Federal Court  Cour fédérale

Date: 20100629

Docket: T-1508-05

Citation: 2010 FC 711

Vancouver, British Columbia, June 29, 2010

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

JANSSEN -ORTHO INC. AND
DAIICHI SANKYO COMPANY, LIMITED

Applicants

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] These protracted proceedings were brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (*NOC Regulations*). Before the Court at this time is a motion brought by the Respondent Apotex Inc. to dismiss these proceedings. A second motion asking for reconsideration by Justice Shore of his decision dated June 17, 2008, was adjourned *sine die* on consent. A third motion was filed by the Applicants for redetermination of Justice Shore's decision of June 17, 2008, but that motion was not set down to be heard at this time.

[2] For the reasons that follow I will Order that these proceedings are terminated with costs to the Applicants fixed at $3000.As a result no further motion is required to be considered.

Adjournment Request

[3] At the outset of the hearing of this motion for dismissal Counsel for Janssen-Ortho requested that the hearing be adjourned *sine die* pending the resolution of a motion and an appeal that his client intends to bring in the Federal Court of Appeal. It was uncertain whether the materials had yet been filed with that Court. No copies were available at the time this motion was heard so that the exact nature of these matters is unclear. The basis for this request was set out in Counsel's letter to the Court dated June 21, 2010, which I repeat in part:

> *We write to request that the motions set down for hearing on Thursday June 24 be adjourned sine die.*
>
> *On June 14 Justice Shore issued reasons indicating that having read the parties submissions on the reconsideration his Lordship was ordered to conduct, he would reach the same conclusions through the same reasons. His Lordship therefore recused himself. This led to Apotex requesting, and your Lordship granting on June 18, the return of the mootness and reconsideration motions to be held on June 24.*
>
> *The whole time I was in Europe and attempting to get instructions from the client which I have now received. The applicant Janssen-Ortho Inc. has instructed us to bring a motion to the Federal Court of Appeal under Rule 399(2)(b) seeking to set aside its order by reason of a matter arising subsequent to its order that Justice Shore reconsider his initial decision. Mr. Charles advises that his client, Daiichi, will also join in the Rule 399 motion.*
>
> *The new matter is, specifically, Justice Shore's Reasons of June 14. Had the Federal Court of Appeal realized that Justice Shore had indeed performed a proper review of the evidence (independent of relying on Justice Hughes' decision in the Novopharm – levofloxacin*

> *case), it would not have ordered that Justice Shore reconsider the case.*
>
> *We will be filing that motion record as soon as possible. In the alternative, we will also be filing an appeal of Justice Shore's Order of June 14 recusing himself. That Notice of Appeal will be filed by Thursday June 24. It remains our concern that this proceeding has somehow been mishandled between two levels of the Federal Court. We believe that to properly align matters, the motion to the Federal Court of Appeal to vary must be heard before it can be said that the issue of mootness has crystallized such that a motion on mootness can be entertained.*
>
> *Given that we are asking the Federal Court of Appeal to set aside its order, Thursday's motion for mootness and reconsideration are premature and until the Federal Court of Appeal determines the matter, the two motions set for Thursday must be adjourned.*

[4] I refused to adjourn the hearing of the motion to dismiss. The fact that a party has or intends to bring a motion or an appeal in the Federal Court of Appeal is not sufficient basis for an adjournment. The exact nature of the motion or appeal is not yet clear, the outcome is far from certain and the effect, if any, on the present proceedings is unknowable. Further, the request for adjournment was made after a pre-motion teleconference was held with the Court and Counsel for the parties just a few days before the motions were to be heard, at which time no suggestion was made by Counsel that an adjournment would be sought. The Court considers that it is best to dispose of the present motion now. If any party wishes to seek an appeal it is, of course, free to do so at which time the Court of Appeal will have the relevant disposition before it.

History of these Proceedings

[5] The history of these proceedings is unusual and complex and includes other litigation in respect of the same patent involved in these proceedings, Canadian Letters Patent No. 1,304,080 (the ’080 Patent). To set out the history in more or less chronological order:

1. The ’080 Patent was issued and granted to Daiichi on June 23, 1992. Because the application for the patent was filed in 1986, before the changes to the *Patent Act*, R.S.C. 1985, c. P-4 were made effective October 1, 1989, the term of the patent expired seventeen (17) years from the date it was granted, that is, on June 23, 2009.

