Federal Court  Cour fédérale

Date: 20090612

Docket: T-1235-02

Citation: 2009 FC 631

Ottawa, Ontario, June 12, 2009

PRESENT: The Honourable Mr. Justice Kelen

BETWEEN:

APOTEX INC.

Plaintiff
(Defendant by Counterclaim)

and

PFIZER CANADA INC.,
PFIZER CORPORATION,
HER MAJESTY THE QUEEN

Defendants
(Plaintiffs by Counterclaim)

REASONS FOR ORDER AND ORDER

[1] This is a motion by the Pfizer Defendants for summary judgment in an action by the Plaintiff Apotex seeking to recover damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, amended by SOR/98-166 (*NOC Regulations*). Apotex alleges that the Pfizer Defendants' unsuccessful application for an order or prohibition delayed the Minister from issuing a Notice of Compliance (NOC) to Apotex for its product Apo-

fluconazole, which this Court found did not infringe Pfizer's Canadian Patent 1,181,076 (the '076 Patent).

FACTS

The '076 Patent

[2] Pfizer's '076 Patent was issued on January 15, 1985 and expired on January 15, 2002. It claimed the drug fluconazole (sold in Canada as DIFLUCAN®), a novel compound used to treat fungal infections. In 1985, Canadian patent law did not permit product claims. The '076 Patent therefore claimed only the process for preparing fluconazole. If a generic company found a non-infringing process for preparing fluconazole, it could avoid infringing the patent.

Legislative Framework

[3] The *Food and Drug Regulations*, C.R.C. 1978, c. 870, require that any person selling a new drug must first hold a valid NOC issued by the Minister. A drug manufacturer becomes eligible to receive a NOC by filing a new drug submission (NDS) with Health Canada. Generic manufacturers wishing to copy a drug which has already been marketed in Canada may file a specific type of NDS known as an "abbreviated new drug submission" (ANDS). In this procedure, rather than showing through clinical studies that the drug is safe and effective, the generic manufacturer need only show that its drug is equivalent to a previously-approved "reference product."

[4] The Minister's policies also permit cross-referenced submissions where everything about one ANDS is the same as another except for the name of the drug and/or the name of the manufacturer. In this case, another generic manufacturer, Nu-Pharm, had first filed an ANDS using

Pfizer's previously -approved fluconozole drug as a reference product. The plaintiff Apotex then cross-referenced its own submission to the Nu-Pharm submission. Therefore, although Nu-Pharm is not a party to this proceeding, its conduct is relevant to the facts of this case.

NOC Proceedings Relating to the '076 Patent

[5] On March 20, 1992, Nu-Pharm filed an ANDS identifying a particular chemical process, the "acetate process," to fabricate fluconazole in bulk. Nu-Pharm subsequently served an NOA on Pfizer alleging that the acetate process did not infringe the '076 Patent. Pfizer initiated prohibition proceedings on June 4, 1993 (T-1352-93).

[6] On or about August 16, 1994, Nu-Pharm served an NOA on Pfizer for another process to manufacture fluconazole known as the "cyclic sulphate process." In response, Pfizer initiated prohibition proceedings (T-1299-95). Nu-Pharm did not amend its ANDS or file a new ANDS relating to the cyclic sulphate process.

[7] On September 12, 1994, the plaintiff Apotex submitted an ANDS to the Minister for Apo-Fluconazole tablets, cross-referencing Nu-Pharm's ANDS. At this time, Nu-Pharm's ANDS did not include the cyclic sulphate process and only contained information related to the acetate process.

[8] On May 1, 1995, Nu-Pharm served another NOA on Pfizer alleging that its tablets would be made using a third process, the "olefin process."

[9] On June 28, 1995, Apotex served an NOA on Pfizer, alleging that its tablets would not infringe the ‘076 patent on the basis that they would be manufactured using the olefin process.

[10] On August 10, 1995, Pfizer commenced prohibition proceedings in response to Nu-Pharm’s third NOA claiming the olefin process (T-1713-95) as well as Apotex’s NOA claiming the olefin process (T-1714-95). At this time, Nu-Pharm had not amended its ANDS to include the olefin process.

