin.

[33] Apotex did not submit a request to the Minister to amend its NDS to provide for an NOC for Apo-lovastatin manufactured using the micro-organism *Coniothyrium fuckelii* until June 27, 1996. On February 27, 1997, Apotex received approval to use the non-infringing AFI-4 process.

[34] Apotex argues that it could have made this regulatory submission earlier. In my view, this assertion is purely speculative. For one thing, the evidence before me shows that Apotex was not aware until late 1995 that *Aspergillus flavipes* and *Aspergillus obscurus* were the same organisms as *Aspergillus terreus*. In other words, until that realization, Apotex would have believed that it was using non-infringing organisms. It follows that, in the “but-for” world, Apotex would not have made serious efforts to get approval for Apo-lovastatin made by the non-infringing AFI-4 process until after late 1995. I am not persuaded that the time to prepare and submit an application for regulatory approval would have been any different in the “but for” world than it was in the real world. Further, there is no persuasive evidence before me to demonstrate that Health Canada’s review of the NDS amendments could have resulted in an

approval earlier than February 27, 1997. In my view, it is unlikely that Apotex would have received regulatory approval for the AFI-4 process until February 1997.

[35] The second aspect of the “but for” world is the operational capacity to produce non-infringing Apo-lovastatin. Apotex and AFI were both actively engaged in developing a non-infringing process involving the use of *Coniothyrium fuckelii* (the AFI-4 process). The question is whether, during the Relevant Period, it was more likely than not that Apotex and AFI could have produced commercial quantities of Apo-lovastatin using the AFI-4 process.

[36] The evidence before me includes the expert opinion of Dr. Lasure that Apotex did not have available to it a non-infringing process to make commercial quantities of Apo-lovastatin prior to March 26, 1997 (Dr. Lasure, Expert Report Ex. 48 at paras 265, 266 and 275). This opinion was shaken considerably on cross-examination, during the course of which Dr. Lasure was reminded of some large-scale production runs by AFI in its Winnipeg facilities between September 23, 1996 and November 19, 1996 (see expert report of Dr. Connors, Ex.101 at paras 82 and 85).

[37] Apotex submits that it and AFI could have stepped up the development of the non-infringing AFI-4 process. As described by Dr. Connors in his expert report (Ex. 101 at paras 107-108):

107. [. . .] AFI could have “pulled out all the stops” and made the AFI-4 project its top priority. Management could have re-assigned staff working on AFI-1, hired new permanent and temporary staff and limited activity on other programs [. . . .]

108. [. . .] Commercial production would have begun in August 1995.

[38] One short-coming of Dr. Connor's evidence is that it ignores the overall corporate picture of Apotex and AFI during the Relevant Period. There appears to be no question that Apotex and AFI could have produced the infringing AFI-1 lovastatin. However, with respect to non-infringing lovastatin, the evidence is far from clear that Apotex would have had, more likely than not, the motivation and the resources to pursue the non-infringing alternative. There was evidence before me that Apotex was putting significant resources into other drugs, thereby arguably preventing Apotex and AFI from any more aggressive pursuit of approvals and production capacity for non-infringing lovastatin.

[39] In addition, even if I agree that Apotex could have scaled up its AFI-4 process more quickly, the problem is, however, that, regardless of Apotex's motivation, it could not have produced non-infringing lovastatin until it had approval to do so. And, it did not obtain approval from Health Canada until February 27, 1997.

[40] From these facts, I conclude that, in the hypothetical world, it is more likely than not that any lovastatin produced and sold by Apotex would have used the *Aspergillus flavipes* micro-organism until the approval of the non-infringing process on February 27, 1997. As established by the evidence before me, *Aspergillus flavipes* is really *Aspergillus terreus*. It follows that a process using *Aspergillus flavipes* would have infringed the '380 Patent. In other words, from the commencement of the Relevant Period to February 27, 1997, it is more likely than not that Apotex would have used the infringing AFI-1 process, assuming the litigation risk

of doing so. Pursuant to s. 8(5), I would exercise my discretion to prohibit Apotex from recovering any compensation during that period.

[41] The situation is different for the last month of the Relevant Period. From February 27, 1997 to the end of the Relevant Period – March 26, 1997 – Apotex would have had the necessary approval to manufacture non-infringing Apo-lovastatin.

[42] The question remains as to whether, in that one month period, Apotex would have used the infringing AFI-1 process rather than the AFI-4 process. The overall conclusion that I reached in the *Infringement Decision* was that, in the “real world”, some but not all of the Apo-lovastatin was produced by the infringing process. I have no evidence beyond speculation, that Apotex would have infringed the '380 Patent during the period of February 27, 1997 to March 26, 1997, once it had the necessary approval for the AFI-4 process. I would not reduce or eliminate Apotex’s entitlement to damages during that period.

VI. Conclusion

[43] Having carefully considered the guidance of the Court of Appeal in the *Appeal Decision* and the evidence before me, I conclude as follows:

1. the Relevant Period for purposes of s. 8 of the *Regulations* is May 25, 1996 to March 26, 1997; and

2. Apotex's losses pursuant to s. 8 of the *Regulations* should be reduced by any amount claimed for the period between May 25, 1996 and February 26, 1997.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. the Relevant Period for purposes of s. 8 of the *Regulations* is May 25, 1996 to March 26, 1997; and
2. Apotex's losses pursuant to s. 8 of the *Regulations* shall be reduced by any amount claimed for the period between May 25, 1996 and February 26, 1997.

“Judith A. Snider”

Judge

Appendix A

Statutory Framework

Section 8 of the 1998 version of the *Regulations* reads as follows:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period

(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.

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) 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 estime d'après la preuve qu'une autre date 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

(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).

une action pour contrefaçon du brevet visé par la demande.

(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (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).

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-1169-01

STYLE OF CAUSE: APOTEX INC. v. MERCK FROSST CANADA LTD.

**REDETERMINATION ON THE BASIS OF THE RECORD AS IT WAS AT
THE CONCLUSION OF FINAL ARGUMENT AT TRIAL PURSUANT TO
THE ORDER OF JUSTICE SNIDER DATED JANUARY 26, 2012**

**REASONS FOR JUDGMENT
AND JUDGMENT:**

SNIDER J.

DATED: MAY 23, 2012

SOLICITORS OF RECORD:

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