2. The ’080 Patent was listed by Janssen-Ortho, a licensee, on a list kept by the Minister under the provisions of the *NOC Regulations* thus requiring a generic such as Apotex to invoke the provisions of those *Regulations* by serving a Notice of Allegation.

3. On July 18, 2005, Apotex served a Notice of Allegation on Janssen-Ortho alleging non-infringement and invalidity of the ’080 Patent on a number of grounds. As a result the Applicants instituted the present proceedings to prohibit Apotex from receiving a Notice of Compliance from the Minister to sell the drug in question in Canada.

4. In different proceedings taken by way of an action, T-2175-04, Janssen-Ortho and Daiichi as Plaintiffs asserted the ’080 Patent against another generic, Novopharm Limited. By a Judgment dated October 17, 2006, it was held that claim 4 of that

patent was valid and infringed. An appeal from this decision was dismissed on June 7, 2007 (A-500-06).

5. In the present proceedings a hearing was held in May 2008 before Justice Shore of this Court. The issues that he was required to determine were set out at paragraph 37 of his Reasons (2008 FC 744):

> ***37*** *This application raises the following issues:*
>
> ***A.*** *Is this application an abuse of process?*
>
> ***B.*** *Would Apotex' marketing of its levofloxacin tablets for oral administration in a dosage strength of 250mg, 500mg and 750mg infringe claim 4 of Janssen's '080 patent?*
>
> ***C.*** *If infringement is the case, are any of Apotex' allegations that the '080 patent is invalid, justified on the following bases:*
> *i) Anticipation*
> *ii) Obviousness;*
> *iii) Claims broader than the invention made and lack of sound prediction.*
>
> ***D.*** *Is Apotex' allegation that the '080 patent is void pursuant to paragraphs 40(1)(*a*) and (*c*) of the Patent Act, justified?*

Justice Shore's Judgment, delivered June 17, 2008, granted an order for prohibition with costs. It said:

> ***THIS COURT ORDERS that:***
>
> *(1) The Applicants be granted the prohibition order for which they applied;*
>
> *(2) The Applicants are entitled to costs to be taxed in accordance with these Reasons.*

6. The decision of Justice Shore was appealed and heard before a panel of the Federal Court of Appeal comprising Justices Nadon, Trudel and Layden-Stevenson.

7. The Federal Court of Appeal rendered its Judgment in the appeal A-373-08 on June 22, 2009, with Reasons cited as 2009 FCA 212. That Judgment as originally issued read:

> ***JUDGMENT***
>
> *The appeal is allowed with costs, the decision of Shore J., 2008 FC 744, dated June 17, 2008, is set aside and the matter is remitted back to him for redetermination on the basis that there is no abuse of process on the part of Apotex Inc. in making the allegations found in its Notice of Allegation and in contesting the application for a prohibition order commenced by the respondents. Shore J. is instructed to assess the evidence before him independently of any findings made by Hughes J. in Janssen-Ortho v. Novopharm Limited, 2006 FC 1234, 300 F.T.R. 166. With respect to the proceedings below, there shall be no order as to costs.*

8. Upon receipt of the Judgment and Reasons Counsel for Janssen-Ortho and Daiichi each sent e-mails to the Court of Appeal requesting certain amendments as well as a declaration as to mootness be included so as to preclude Apotex from claiming section 8 relief.

9. On June 25, 2009, the Federal Court of Appeal, by way of a letter to Counsel signed by a student, revised that Judgment and the Reasons only to change the word "decision" to "judgment" as follows:

> *The revisions are as follows:*
>
> *7) Page 1:*
> - *Whereas "The appeal is allowed with costs, the decision …" has been amended to read "… The appeal is allowed with costs, the judgment…"*
>
> *8) Page 27:*
> - *Whereas "… set aside the Judge's decision and remit …" has been amended to read "… set aside the Judge's judgment and remit …"*

10. The Reasons delivered by the Federal Court of Appeal indicated that the Court was not unanimous. Nadon J.A. wrote the majority Reasons with which Trudel J.A. agreed. Layden-Stevenson J.A. dissented in part. It is noted that the Judgment of Shore J. was not in the words of section 8 "reversed" but rather sent back for redetermination.

