

Date: 20080318

Docket: T-2102-07

Citation: 2008 FC 359

Ottawa, Ontario, March 18, 2008

PRESENT: The Honourable Mr. Justice Beaudry

BETWEEN:

**SCHERING-PLOUGH CANADA INC.
and SCHERING CORPORATION**

Applicants

and

**PHARMASCIENCE INC., SEPRACOR INC.,
and THE MINISTER OF HEALTH**

Respondents

REASONS FOR ORDER AND ORDER

[1] This is an application brought by respondent, Pharmascience Inc. (Pharmascience) to strike, set aside or reject the notice of appearance filed by respondent Sepracor Inc. (Sepracor) pursuant to Rule 305 of the *Federal Courts Rules*, SOR/98-106 (the Rules).

BACKGROUND

[2] Pharmascience brings a motion to strike, set aside or reject the notice of appearance, because it was not made in accordance with Form 305; Sepracor replaced with the word “oppose”, which is prescribed by the Form, with “participate”.

[3] Sepracor is the owner of Canadian Patent No. 2,276,136, one of two patents whose validity is at issue. As such, Sepracor wishes to support the position of the applicant, Schering-Plough Canada Inc. (Schering-Plough), who is the “first person” as defined by the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (PM(NOC) Regulations).

<p>2. “first person” means the person referred to in subsection 4(1);</p> <p>4. (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.</p>	<p>2. «première personne» La personne visée au paragraphe 4(1).</p> <p>4. (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.</p>
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[4] The first person may apply to the Court for an order prohibiting the Minister from issuing an NOC, pursuant to subsection 6(1) of the PM(NOC) Regulations. The first person therefore has the ability to commence an application. The owner of a patent, if different from the first person, is required by subsection 6(4) of the PM(NOC) Regulations to be made a party to the application. However, paragraph 303(1)(b) of the Rules provides that every person required to be named as a party under an Act of Parliament pursuant to which the application is brought, must be named as a respondent. As such, Sepracor is named as a respondent. Subsections 6(1) and 6(4) of the PM(NOC) Regulations and paragraph 303(1)(b) of the Rules provide the following:

6. (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(a), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.

(4) Where the first person is not the owner of each patent that is the subject of an application referred to in subsection (1), the owner of each such patent shall be made a party to the application.

303. (1) Subject to subsection (2), an applicant shall name as a respondent every person

(a) directly affected by the order sought in the application, other than a tribunal in respect of which the application is brought; or

(b) required to be named as a party under an Act of Parliament pursuant to which the application is brought.

6. (1) La première personne peut, au plus tard quarante-cinq jours après avoir reçu signification d'un avis d'allégation aux termes de l'alinéa 5(3)a), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer l'avis de conformité avant l'expiration du brevet en cause.

(4) Lorsque la première personne n'est pas le propriétaire de chaque brevet visé dans la demande mentionnée au paragraphe (1), le propriétaire de chaque brevet est une partie à la demande.

303. (1) Sous réserve du paragraphe (2), le demandeur désigne à titre de défendeur :

a) toute personne directement touchée par l'ordonnance recherchée, autre que l'office fédéral visé par la demande;

b) toute autre personne qui doit être désignée à titre de partie aux termes de la loi fédérale ou de ses textes d'application qui prévoient ou autorisent la présentation de la demande.

ISSUES

[5] The issues on this motion are as follows:

- a) Is there a conflict between subsection 6(4) of the PM(NOC) Regulations and the Rules, such that the PM(NOC) Regulations should prevail, or was Sepracor properly named as a respondent?
- b) Can a respondent party file a notice of appearance if it does not intend to oppose the application?

PHARMASCIENCE ARGUMENTS

[6] Pharmascience submits that, pursuant to Rule 305, a notice of appearance may only be filed by a respondent who intends to oppose an application. Pharmascience submits that the notice of appearance filed by Sepracor is not in compliance with Rule 305 and Form 305, as it has been interpreted by the Federal Court of Appeal in *Canadian Tire Corp. v. Canadian Bicycle Manufacturers Assn.*, [2005] F.C.J. No. 2023, 2005 FCA 408.