[11] On June 27, 1996, Nu-Pharm sent a letter to the Minister containing process maps of alternative manufacturing processes for the drug including the olefin process. No additional correspondence relating to processes for the manufacturing of the drug was sent to the Minister by either Nu-Pharm or Apotex. The Minister did not review the letter.

Decisions of the Federal Court Relating to the ‘076 Patent

[12] As described below, this Court found that the acetate process and the cyclic sulphate process infringed Pfizer’s ‘076 Patent, but that the olefin process did not infringe the ‘076 Patent.

[13] On August 18, 1997, this Court issued prohibition Orders in court files T-1352-93 (the Nu-Pharm proceeding relating to the acetate process), T-1299-95 (the Nu-Pharm proceeding relating to the cyclic sulphate process) and T-2389-94 (the Apotex proceeding relating to the cyclic sulphate process). Mr. Justice Richard, as he then was, found that the allegations that the acetate and cyclic sulphate processes would not infringe the ‘076 patent were unjustified: *Pfizer Canada Inc. v.*

Apotex Inc., (1997) 77 C.P.R. (3d) 547, 73 A.C.W.S. (3d) 665. (These three court files were heard together and the reasons for the decision applied to all three: see *Pfizer v. Apotex*, (1997) 77 C.P.R. (3d) 547, at paras. 10-12).

[14] On January 30, 1998, the application in T-1714-95 (the Apotex proceeding based on the olefin process) was dismissed by Madam Justice Reed: *Pfizer Canada Inc. v. Apotex Inc.*, (1998) 142 F.T.R. 1, 78 C.P.R. (3d) 3. <u>According to Apotex, Pfizer is liable from the commencement of the prohibition proceeding on August 10, 1995 up to this date, January 30, 1998</u>.

[15] At this time, neither Nu-Pharm nor Apotex had amended its ANDS to include the olefin process. The Minister did not issue an NOC to Apotex following the dismissal of file T-1714-95, on the basis that no information about the non-infringing process was included in Nu-Pharm's, and therefore Apotex's, ANDS.

[16] On March 16, 1998, Apotex commenced an application in this Court (T-429-98) seeking to compel the Minister to issue an NOC to Apotex for Apo-fluconazole. Neither Pfizer nor Nu-Pharm was a party to these proceedings. Apotex argued that Nu-Pharm's June 27, 1996 letter had constituted the filing of the olefin process by Nu-Pharm in its ANDS and that, as Apotex's ANDS cross-referenced Nu-Pharm's, it did not need to take additional steps to include the olefin process in its ANDS. The Minister took the position that any change in the process needed to be made through a "Supplemental New Drug Submission" or a "Notifiable Change" as provided in the "Changes to

Marketed New Drugs Policy" Guidance Document published by Health Canada, which was in effect as of April 4, 1994.

[17] In June 1998, Apotex, Nu-Pharm and the Minister entered into an agreement whereby Nu-Pharm and Apotex would submit a notifiable change and supporting documentation and the Minister would then issue an NOC. The mandamus application against the Minister was discontinued.

[18] Nu-Pharm filed a Notifiable Change Submission with the Minister of June 29, 1998. This submission was found to be deficient by the Minister and a screening deficiency notice was issued. The additional information was sent to the Minister by Nu-Pharm and was approved on October 9, 1998.

[19] Apotex's Notifiable Change Submission was received by the Minister on October 9, 1998 and its ANDS was approved on the same day based on its cross-reference to the Nu-Pharm ANDS.

ISSUE

[20] The issue in this proceeding is whether Apotex's Statement of Claim fails to disclose a genuine issue for trial so that summary judgment should be granted; in particular, whether Pfizer's application for an order of prohibition caused any of the damages allegedly suffered by Apotex, such that Pfizer is liable under s. 8 of the *NOC Regulations.* Apotex submits that it would have received a NOC for the olefin process much earlier "in the absence of the *NOC Regulations*", i.e. if

Pfizer had not commenced prohibition proceedings against Apotex on August 10, 1995 with respect to the olefin process.

