Federal Court of Appeal  Cour d'appel fédérale

Date: 20111219

Docket: A-10-11

Citation: 2011 FCA 364

CORAM: **EVANS J.A.**
GAUTHIER J.A.
STRATAS J.A.

BETWEEN:

APOTEX INC.

Appellant

and

MERCK & CO., INC. and
MERCK FROSST CANADA CO.

Respondents

AND BETWEEN:

MERCK & CO., INC. and
MERCK FROSST CANADA CO.

Respondents

and

APOTEX INC. and
HER MAJESTY THE QUEEN
IN RIGHT OF CANADA
as represented by the
ATTORNEY GENERAL OF CANADA

Apotex Inc., Appellant

Heard at Toronto, Ontario, on November 28, 2011.

Judgment delivered at Ottawa, Ontario, on December 19, 2011.

REASONS FOR JUDGMENT BY: EVANS J.A.

CONCURRED IN BY: GAUTHIER J.A.
STRATAS J.A.

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REASONS FOR JUDGMENT

EVANS J.A.

Introduction

[1] This is an appeal from a decision of the Federal Court (2010 FC 1264) in which Justice Snider (Judge) dismissed a statement of claim by Apotex Inc. seeking compensation from Merck & Co. Inc., Merck Frosst Canada Ltd., and Merck Frosst Canada & Co. (collectively Merck) under section 8 of the *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 (PMNOC Regulations).

[2] Apotex' claim is for loss allegedly sustained in the period that it was prevented from selling a generic version of the medicine lovastatin by the statutory stay imposed as a result of Merck's application under subsection 6(1) of the PMNOC Regulations.

[3] In that application, Merck requested an order prohibiting the Minister of Health (Minister) from issuing a Notice of Compliance (NOC) authorizing Apotex to market its version of lovastatin in Canada. Merck submitted that Apotex' allegations of invalidity and non-infringement of Merck's Canadian Patent No. 1,161,380 ('380 patent) were not justified. The '380 patent was for lovastain made by a particular process, referred to in this litigation as AFI-1.

[4] Merck's application for an order of prohibition was dismissed without an adjudication of its merits, and the Minister granted Apotex an NOC. Apotex then started to manufacture and import lovastin, and to sell tablets containing lovastatin in Canada.

[5] Merck subsequently commenced an infringement action against Apotex, alleging that it had infringed the ’380 patent. In this action, the Judge found the patent to be valid and held that some of the lovastatin tablets sold by Apotex had been made by the infringing process. However, she also held that Merck had not proved that all Apotex’ lovastatin was infringing: Apotex had patented another process for making lovastatin (referred to in this litigation as AFI-4) that did not infringe the ’380 patent. The Judge’s decision is reported at 2010 FC 1265. This Court dismissed Apotex’ appeal from her decision in reasons released today: see 2011 FCA 363.

[6] The present appeal raises three issues. First, is Apotex’ claim for compensation governed by the version of section 8 of the PMNOC Regulations enacted in 1993 (1993 Regulations) or that enacted in 1998 (1998 Regulations)? This, in turn, depends on whether Merck’s application for prohibition was “pending” on March 11, 1998, the date that the 1998 Regulations came into effect. Second, has Apotex established an entitlement to compensation under subsection 8(1) of the applicable version of section 8? Third, if it has, should this Court determine the basis on which compensation is to be calculated and what defences to Apotex’ claim are available to Merck, or should it remit these issues to the Judge?

[7] I would answer these questions as follows. Merck’s application for prohibition was “pending” on March 11, 1998, and the 1998 Regulations therefore apply. Merck is liable to Apotex under subsection 8(1) for loss suffered as a result of the Minister’s delay in issuing the NOC to Apotex. The legal and factual issues relevant to the amount of compensation (if any) payable by Merck to Apotex are not appropriately decided at first instance in this Court.

[8] Accordingly, I would allow the appeal and remit the matter to the Judge to determine the legal and factual issues necessary to quantify Merck's liability to Apotex under section 8 of the 1998 Regulations.

Issue 1: Does the 1993 or 1998 version of the Regulations apply?

[9] Whether the 1993 or 1998 version of section 8 of the PMNOC Regulations applies is governed by the transitional provision, subsection 9(6) of the 1998 Regulations.

9(6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations.	9(6) L'article 8 du même règlement, édicté par l'article 8, s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.

[10] In order to determine whether Merck's application for an order of prohibition under subsection 6(1) of the PMNOC Regulations was "pending" when the 1998 Regulations came into force, I shall first set out the chronology of key events and then review the applicable law.

(i) *chronology*

[11] **June 1, 1993:** Merck commenced its application for prohibition, arguing that Apotex' allegations that the '380 patent was invalid, and that its version of lovastatin would not infringe, were not justified.

[12] **September 6, 1995:** The Federal Court, Trial Division, extended the 30-month statutory stay from December 1, 1995 to December 1, 1996.

[13] **February 13, 1997:** Merck applied for an extension order under subsection 7(5) of the PMNOC Regulations.