11. The matter was returned to Justice Shore for a redetermination in accordance with the Judgment of the Federal Court of Appeal. On June 14, 2010, Justice Shore recused himself from the matter, providing Reasons cited as 2010 FC 643. He wrote at paragraph 7 of the Reasons and in the Order:

> *Thus, after time and much reflection, subsequent to receiving the new written pleadings of the parties, the undersigned recognizes he cannot in good conscience, in the integrity of spirit necessary for intellectual honesty, required for the independence of a judge, sit on this matter, yet again, without reaching the same conclusions through the same reasons. As a result, in fairness to the parties, the following decision has been reached in the Order below.*

ORDER

> ***THIS JUDGE ORDERS that*** *he recuse himself from sitting on this matter; and that he remit to the Chief Justice of this Court the case to be heard by a different judge of this Court.*

12. Meanwhile on June 23, 2009, the ’080 Patent had expired and Apotex was granted a Notice of Compliance by the Minister permitting it to sell its generic version of the drug in question in Canada. Thus the prohibition sought in these proceedings is pointless.

Issues

[6] Given this history the Court must resolve the following issues:

a. Given that the ’080 Patent has expired and Apotex has received its Notice of Compliance should this application be dismissed as moot?
2. Even if the matter is moot should it be heard as a matter of the Court’s discretion or because the Federal Court of Appeal said it must?

Mootness

[7] In normal circumstances a proceeding that has become moot by reason of the subsequent occurrence of events will not be heard by a court. There is no longer a live dispute that should be resolved and the resources of the court are better spent elsewhere. In the present proceedings the Applicants have sought to prohibit the issuing of a Notice of Compliance to Apotex to sell a drug in Canada protected by the ’080 Patent. Events have moved on, the Patent has expired and Apotex has

received its Notice of Compliance. On the face of things there is nothing left for adjudication, the matter is moot.

[8] There is however, a matter that has arisen in several proceedings of this kind under the *NOC Regulations*, it is that of section 8 which provides, in the current version which in this respect is not different from the version in existence when these proceedings were commenced:

> *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.*
>
> …

[9] Thus, if these proceedings are dismissed, Apotex would, under section 8 be entitled to make a claim for any loss suffered during a stipulated period. There is, however, no evidence in the record that would indicate that Apotex would commence section 8 proceedings or if it did, whether it would be in a position to claim a loss or whether that loss is substantial or trivial. Should the Court nonetheless hear the matter is a question involving the exercise of discretion.

[10] Janssen-Ortho and Daiichi argue that, in accordance with the principles laid down by the Supreme Court of Canada in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342, the Court should hear this matter which may be seemingly moot on the basis that a finding may have a practical effect namely whether Apotex would have a right to commence an action for recovery under section 8 of the *NOC Regulations*.

[11] Second, the Applicants Janssen-Ortho and Daiichi argue that the Judgment of the Federal Court of Appeal requires a redetermination with certain conditions as to ignoring certain matters arising from the Novopharm action previously discussed, thus a redetermination must take place.

Analysis

[12] The issues must be considered in the context of the words used in the *NOC Regulations* in particular section 8. That section speaks of an application that is *"dismissed by the Court hearing the application":*

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 concludes that* *(i) the certified date was, by the operation of An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or*	***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 conclut :* *(i) soit que la date attestée est devancée en raison de l'application de la Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique), chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus*

(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 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).

(6) The Minister is not liable for damages under this section.

SOR/98-166, ss. 8, 9; SOR/2006-242, s. 5.

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 pour 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 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) Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

DORS/98-166, art. 8 et 9; DORS/2006-242, art. 5.

[13] It would have been easy for the *NOC Regulations* simply to say "dismissed" or even "dismissed by the court" but they say something more, they say *"dismissed by the court hearing the application [emphasis added*]".

[14] The *NOC Regulations* clearly recognize the difference between the application and the hearing of the application. Section 6(1) permits a "first person" to "apply to a Court" for an order of prohibition. Section 6(5) permits the application to be dismissed in certain circumstances. Sections 7(1)(e) and (f) allow the Minister to issue a Notice of Compliance after the expiration of 24 months from the institution of an application or upon expiry of the relevant patent except, in the circumstances set out in section 7(2)(b) where the Court has earlier declared the patent not to be infringed or invalid. Section 7(4) says that 7(1)(e) (the 24-month period) ceases to apply if a court hearing the application has dismissed the application.