RELEVANT LEGISLATION

[21] The parties agree that section 8 in the *NOC Regulations*, as amended by SOR/98-166 applies. It provides:

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 compensate the second person for the loss referred to in subsection (1).

(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) 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).

ANALYSIS

The test for Summary Judgment

[22] Rule 216(1) of the *Federal Court Rules* provides that summary judgment should be granted where there is no genuine issue for trial.

Where no genuine issue for trial	Absence de véritable question litigieuse
216. (1) Where on a motion for summary judgment the Court is satisfied that there is no genuine issue for trial with respect to a claim or defence, the Court shall grant summary judgment accordingly.	**216.** (1) Lorsque, par suite d'une requête en jugement sommaire, la Cour est convaincue qu'il n'existe pas de véritable question litigieuse quant à une déclaration ou à une défense, elle rend un jugement sommaire en conséquence.

[23] Rule 216(2) provides that the Court may grant summary judgment where the only genuine issue is a question of law:

Genuine issue of amount or question of law	Somme d'argent ou point de droit
(2) Where on a motion for summary judgment the Court is satisfied that the only genuine issue is	(2) Lorsque, par suite d'une requête en jugement sommaire, la Cour est convaincue que la seule véritable question litigieuse est
…	…
(*b*) a question of law, the Court may determine the question and grant summary judgment accordingly.	*b*) un point de droit, elle peut statuer sur celui-ci et rendre un jugement sommaire en conséquence.

[24] Subsection (3) of Rule 216 provides that the Court may grant summary judgment in certain circumstances where a genuine issue exists :

Summary judgment	Jugement de la Cour
(3) Where on a motion for summary judgment the Court decides that there is a genuine issue with respect to a claim or defence, the Court may nevertheless grant summary judgment in favour of any party, either on an issue or generally, if the Court is able on the whole of the evidence to find the facts necessary to decide the questions of fact and law.	(3) Lorsque, par suite d'une requête en jugement sommaire, la Cour conclut qu'il existe une véritable question litigieuse à l'égard d'une déclaration ou d'une défense, elle peut néanmoins rendre un jugement sommaire en faveur d'une partie, soit sur une question particulière, soit de façon générale, si elle parvient à partir de l'ensemble de la preuve à dégager les faits nécessaires pour trancher les questions de fait et de droit.

[25] In *Rachelex Holdings Inc. v. W & M Wire and Metal Products Ltd.*, 2007 FC 502, 15 A.C.W.S. (3d) 629, I set out the test for summary judgment at para. 8 (citing my decision in *Spenco Medical Corp. v. Emu Polishes Inc.*, 2004 FC 963 at paras. 6-8):

> ...The Court is not to grant summary judgment where it is shown that there is a genuine issue for trial. However, Rule 216(3) specifically permits this Court to grant summary judgment even where there is a genuine issue for trial so long as the Court "is able on the whole of the evidence to find the facts necessary to decide the questions of fact and law" …

[26] In *Granville Shipping Co. v. Pegasus Lines Ltd. S.A.*, [1996] 2 F.C. 853 (F.C.T.D.), Madam Justice Tremblay-Lamer set out the general principles applicable to a motion for summary judgment at paragraph 8:

> ¶8 I have considered all of the case law pertaining to summary judgment and I summarize the general principles accordingly:
> 1. the purpose of the provisions is to allow the Court to summarily dispense with cases which ought not proceed to trial because there is no genuine issue to be tried (Old Fish Market Restaurants Ltd. v. 1000357 Ontario Inc. et al., [1994] F.C.J. No. 1631, 58 C.P.R. (3d) 221 (T.D.));
> 2. there is no determinative test [...] but Stone J.A. seems to have adopted the reasons of Henry J. in Pizza Pizza Ltd. v. Gillespie [(1990), 75 O.R. (2d) 225 (Gen. Div.)]. It is not whether a party cannot possibly succeed at trial, it is whether the case is so doubtful that it does not deserve consideration by the trier of fact at a future trial;
> 3. each case should be interpreted in reference to its own contextual framework [...];
> 4. provincial practice rules (especially Rule 20 of the Ontario Rules of Civil Procedure, [R.R.O. 1990, Reg. 194]) can aid in interpretation [...];
> 5. this Court may determine questions of fact and law on the motion for summary judgment if this can be done on the material before the Court [...];
> 6. on the whole of the evidence, summary judgment cannot be granted if the necessary facts cannot be found or if it would be unjust to do so [...] ;
> 7. in the case of a serious issue with respect to credibility, the case should go to trial because the parties should be cross-examined before the trial judge [...] The mere existence of apparent conflict in the evidence does not preclude summary judgment; the court should take a "hard look" at the merits and decide if there are issues of credibility to be resolved.