[14] **March 26, 1997:** The Federal Court, Trial Division (*per* Justice Rothstein) held that the Court had no jurisdiction either to extend the statutory stay after its expiry, or to issue an order of prohibition after the statutory stay had expired. Merck's application for prohibition was accordingly dismissed without an adjudication of whether Apotex' allegations of invalidity and non-infringement were justified: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1997), 127 F.T.R. 18, 72 C.P.R. (3d) 148 (*Merck FCTD 1997*).

[15] **March 27, 1997:** The Minister issued an NOC to Apotex for its generic lovastatin.

[16] **April 1997:** Merck filed an appeal to the Federal Court of Appeal from the decision in *Merck FCTD 1997*.

[17] **April 21, 1999:** The Federal Court of Appeal dismissed Merck's appeal from *Merck FCTD 1997* on the ground that issuing an NOC to Apotex in March 1997 rendered it moot: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1999), 240 N.R. 195 (F.C.A.) *(Merck FCA 1999).*

[18] Thus, when section 8 of the 1998 Regulations came into effect on March 11, 1998, the Federal Court had already dismissed Merck's application for prohibition, and Merck had filed an appeal from this decision, but the appeal had not yet been decided.

(ii) *law*

[19] A few days before the hearing of the present appeal, another panel of this Court released its decision in *Merck Frosst Canada & Co. v. Apotex Inc.* 2011 FCA 329 (*Merck Frosst)*, a case concerning another drug, but the same parties and the interpretation of the words "application pending" in subsection 9(6) of the 1998 Regulations.

[20] The Judge in the present case did not, of course, have the benefit of this decision when she concluded that the 1993 version of section 8 applied. She held that, on the facts before her, Merck's appeal was not pending because its application for prohibition had been determined in the final decision of the Federal Court in *Merck FCTD 1997*.

[21] In *Merck Frosst*, the question was whether the patent holder's application for prohibition was "pending" on March 11, 1998, while it was awaiting the Supreme Court of Canada's determination of Apotex' appeal from a decision of this Court upholding the decision of the Federal Court, Trial Division to issue an order of prohibition. The Supreme Court allowed Apotex' appeal on July 9, 1998, and the NOC was issued soon thereafter.

[22] Giving the reasons of this Court, Justice Stratas stated (at para 17):

> … the correct test for determining whether an application is "pending" is whether the application remains alive either at first instance, or on appeal.

Applying this test, he noted (at para. 21) that the Supreme Court had the power to give the judgment that the Federal Court, Trial Division should have given. It exercised that power by dismissing the application for prohibition.

[23] Merck argues that *Merck Frosst* is distinguishable because, in the present case, its application for prohibition was dismissed by the Federal Court in *Merck FCTD 1997* on the ground that the Court had no jurisdiction either to extend the statutory stay after it had expired or to prohibit the Minister from issuing an NOC after the NOC has been issued.

[24] I disagree with this argument for three reasons. First, Merck's prohibition application remained alive on March 11, 1998, in the sense that this Court had jurisdiction to hear Merck's appeal from *Merck FCTD 1997*. Even though the issue of the NOC rendered the application moot, the Court nonetheless could have exercised its discretion to decide the question in dispute and, if it allowed the appeal, it could have granted the application, although there was nothing left to prohibit.

[25] In giving the reasons of the majority in *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 187, 282 D.L.R. (4th) 69, Justice Nadon stated that the expiry of a statutory stay does not deprive this Court of jurisdiction to hear an appeal. Thus, referring to *Pfizer Canada Inc. v. Apotex Inc*., (2001), 266 N.R. 371 (F.C.A.), he said (at para. 52):

> It is important to note that Isaac C.J. did not conclude that the Court was without jurisdiction to make the order sought because the statutory stay had expired, but

> rather that the Court would not exercise its jurisdiction because the matter had become moot.

[26] Further, Nadon J.A. stated (at para. 58) that Rothstein J. was wrong to have concluded in *Merck FCTDC 1997* that the expiry of the statutory stay deprived the Federal Court of jurisdiction over the application for an order of prohibition under subsection 6(1) of the PMNOC Regulations, whether or not the Minister had issued an NOC. This reasoning applies equally when an NOC is issued before the expiry of the statutory stay: the application may become moot, but it is not beyond the Court's jurisdiction.

[27] Second, subsection 9(6) is a transitional provision which, statutory language permitting, should be interpreted in a way that makes it easy to apply. There is much to be said for bright line tests in the application of transitional provisions: fine distinctions between questions of law and questions of jurisdiction can only introduce unnecessary confusion in this context, as they have in others.

[28] Third, the statutory objective of the 1998 version of section 8 was more to clarify the meaning of the obscurely drafted 1993 version, than to amend its substance: see Regulatory Impact Analysis Statement*, Canada Gazette Part II*, vol. 132, No. 7 at 1056. Hence, undue restrictions should not be placed on the circumstances in which parties are entitled to have their legal rights determined in accordance with the more recent version of the Regulations that is drafted so as to express the legislator's intent more clearly.