[15] Thus the *NOC Regulations* recognize a difference between the application and the hearing of the application. A hearing requires a meaningful judicial assessment of the matter by the court. The circumstances are similar to those discussed by McLachlin C.J. of the Supreme Court of Canada in *United States of America v. Ferras*, [2006] 2. S.C.R. 77 at paragraph 25:

> *An independent judicial phase and an impartial judge are elements of the third and ultimate right – the right to a "hearing". The right to a hearing engages procedural guarantees appropriate to the context: see Baker v. Canada (Minister of Citizenship and Immigration), [1999] 2 S.C.R. 817. Substantially, it entails, at a minimum, a meaningful judicial assessment of the case on the basis of the evidence and the law. A judge considers the respective rights of the litigants or parties and makes findings of fact on the basis of evidence and applies the law to those findings. Both facts and law must be considered for a true adjudication. Since Bonham's Case, the essence of a judicial hearing has been the treatment of facts revealed by the evidence in consideration of the substantive rights of the parties as set down by law. It follows that the extradition judge must judicially consider the facts and the law and be satisfied that they justify committal before ordering extradition. The judge must act as a judge, not a rubber stamp.*

[16] Also similar are the circumstances considered by the Federal Court of Appeal in *Salinas v. Canada (Minister of Employment and Immigration)*, [1992] 3 F.C. 247 where Stone J.A. for the Court wrote at paragraph 252 that a hearing was a separate step within a wider proceeding:

> *In general, the provisions of section 68 endow the Refugee Division with powers and duties in relation to any "proceedings" before it. It is apparent that a distinction has thus been drawn by Parliament between "proceedings" and a "hearing" before the Refugee Division which is to be conducted in the manner required by section 69.1 of the Act. A "hearing" is but a step, albeit an important step, in any "proceedings" which is a wider term encompassing the entire matter before the Refugee Division including the hearing of the claim itself.*

[17] Therefore a section 8 claim for loss is not triggered by a dismissal alone but only by a dismissal by a Court hearing the matter.

[18] Therefore the question becomes whether, notwithstanding that the matter is moot, the Court should hear the matter.

[19] The Federal Court of Appeal has, in a series of decisions, considered whether a hearing should be held, notwithstanding mootness, when section 8 of the *NOC Regulations* is involved. The governing principles are those established by the Supreme Court of Canada in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342 and summarized by that Court in *Doucet-Boudreau v. Nova Scotia*, [2003] 3 S.C.R. 3 at paragraph 18, as follows:

> *(1) The presence of an adversarial context;*
>
> *(2) The concern for judicial economy; and*
>
> *(3) The need for the Court to be sensitive to its role as the adjudicative branch of our political framework.*

[20] Chief Justice Isaac sitting in the Federal Court of Appeal made the first substantive decision in respect of the existence of a section 8 question and mootness in *Pfizer Canada Inc. v. Apotex Inc.* (2001), 11 C.P.R. (4th) 245 where he wrote at paragraphs 23 and 24 that simply to argue that section 8 may or may not come into play is insufficient to overcome a question of mootness:

> ***23*** *I do not accept the appellants' contention that this Court should exercise its discretion to hear appeals which are otherwise moot in order to clarify their potential liability for damages under section 8 of the Regulations. At the relevant time, that section read:*
>
> *8. (1) The first person is liable to the second person for all damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond the expiration of all patents that are the subject of an order pursuant to subsection 6(1).*

> *(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).*
>
> *I find no merit in the argument, because its acceptance would result in subversion of the regulatory scheme.*
>
> ***24*** *To my mind, there is always an incentive in the first person who has sought and lost a prohibition application to try and eliminate a potential liability in damages. The incentive would apply equally to the second person who recognizes that setting aside a prohibition order on appeal could result in a damage award. If this Court decided to hear the appeal on this ground, the universal incentive to seek or to avoid section 8 damages would, in my opinion, always prevail over the issue of mootness. Such a result would be at variance with the stated intention of the regulation-making authority that:*
>
> *These Regulations are needed to ensure this new exception to patent infringement is not abused by generic drug applicants seeking to sell their product in Canada during the term of their competitor's patent while nonetheless allowing generic competitors to undertake the regulatory approval work necessary to ensure they are in a position to market their products immediately after the expiry of any relevant patents.*
>
> *Anticipated Impact*
>
> *These Regulations together with subsection 55.2(1) will allow patentees to enjoy full patent protection while ensuring off-patented competitors will be able to enter the marketplace immediately upon the expiry of all patents pertaining to a medicine.*