[27] The Federal Court of Appeal affirmed this test in *ITV Technologies Inc. v. WIC Television Ltd.*, 2001 FCA 11, [2001] F.C.J. No. 400 (F.C.A.), and quoted it with approval in *MacNeil Estate v. Canada (Indian and Northern Affairs Department)*, 2004 FCA 50, 316 N.R. 349, wherein the Court provided the guidelines specifically with respect to the application of Rule 216(3) at paras. 32-29. I summarized these guidelines in *Rachelex Holdings*, supra, at para. 8 as follows:

> 1. where an issue of credibility arises from evidence presented, the case should not be decided on summary judgment under rule 216(3)

> but rather should go to trial because the parties should be cross-examined before the trial judge (see paragraph 32 of *MacNeil Estate*);
> 2. under rule 216(3), motions judges can only make findings of fact or law provided the relevant evidence is available on the record and does not involve a "serious" question of fact or law which turns on the drawing of inferences (see paragraph 33 of *MacNeil Estate*);
> 3. Rule 216(3) permits a judge on a motion for summary judgment**,** after finding that a "genuine issue" exists, to conduct a trial on the affidavit evidence with a view to determining the issues in the action. However, this is not always possible, particularly where there are conflicts in the evidence, where the case turns on the drawing of inferences or where serious issues of credibility are raised (see paragraph 46 of *MacNeil Estate*);
> 4. Parties responding to a motion for summary judgment do not have the burden of proving all of the facts in their case; rather ... responding parties have only an evidentiary burden to put forward evidence showing that there is a genuine issue for trial ... (see paragraph 25 of *MacNeil Estate*).

[28] Apotex submits that matters relating to s. 8 of the *NOC Regulations* have not been granted summary judgment in the past because s. 8 is a complex regulatory scheme involving legal issues not suitable for resolution on a summary basis. Apotex relies on several cases referred to below.

[29] These cases involved the construction of s. 8 to answer questions of law raised by the parties. In the present case, as I discuss below, Apotex submits that this motion raises serious issues of law requiring statutory interpretation. Although Rule 216(2) of the *Federal Court Rules, supra,* provides that the court may grant summary judgment where the only genuine issue is a question of law, I agree that where there are difficult legal questions requiring the legal construction of a complex statutory framework, summary judgment is not appropriate. I will deal with this issue in

greater detail in addressing Apotex's submissions in relation to the issues of law raised by this motion below.

Is there a genuine issue for trial?

[30] Pfizer submits that it did not cause any damages to Apotex. According to Pfizer, a NOC could not be issued to Apotex until it amended its ANDS (i.e., until Nu-Pharm amended its ANDS, and Apotex's cross-referenced ANDS) to include the only non-infringing process, the olefin process. The NOC was issued after Apotex filed its Notifiable Change Submission adding the olefin process to its ANDS. Pfizer's submission, therefore, is that it is not responsible for any portion of the delay between Apotex's ANDS filing and the issuance of the NOC almost four years later.

[31] Pfizer argues that Apotex cannot establish any causal relationship between the damages it alleges and the NOC proceedings in T-1714-95 (the proceeding relating to the olefin process). Pfizer submits that where a plaintiff cannot establish a causal relationship between the damages it alleges and the conduct of the defendant, summary judgment is appropriate.