[7] In *Canadian Tire*, above, the Federal Court of Appeal found that a notice of appearance that stated an intent to “support the Application” was not acceptable, as it did not comply with either the language or intent of Rule 305:

[8] The domestic producers say that rule 305 means that only a respondent who intends to oppose the application may serve and file a notice of appearance. Since the notice of appearance served and filed by the importers states that they “support the Application”, it does not comply with rule 305 and the Court should reject it.

[9] In support of this interpretation of rule 305, the domestic producers rely on a decision of Stone J.A. in *Society of Composers, Authors and Music Publishers of Canada v. Canadian Assn. of Internet Providers*, [2001] F.C.J. No. 166, 2001 FCA 4 (“SOCAN”), in which he struck the records of two parties who were not opposing an application, but advancing supportive arguments. He said (at para. 11)

As I see it, Rule 305 was intended to play a pivotal role in the overall scheme and operation of the Part 5 rules. That Rule requires a named respondent to signify by way of a notice of appearance an intention "to oppose an application". This step allows the parties and the Court to know at an early stage which of the named respondents will truly oppose the section 28 application. The service and filing of the notice of appearance ensure that any respondent truly opposed to the application will be served with all further documents in the proceeding and so enable effective participation. As I have already stated, if no notice of appearance is filed, Rule 145(a) disentitles a named respondent from being served with any further documents in the section 28 proceeding. [Emphasis in original]

[10] The importers make two responses. First, they say that SOCAN is distinguishable. They argue that the respondents in SOCAN were interveners before the Copyright Board, the administrative tribunal under review. Further, the respondents in that case had filed notices of appearance which indicated that they intended to oppose the application for judicial review, but then filed an application record in support of the application for judicial review.

[11] I do not agree. These differences are not material to the rationale provided by Stone J.A. for interpreting rule 305 to permit respondents to file a notice of appearance only if they intend to oppose an application for judicial review. The purpose of rule 305 is to enable the parties and the Court to know at an early stage of the proceeding which respondents intend to oppose an application, and thus to limit the serving and filing of application records accordingly.

[13] The second argument advanced on behalf of the importers is that, if not permitted to file a notice of appearance, they will be denied their right to procedural fairness, since they will have no opportunity to defend their interests, which would be adversely affected if the application were dismissed. This is because, unless they have entered a notice of appearance, they will have no right to notice of any further steps or documents in the proceeding: rule 145. They say that their perspective is different from that of the applicant, Canadian Tire, and that they may have different arguments to make in support of the application.

[14] I do not accept this argument. If the importers are concerned about ensuring that their interests are fully canvassed, they may seek intervener status in Canadian Tire's application pursuant to rule 109. Alternatively, they could have applied to be joined as applicants.

SEPRACOR ARGUMENTS

[8] Sepracor raises several issues in response, and submits that *Canadian Tire*, above, is not applicable to a case brought pursuant to the PM(NOC) Regulations.

[9] Sepracor argues that subsection 6(4) of the PM(NOC) Regulations requires that the patentee be added as a party to the underlying application. However, it contends that the Regulations contain no requirement that the patentee be added as either an applicant or a respondent, and as such it is open to the applicant to name the patentee as a respondent.

[10] Sepracor cites two recent cases decided by Justice Hughes that support this principle: *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2007] F.C.J. No. 237, 2007 FC 167, and *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2007] F.C.J. No. 239, 2007 FC 169, for which a single decision was rendered (hereinafter jointly referred to as *Pfizer Canada*). At paragraph 15, Justice Hughes stated:

[15] It is not fatal to an application that the owner of the patent who is not a "first person" was not a party initially provided that the owner is joined as a party at an appropriate subsequent time. The purpose in joining the owner is clear, the owner should be before the Court when its patent is under consideration. If the owner will not join as an Applicant it can be joined as a Respondent.