[21] Subsequently, the Federal Court of Appeal in *Bayer AG v. Apotex Inc.* (2004), 32 C.P.R. (4^{th}) 449 was faced with a revised version of section 8. Rothstein J.A. (as he then was) wrote the decision of that Court in which he distinguished Isaac C.J.'s decision as *obiter* and that it dealt with an earlier version of section 8. He wrote that the generic in that case was entitled to have its appeal

heard notwithstanding the expiry of the patent in order to preserve a right to compensation under section 8. I repeat paragraphs 12 to 16 of his decision:

> ***12*** *I do not think the obiter dicta of Isaac J.A. in Pfizer are applicable in this case or, indeed, at all under the current version of section 8 of the Regulations. First, unlike a patentee, a generic can not commence an action for infringement if it is denied a remedy under section 8. The only way in which a generic can recover damages or lost profits caused by an erroneous prohibition order is to have the Court of Appeal reverse the Federal Court and then seek damages under section 8.*
>
> ***13*** *Second, section 8 of the Regulations to which Isaac J.A. referred in Pfizer (SOR/93-133) has now been replaced (SOR/98-166). The regulatory impact analysis statement of the current Regulations states in relevant part:*
>
> > *A clearer indication is given to the Court as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug, and the factors that may be taken into account in calculating damages.*
>
> *Unlike the former section 8, the current section 8 expressly refers to the reversal on appeal of a prohibition order giving rise to liability by a patentee to a generic manufacturer.*
>
> ***14*** *There is no indication in section 8 that the reversal on appeal must occur prior to expiry of the patent at issue or the issuance of a Notice of Compliance to the generic. Nor is there any rationale for such a requirement. If a generic manufacturer has been wrongly excluded from the market during the lifetime of a patent, the fact that an appeal is decided after the patent expires should have no bearing on the generic's entitlement to damages. In my respectful opinion, it would be inconsistent with the object of the current Regulations to deprive a generic manufacturer of the opportunity to avail itself of section 8 of the Regulations merely because a patent has expired or a Notice of Compliance has issued. The liability referred to in section 8 arises from the period prior to the expiry of the patent or issuance of the Notice of Compliance to the generic and the mere fact that the appeal is*

> *decided after that date has no bearing on the application of section 8.*
>
> ***15*** *Bayer also argues that Apotex should have attempted to have the appeal expedited in order that it be decided before expiry of the '067 Patent and issuance of the Notice of Compliance to Apotex. It says that Apotex's failure to do so constitutes an inordinate delay which should cause the Court to exercise its discretion against hearing the appeal.*
>
> ***16*** *I do not accept Bayer's argument that there has been inordinate delay. That an appellant does not seek to expedite an appeal does not, of itself, amount to inordinate delay in the absence of other circumstances. For example, where an appellant seeks and obtains a stay of a decision pending appeal, an application to expedite will always be appropriate and failure by an appellant to make such application and to proceed diligently may result in the Court considering there to have been inordinate delay. However, there are no such extenuating circumstances here. There is no connection between the expiry of a patent or the issuance of a Notice of Compliance to a generic manufacturer on the one hand and the preservation of a right to compensation for loss under section 8 on the other.*

[22] Next is the decision of the Federal Court of Appeal in *Aventis Pharma Inc. v. Apotex Inc.* (2006), 53 C.P.R. (4th) 447. The facts are complex. A prohibition order respecting the same patent had been granted against Apotex by an earlier decision of Simpson J. of this Court. A second proceeding heard by Tremblay-Lamer J. of this Court involving the same patent was dismissed. The patentee, Aventis, sought to appeal from Tremblay-Lamer J.'s decision; however, the patent had expired by that time. Aventis argued that the appeal should be heard nonetheless since a section 8 liability may arise. The Court of Appeal refused to hear the matter as the possible liability was too remote and speculative. Noël J.A. for the Court wrote at paragraphs 15 to 21:

> ***15*** *The fact that Aventis also sought a declaration invalidating the Notice of Allegation that gave rise to the proceeding before*

Tremblay-Lamer J. is also of no assistance to Aventis. The purpose of such a declaration was to prevent Apotex from entering the market pending the expiration of the '457 patent. Since the patent has expired, nothing can flow from a decision on appeal on this point.