[32] Apotex submits that this motion should be denied for a number of reasons including:

1. Apotex submits it would have received the NOC on June 27, 1996, or at least well before January 30, 1998

[33] The earliest possible date that the olefin process, the *only* non-infringing process claimed by Apotex, can possibly be found to have been included in Apotex's ANDS is June 27, 1996, when

Nu-Pharm sent a letter to the Minister containing information about the olefin process. According to Apotex, this letter constituted inclusion of the olefin process in Nu-Pharm's (and consequently, its own) ANDS. However, the undisputed evidence is that the Minister did not consider this letter to have amended Nu-Pharm's ANDS to include the olefin process. This conduct of the Minister is unrelated to any action by Pfizer.

[34] Apotex submits that in the absence of the *NOC Regulations*, if the Minister had required a notifiable change, there is evidence that the dispute between Apotex and the Minister would have taken place starting in July 1996, rather than after January 30, 1998 when the Federal Court dismissed the Pfizer application for prohibition with respect to the olefin process. Apotex submits that in this scenario, given that the dispute with the Minister took nine months to resolve, Apotex would have been issued an NOC nine months later. Dr. Bernard Sherman, the Chairman and CEO of Apotex, testified that the dispute with the Minister would have been resolved earlier had it not been for Pfizer's application (Transcript of the cross-examination of Bernard Sherman, Exhibit DP-1, Affidavit of Denise Pope, Tab 17-A, Q. 128 at p. 510) :

> … if Pfizer had not brought the prohibition application, then the Notice of Compliance would have issued years earlier and/or the delay occasioned by the Minister would have occurred much earlier and been over much earlier. I think that even the delay caused by the Minister might be attributable to Pfizer, in that had Pfizer not brought the prohibition application, none of this would have happened and the Notice of Compliance would have been issued years earlier.

2. <u>Apotex submits that there are issues of credibility warranting a trial</u>

[35] Apotex submits that the evidence supporting its position (namely that the Minister would not have required a Notifiable Change Submission or, in the alternative, that the dispute with the Minister would have been resolved earlier), demonstrates serious factual questions as to what would have occurred in the absence of the *Regulations.* Apotex submits that, at a minimum, the evidence in its favour raises issues of credibility sufficient to defeat a motion of summary judgment.

[36] The Court accepts that there is a genuine issue for trial with respect to whether a Notice of Compliance would have been issued in the absence of these Regulations at an earlier date. The statutory obligation of the Court under paragraph 8(1)(a) of the *NOC Regulations* is to review the evidence and determine if the Court is satisfied that the NOC would have issued on an earlier date but for the commencement of the prohibition application by Pfizer against Apotex with respect to the olefin process. This evidence must be weighed by the Court, including an assessment of its credibility.

3. Apotex submits that the proper interpretation of section 8 of the *NOC Regulations* and the facts warrant a trial

[37] In *Apotex Inc. v. Merck & Co.,* 2008 FC 1185, 335 F.T.R. 225, Justice Hughes stated at para. 86:

> ¶ 86 The object of the *PM(NOC) Regulations* …is to create a kind of "balance" between the rights of patentees and access by the Canadian public to affordable drugs…A person having certain kinds of patents relating to medicines is given a right to delay and possibly preclude a generic from getting rather easy access to the market by copying and referencing a patentee's innovations and testing, the generic is given a right, section 8, to compensation if the delay is unwarranted.

[38] Apotex has raised issues relating to the construction of s. 8, namely the meaning of the phrase "in the absence of these *Regulations.*" In particular, Apotex argues that Pfizer is liable under s. 8 if the Minister would have hypothetically issued the NOC earlier "but for" the prohibition proceeding.