[11] Sepracor advances that it is clear that a respondent/patentee in a proceeding under the PM(NOC) Regulations will not be opposing an application which seeks to defend the validity of its patent, and that the notice of appearance must therefore be modified to accommodate this unique situation. It also argues that if a patentee was not able to be named as a respondent unless it intended to oppose an application, then subsection 6(4) of the PM(NOC) Regulations, would be meaningless.

[12] Sepracor submits that there is clearly a conflict between subsection 6(4) of the PM(NOC) Regulations, which does not specify how the patentee must be named when added as a party, and paragraph 303(1)(b) of the Rules, which requires that every person required to be named as a party by an act of Parliament under which the application is brought, must be named as a respondent.

[13] Sepracor relies on paragraph 14 of *Pfizer Canada*, above, in support of the position that the PM(NOC) Regulations prevail in case of a conflict with the Rules:

[14] I do not view the matter in the same way as the generics Pharmascience and Cobalt do. Section 6(1) is the mandatory provision, a "first party" must commence an application directed to the Minister within 45 days of receipt of a notice of allegation. That is mandatory. Once the application is commenced the matter falls to be determined, as to procedure, under the *Federal Courts Rules* unless there is a conflict with the *NOC Regulations*, in which case the *Regulations* prevail. [...]

[14] Finally, Sepracor is of the view that a modified notice of application meets the concerns of the Court in *Canadian Tire*, and *SOCAN*, cited above, and therefore, the notice of appearance in this case allows the parties to know at an early stage which parties will truly oppose the application.

PHARMASCIENCE REPLY

[15] In its reply, Pharmascience pleads that there is no conflict between the PM(NOC) Regulations and the Rules, as alleged by Sepracor, and as such the assertion that *Canadian Tire* does not find application in the case at bar is without merit. Pharmascience cites Professor Ruth Sullivan in Sullivan and Driedger on the Construction of Statutes (4th ed., Butterworths, 2002), at pp. 264:

Overlapping provisions are presumed to apply. When two provisions are applicable without conflict to the same facts, it is presumed that each is meant to operate fully according to its terms. So long as overlapping provisions *can* apply, it is presumed that they are meant to apply...

[16] Pharmascience contends that subsection 6(4) of the PM(NOC) Regulations and Rule 303 can coexist; the Rules complement the PM(NOC) Regulations rather than conflict with them.

ANALYSIS

Sepracor is a properly named respondent

[17] Before determining the fundamental issue of this motion, I must determine whether a conflict exists between the PM(NOC) Regulations and the Rules.

[18] At the hearing, it was brought to my attention that *Pfizer Canada*, above, was appealed to the Federal Court of Appeal (*Pfizer Canada Inc. v. Canada (Minister of Health)*, [2008] F.C.J. No. 54, 2008 FCA 15 (F.C.A.)). The appeal was dismissed. The judgment of the Court was delivered orally. Paragraphs 7 and 8 state:

[7] Subsection 6(4) of the *NOC Regulations* while mandatory does not give any time limit for the patentee to be added as a party. The motions judge was correct in supplementing the provision with the assistance of the *Federal Courts Rules*.

[8] In *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2007] F.C.J. No. 267, 2007 FC 205; aff'd [2007] F.C.J. No. 923, 2007 FCA 244, the Federal Court (Phelan J.) explained at paras. 17, 18 and 19 that the *Federal Courts Rules* apply to proceedings initiated under the *Regulations* to the extent that the Rules do not conflict with the *Regulations* themselves. He wrote:

[17] The *Regulations* are not a complete code. There are numerous aspects of NOC proceedings which are governed either by the *Federal Courts Act* or its *Rules*. The *Regulations* enjoy supremacy only in respect of matters which conflict with the more general provisions found in the *Act* or the *Rules*.

[18] The fundamental requirement under the *Regulations* is that an application to the Court must be commenced within 45 days of the notice of allegation. The Court has no jurisdiction to extend the 45 days because the general rule on extensions would be in direct conflict with Regulation s. 6(1). (*Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1997), 72 C.P.R. (3d) 453 (F.C.T.D.))