16 *The only issue, therefore, is whether this Court should nevertheless exercise its discretion to hear the appeal. In this respect, Aventis claims that, absent a favourable decision on appeal, it will be exposed to damages pursuant to section 8 of the NOC Regulations, and that, as a result, it finds itself in the same position as Apotex in the Bayer case. As such, Aventis urges the Court to exercise its discretion in the same way.*

17 *We first note that unlike Apotex in the Bayer case, Aventis has, as a patentee the right to undertake a patent infringement action (circumstances permitting) and, if successful, obtain compensation either in the form of damages or loss of profits.*

18 *In addition, Aventis' potential exposure to damages under section 8 is too remote and speculative to justify our hearing the appeal.*

19 *Under that provision, a first person is liable for any loss suffered during the period beginning on the date on which a Notice of Compliance would have been issued in the absence of the NOC Regulations. This provision is intended to allow a second person to be compensated with respect to an application made by a first person that is shown to have been unsuccessful by reason of, inter alia, a dismissal at first instance or a reversal of a prohibition order on appeal.*

20 *In this case, Apotex chose to first proceed with its conditional allegation before Simpson J. It did not seek to accelerate its appeal from that decision with the result that, insofar as this decision is concerned, none of the events mentioned in section 8 have taken place. Simpson J.'s prohibition order has remained in effect until the expiration of the '457 patent. Based on the limited record that we have, and without pre-judging the issue, if it should arise in the context of a section 8 application, the section 8 exposure is in our view speculative.*

21 *In order to satisfy us that the appeal ought to be heard despite its mootness, it was incumbent upon Aventis to show, on a*

> *balance of probabilities that a decision on appeal will have a practical effect on the rights of the parties (Borowski, at 358-62 as applied in Bayer, supra). This demonstration has not been made.*

[23] The matter was further considered by the Federal Court of Appeal, not in the context of proceedings under the *NOC Regulations*, but in an action by a generic, Apotex, to impeach a patent which Apotex argued would affect a section 8 proceeding that it intended to commence if the patent were held to be invalid. The patent had expired. The Court declined to exercise its discretion to hear the matter as it was moot. Sexton J.A. for the Court wrote at paragraphs 17 to 19 in *Aktiebolaget Hassle v. Apotex Inc.* (2008), 65 C.P.R. (4th) 5:

> ***17*** *The existence of an adversarial context in the present case depends on the respondent at some future date commencing an action for damages pursuant to section 8 of the NOC Regulations. The respondent claims that the section 8 action will commence pending success in this action, success in another action involving Canadian Patent No. 1,292,693 (which also relates to omeprazole), and overturning the corresponding prohibition orders ab initio. We would point out that at the moment there are no other live proceedings which would be impacted by the Court allowing this action to proceed. This Court in Sanofi Aventis v. Apotex (2006) 53 C.P.R. (4th) 447 held that a potential claim under section 8 of the NOC Regulations was too speculative to warrant a Court hearing an appeal relating to an expired patent. While we therefore have some doubt regarding the existence of an adversarial context in this case, we need not base our decision on this issue in light of the reasons to dismiss the proceeding on the grounds of judicial economy.*
>
> ***18*** *The concern for judicial economy strongly militates against allowing this action to proceed. Factors under this heading to consider include whether a resolution of this case would be in the public interest (Borowski paragraph 37), whether anything in the action raises important issues that may be evasive of review (Doucet at paragraph 20; Borowski at paragraph 36), and whether the case will be of "brief duration" (Borowski at paragraph 36). In the present case, all of these considerations warrant dismissing the*

> *action. In terms of a whether a resolution of this case is in the public interest, it should be pointed out that the Statement of Claim of the respondent simply asks for "a declaration that each of the claims of the '751 Patent is invalid, void and of no force and effect." Given that this case is only about a claim for the invalidity of an expired patent and nothing else, the interests in this case do not extend beyond the parties. Moreover, there is nothing about this action that suggests that there are important issues raised that are evasive of review. The grounds of invalidity alleged -- anticipation, obviousness, double patenting, and inutility -- are all legal issues that are often dealt with in other proceedings. Nor would this be a case of brief duration: even ignoring the possibility of appeals, the action is scheduled to take ten days alone. Essentially, the respondent has provided no compelling reason to justify the unacceptable drain of judicial resources that would result if this action were allowed to proceed. Indeed, it could be argued that if this case were as pressing as the respondent suggests, one might have expected a trial to have already taken place given that this action was commenced in 2003.*
>
> ***19*** *For these reasons, this Court will decline to exercise its discretion to allow the moot action to continue. Since we have concluded that the matter is moot and should be dismissed in this regard, there is no reason to address the issue of standing.*