[29] Accordingly, the question is whether Merck is liable to compensate under the 1998 version of subsection 8(1).

Issue 2: Did Merck's application for prohibition under subsection 6(1) of the PMNOC Regulations make it liable under section 8 of the 1998 Regulations for loss caused by the Minister's delay in issuing an NOC to Apotex for its lovastatin tablets?

[30] Section 8 of the 1998 Regulations provides 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	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 is satisfied on the evidence that another date is more appropriate; and	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) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.
(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to	(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une

compensate the second person for the loss referred to in subsection (1).	ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).
(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.	(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action pour contrefaçon du brevet visé par la demande.
(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).	(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) 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).

[31] References in section 8 to the “first person” connote the innovator drug company, and to the “second person”, the generic drug company.

[32] The Judge did not consider the application of these provisions to the facts of this case. She concluded (at para. 28) that the 1993 version of section 8 applied, and interpreted it as entitling Apotex to compensation only when the Minister issued the NOC after all relevant patents had expired. Since the ’380 patent was extant in the period that Apotex claims it was kept off the market

by the application of paragraph 7(1)(*e*) of the PMNOC Regulations, the Judge concluded that Merck was not liable to compensate Apotex for loss suffered as a result of the delay to its entry onto the market.

[33] Merck's principal argument in this Court was that Apotex is not entitled to compensation under subsection 8(1). It said that, after obtaining an NOC, Apotex immediately started to infringe the '380 patent by selling tablets containing lovastatin made by Apotex Fermentation Inc., a wholly owned subsidiary of Apotex, using the patented process, AFI-1. The infringement continued when Apotex imported lovastatin from a company in China that had made it by the infringing process. It cannot have been the legislator's intention, Merck says, to compensate an infringer for loss suffered as a result of being prevented by the statutory stay from starting to infringe sooner. Merck interprets subsection 8(1) in light of the maxim that a cause of action does not arise from an illegal or immoral act of the plaintiff: *ex turpi causa actio non oritur*.

[34] An assessment of this argument calls for an examination of the structure of section 8 and an identification of the issues that are in play in this appeal and those that are not. Subsection 8(1) of the 1998 Regulations defines when a first person is liable to compensate a second person. As applicable to the facts of the present case, the first requirement is that the first person's application under subsection 6(1) is dismissed. Apotex satisfies this requirement: Merck's application was dismissed in *Merck FCTD 1997*, which was affirmed by this Court in *Merck FCA 1999*.

[35] The other requirement is that the second person must have suffered loss in the period starting on the date, as certified by the Minister, on which an NOC would have been issued in the absence of the Regulations (unless the Court is satisfied on the evidence that another date is appropriate), and ending on the date of the dismissal of the application for prohibition.

[36] I do not accept Merck's submission that the Court should read into this provision limiting words to the effect, "unless the second person's claim is based on the loss that is has suffered by being prevented from infringing the first person's patent earlier." The presumption against reading words into a statutory text may be rebutted when demanded by context and legislative objective. In my view, it is not necessary to read an *ex turpi causa* exception into subsection 8(1) in order to prevent patent infringers from unjustly recovering compensation from a first person.

[37] This is because subsection 8(5) confers a broad discretion on the court when assessing the amount of compensation that the second person must pay. It provides that the court "shall take into account all matters that it considers relevant to the assessment of the amount," including any conduct by either party that contributed to the delay in the disposition of the first person's application for prohibition. In my view, this provision enables the Court to determine in its discretion whether, and to what extent, a second person's claim for compensation should be reduced, or eliminated.

[38] The Court's broad discretion under subsection 8(5) allows it, when considering arguments based on *ex turpi causa*, to have regard to the factual situation in its entirety, including its nuances.

In the present case, one such nuance is that not all the tablets sold by Apotex were found in the infringement action to contain lovastatin made by the infringing process. A court is likely to find it easier to apply the *ex turpi causa* principle through an exercise of judicial discretion than through the definition of liability. Discretion enables the court to assess the appropriate amount of compensation payable (including nil) in a manner that properly takes account of all the relevant facts.

Issue 3: Are the remaining legal and factual issues concerning the amount of compensation (if any) payable to Apotex under section 8 appropriately decided in this appeal?

[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.

Conclusion

[42] For these reasons, I would allow the appeal with costs here and below, set aside the decision of the Federal Court, and remit the matter to be re-determined by the Judge in accordance with these reasons.

"John M. Evans"
J.A.

"I agree
Johanne Gauthier J.A."

"I agree
Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

Andrew Brodkin	FOR THE APPELLANT APOTEX INC.
Steven G. Mason	FOR THE RESPONDENT MERCK & CO., INC. and MERCK FROSST CANADA

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE APPELLANT APOTEX INC.
McCarthy Tétrault LLP Toronto, Ontario	FOR THE RESPONDENT MERCK & CO., INC. and MERCK FROSST CANADA