[19] However, once the matter is commenced within the statutory time limits, the *Federal Courts Rules*, SOR/98-106, apply except where there is a conflict. The *Act* and *Rules* apply to a number of matters not specifically addressed in the *Regulations* including the right to appeal. (*Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 51 C.P.R. (3d) 329 (F.C.A.) at 336).

[19] It is my opinion that no conflict exists between subsection 6(4) of the PM(NOC)

Regulations and paragraph 303(1)(b) of the Rules. I agree with Pharmascience's submission that the

provisions must be construed to be overlapping provisions. When read as an overlapping paragraph, 303(1)(b) of the Rules merely brings an additional requirements to subsection 6(4) of the PM(NOC) Regulations, that is that the patentee must be named as a respondent.

[20] Having determined that Sepracor was properly named as a respondent, the fundamental question raised by this motion must now be addressed.

A named respondent cannot file a modified notice of appearance in order to present arguments supporting the applicants' position

[21] The real issue before the Court is not whether the notice of appearance should be struck, set aside or rejected because of a technical defect to Form 305, but rather whether Sepracor may make representations in support of the applicant, Schering-Plough, by virtue of the fact that it modified the notice of appearance to reflect its real interest. It is my opinion that Sepracor may not.

[22] I agree with Pharmascience's contention that *Canadian Tire*, above, finds application in the case at bar; following the decision of the Federal Court of Appeal, Sepracor may not file and serve a modified notice of appearance in order to make submissions that further the position of the applicant, Schering-Plough. Only a respondent who intends to oppose the application may file and serve a notice of appearance.

[23] At the hearing, Secpracor cited *Aventis Pharma Inc. v. Apotex Inc.*, [2004] F.C.J. No. 688, 2004 FC 570, in support of its submission that a respondent may present arguments in support of the applicant's position. Justice Gauthier wrote at paragraph 19:

[19] It is clear from the decisions of McGillis J. in *Apotex Inc. v. Canada (Minister of Health)*, (2000) 4 C.P.R. (4th) 421 and Blanchard J. in *Nu-Pharm Inc. v. Canada (Attorney General)*, (2001) 14 C.P.R. (4th) 280 (affirmed at (2002) 17 C.P.R. (4th) 288) that under the *Federal Court Rules*, 1998, there is no provision permitting the Court to limit the rights of a person who is a proper and necessary party to a proceeding. Thus, the respondent/patentee should be entitled to participate fully in the proceeding and [sic] this includes the fundamental right to present its evidence.

[24] I am not persuaded that *Aventis Pharma*, above, is determinative of the present issue. The aforementioned order was rendered in the context of a motion to strike evidence. The motion before the Court in the present case is a motion to strike, set aside or reject a notice of appearance under Rule 305, a situation which was squarely dealt with in *Canadian Tire*, above. *Canadian Tire* applies precisely to the facts of the present application, and post-dates the decision cited by Sepracor.

[25] Sepracor argued at the hearing that Pharmascience's concerns could be dealt with by adopting a schedule following which evidence would be submitted. Had Pharmascience consented to the implementation of a schedule, this argument might be persuasive. However, the use of a schedule is not provided for by the *Rules* and as such cannot be imposed on a party who does not consent to its use.

[26] For the foregoing reasons, it is my opinion that the notice of appearance must be rejected. If Sepracor wishes to make representations that support the application, it may seek intervener status pursuant to Rule 109, or apply to be joined as an applicant pursuant to Rule 104.

ORDER

THIS COURT ORDERS that the notice of appearance filed on behalf of Sepracor be struck from the Court's Record. Costs in the cause.

"Michel Beaudry"

Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: T-2102-07

STYLE OF CAUSE: **SCHERING-PLOUGH CANADA INC. and
SCHERING CORPORATION
AND PHARMASCIENCE INC.,
SEPRACOR INC. and THE MINISTER OF HEALTH**

PLACE OF HEARING: Ottawa, Ontario

DATE OF HEARING: February 26, 2008

**REASONS FOR ORDER
AND ORDER:** Beaudry J.

DATED: March 18, 2008

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