[39] Apotex submits that matters relating to s. 8 of the *NOC Regulations* have not been granted summary judgment in the past because s. 8 is a complex regulatory scheme involving legal issues not suitable for resolution on a summary basis. Pfizer confirms that this Court has never granted summary judgment on a damage claim pursuant to section 8 of the *NOC Regulations.* Apotex points to *Apotex Inc. v. Eli Lilly and Co*, 2004 FCA 358, 36 C.P.R. (4th) 111, wherein the Federal Court of Appeal found that whether a "first person" within the meaning of section 8 can include a parent corporation directing an action in the name of its subsidiary was a legal question requiring a trial, per Evans J.A. at paras. 13-16; *Apotex v. Merck & Co.*, 2004 FC 314, 248 F.T.R. 82, wherein Snider J. considered the interpretation of s. 8, and in particular whether a party can bring a claim for unjust enrichment under s. 8, stating at para. 17 that "on no less than 11 occasions, this Court and the Federal Court of Appeal have concluded that issues of interpretation of s. 8 should proceed to trial" and at para. 20 that s. 8 is a "complex regulatory regime"; *Apotex Inc. v. Canada,* 2003 FCT 414, 25 CPR (4th) 479, wherein Russell J. considered the availability of "first person profits" in a s. 8 claim, stating at para. 28 that such "complex and far-reaching issues require a more thoroughgoing contextual explanation of the meaning and purposes of section 8 than was placed before me on this motion and are the proper domain of the trial judge"; .*Apotex Inc. v. Syntex Pharmaceuticals International Ltd.,* 2004 FC 38,129 A.C.W.S. (3d) 1200, wherein Hugessen J. cited the decisions of

Russell J. in *Apotex v. Canada*, supra, and Snider J. in *Apotex v. Merck*, supra, declining to grant summary judgment and stating at para. 1 that "it would take strong reasons to justify" departing from their exercise of discretion in declining to grant summary judgment where issues of law are raised; and *Apotex Inc. v. Merck & Co.* (2005) 44 C.P.R. (4th) 423, per Gauthier J. at paras. 21-28.

[40] These cases involved the construction of s. 8 to answer questions of law raised by the parties. In the present case, Apotex submits that the dispute between the parties raises a question of law as to the meaning of the phrase "in the absence of the *Regulations*" in s. 8. Specifically, Apotex makes the following submissions:

> *i.* whether a consideration of what would have transpired in "the absence of [the] *Regulations*" permits the Court to consider the outcome of *any* proceedings, including successful proceedings, under the *NOC Regulations*, i.e. whether the Court can consider the impact of the prohibition proceedings relating to the acetate and olefin cases in determining causes for delay; and
>
> *ii.* whether the Court can find that the Minister would have engaged in "conduct that is unlawful" i.e. whether Pfizer must establish that the Minister would have imposed the same requirements if Pfizer had not commenced prohibition proceedings.

[41] The Court finds that the dispute between Pfizer and Apotex is based on two differing interpretations of section 8 of the *NOC Regulations*. Pfizer submits that the delay was not caused by Pfizer's prohibition proceedings relating to the olefin process. This is shown by the fact that even when the prohibition application was dismissed by the Federal Court on January 30, 1998, the Minister found that Apotex had not provided the Minister with the required information for the Minister to grant the NOC. This was finally resolved after Apotex filed a Notifiable Change submission and provided further information in response to a "screening deficiency notice". As a

result, the Minister issued the NOC to Apotex on October 9, 1998, more than nine months after the Federal Court dismissed the prohibition application by Pfizer against Apotex.

[42] Apotex submits that the proper interpretation of section 8 is that "in the absence of the Regulations", Pfizer would not have filed the prohibition application, and the Minister of Health would have hypothetically issued the NOC to Apotex much sooner, and sometime after the June 27, 1996 date when Nupharm provided Health Canada with information regarding the olefin process. Moreover, Apotex submits that the Minister would not have been so stringent in the Minister's requirements from Apotex if the prohibition proceeding had not been commenced by Pfizer.

[43] There is strong support in the case-law for the proposition that, where a question of law in relation to s. 8 is raised in relation to the facts, summary judgment is not appropriate. On this basis, I find that summary judgment is not appropriate in this case.

[44] For these reasons, the Court finds that this motion for summary judgment by the Pfizer defendants must be dismissed.

ORDER

THIS COURT ORDERS that:

This motion by the Pfizer defendants for summary judgment is dismissed with costs in the cause.

"Michael A. Kelen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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