[24] In the present proceedings, Apotex's Counsel seeks to draw out a principle from these decisions to the effect that a generic would always be granted a hearing notwithstanding mootness whereas a patent holder will never be granted a hearing. Attention is drawn to a series of decisions of the Federal Court of Appeal of which *Biovail Corporation v. Canada (Minister of National Health and Welfare)* (2006), 46 C.P.R. (4th) 413 is typical in which Sharlow J.A. for the Court wrote at paragraph 5:

> ***5*** *A long and unquestioned line of authority from this Court establishes that an appeal from an order dismissing an application for a prohibition order under the NOC Regulations becomes moot when the notice of compliance is issued: Merck Frosst Canada Inc. v. The Minister of Health and Apotex Inc. (1999), 240 N.R. 195 (F.C.A.) (leave to appeal dismissed, [1999] S.C.C.A. No. 313),*

> *Pfizer Canada Inc. v. Apotex Inc. (2001), 266 N.R. 371 (F.C.A.), (leave to appeal dismissed, [2001] S.C.C.A. No. 111), Novartis A.G. v. Apotex Inc., [2002] F.C.J. No. 1551, 2002 FCA 440, AstraZeneca AB v. Apotex Inc., [2004] F.C.J. No. 1006, 2004 FCA 224, (leave to appeal dismissed, [2004] S.C.C.A. No. 391), Janssen-Ortho Inc. v. Novopharm Ltd., [2005] F.C.J. No. 1196, 2005 FCA 6.*

[25] Reference was made also to *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 62 C.P.R. (4th) 161, a split decision of the Federal Court of Appeal in which Sexton and Ryer J.J.A. dismissed an appeal as moot whereas Pelletier J.A. would have heard it as a matter of discretion. Sexton J.A. held that the patentee who was seeking a hearing had other remedies such as an infringement action. He wrote at paragraph 45:

> ***45*** *Once again, innovators like Eli Lilly are not without remedy. They may still commence an infringement action. Thus, even though Eli Lilly cannot proceed with this appeal, it certainly can seek an injunction, damages, and/or loss of profits via an infringement action, which it has done. It has the same remedy against other generics if it considers infringement is occurring.*

[26] Pelletier J.A. was of a different view. He wrote at paragraph 53:

> ***53*** *Even though proceedings under the Patented Medicines (Notice of Compliance) Regulations ("NOC") do not result in an in rem finding of invalidity, the patent law principles applied in NOC proceedings are necessarily the same as those applied in an infringement action. There is only one law of patents. Decisions of this Court addressing principles of patent law in the context of NOC proceedings are regularly and consistently cited as authority in other NOC proceedings. They are also cited as authority in patent litigation unrelated to NOC proceedings. See, for example, Calgon Carbon Corp. v. North Bay (City), 2006 FC 1373, [2006] F.C.J. No. 1719 at paragraphs 125 and 126, Johnson & Johnson Inc. v. Boston Scientific Ltd., 2004 FC 1672, [2004] F.C.J. No. 2040 at paragraphs 52,75 and 97, Jay-Lor International Inc. v. Penta Farm Systems Ltd., 2007 FC 358, [2007] F.C.J. No. 688,*

> *at paragraphs 74 and 77, Wessel v. Energy Rentals Inc., 2004 FC 791, [2004] F.C.J. No. 952 at paragraph 21, Varco Canada Ltd. v. Pason Systems Corp., 2006 FCA 100, [2006] F.C.J. No. 375 at paragraph 4.*

[27] Given the wealth of decisions by the Federal Court of Appeal on the question as to whether, notwithstanding mootness, a matter should be heard when section 8 of the *NOC Regulations* is involved, I do not ascribe to Apotex's view that the matter is as automatic as its Counsel would like it to be. It is not simply that a generic gets a hearing if it wants to while a patent holder does not. Oddly, in the present motion before me, Apotex is the one arguing that no hearing is required whereas the Applicants, the patent holders, want a hearing. If it was so automatic, the proceedings in such circumstances would simply be terminated without Apotex having an opportunity to invoke section 8.

[28] In my determination a Court faced with circumstances such as the present must not make an automatic determination. It must consider the circumstances as set out on the record. Here there is nothing on the record upon which the Court can rely in making such a determination. Apotex's Counsel candidly acknowledged that there is no certainty that Apotex would in fact commence section 8 proceedings if a rehearing of the matter resulted in a conclusion different from the first determination by Justice Shore or, if it did, whether there was any prospect of success on the part of Apotex or, if successful, whether the recovery would be trivial thus not worth the effort, or substantial. I consider the matter, just as the Federal Court of Appeal did in *Aventis supra*, to be remote and speculative. I decline to exercise any discretion vested in this Court to hear the matter.

[29] Now I turn to the next matter raised, that of the Judgment of the Federal Court of Appeal directing that there be a “redetermination” and setting out certain restrictive conditions.

[30] Counsel for each party made reference to the Reasons of the Federal Court of Appeal and to exchanges of correspondence by way of e-mail between Counsel and the Court of Appeal following release of the Reasons and Judgment which ultimately resulted in a correction to the Reasons and Judgment substituting the word “judgment” for “decision” as previously referred to in the historical review in these present Reasons. Apotex urges, in reading the Applicants Counsel’s correspondence, that the Court of Appeal was asked to address the issue of section 8 and mootness, and the fact that its revised Judgment and Reasons do not do so indicates that the Court refused to do so. The Applicants argue on the other hand that, implicit in the Reasons and Judgment, including that part of the Judgment directing Justice Shore what not to take into consideration, is a direction from the Court that the matter is not moot and that a hearing must take place.

[31] I have reviewed this exchange of correspondence, the original Reasons and Judgment, and the revisions to the Reasons and Judgment. I conclude that both Apotex and the Applicants are reading too much into this material. The Federal Court of Appeal did not reverse Justice Shore, the matter was returned to this Court for redetermination. In conducting such a redetermination this Court was directed to ignore certain matters respecting the decision in the Novopharm action T-2175-04. There is no requirement, implicit or explicit, that a hearing or re-hearing take place. If a redetermination can be made on the basis of a motion for dismissal that is entirely consistent with the Judgment of the Federal Court of Appeal.

[32] A determination of a matter does not mean that there must be a hearing. A proceeding may be "determined" or "redetermined" without a hearing taking place. A "determination" is simply "a bringing or coming to an end; a termination" as defined by the Oxford Dictionary. This point was made by Wachowich J. (as he then was) in *O'Brien v. Non-Marine Underwriters, Lloyds, London* (1991), 85 Alta. L.R. (2d) 358:

> *The Legislature, through s. 235(1) and Statutory Condition 11, has deemed the appraisal process set out in s. 204 to be a part of insurance contracts in Alberta. The final and binding nature of this process is consistent with the legislation's purpose.*
>
> *To conclude that the decision of an umpire is binding and conclusive upon the parties does not deprive the O'Briens of a cause of action. The action remains; it is the valuation of the loss which as been determined.*
>
> *To conclude that the appraisal process is binding is not inconsistent with the use of the word "determine" in s. 204(3). The Insurance Act does not define "determine". The Oxford English Dictionary defines "determine" as: "to put an end or limit to"; "to settle or decide". The legislation is clear. The appraisal process is final and binding.*
>
> *After consideration of the authorities, of the wording of the legislation and of the purpose of s. 204 of the Insurance Act, I find that the appraisal process is binding.*

[33] I find that the Judgment of the Federal Court of Appeal that the matter be "redetermined" simply meant that this Court is allowed to bring to bear all the normal considerations, including termination of a proceeding for mootness, without necessarily having a further hearing of the matter.

[34] Thus, I will grant the motion to dismiss; however, since the dismissal is without a “hearing”, it will not trigger the provisions of section 8 of the *NOC Regulations*. To avoid confusion I will “terminate” these proceedings.

[35] In the circumstances there is no need to consider the other motions.

[36] As to costs, Counsel have agreed that the successful party should be awarded costs fixed at $3000 and I will so Order.

ORDER

For the reasons provided:

THIS COURT ORDERS that:

1. These proceedings are terminated.

2. The Applicants are entitled to costs to be paid by Apotex in the sum of $3000.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1508-05
STYLE OF CAUSE:	JANSSEN -ORTHO INC. AND DAIICHI SANKYO COMPANY, LIMITED v. APOTEX INC. AND THE MINISTER OF HEALTH
PLACE OF HEARING	Toronto, ON
DATE OF HEARING:	June 24, 2010
REASONS FOR ORDER AND ORDER:	HUGHES J.
DATED:	June 29, 2010

APPEARANCES:

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