Date: 20070214

Dockets: T-899-06

Citation: 2007 FC 167

Toronto, Ontario, February 14, 2007

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

PFIZER CANADA INC. and PFIZER INC.

Applicants

and

THE MINISTER OF HEALTH and PHARMASCIENCE INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] The Applicants Pfizer Canada Inc. and Pfizer Inc. have brought a motion to add Pfizer Limited as a party to these proceedings. The Respondent, Pharmascience Inc. opposes this motion, and has itself brought a motion to strike these proceedings in respect of one of the patents at issue, the '393 patent, on the basis that Pfizer Limited was not included as one of the Applicants when these proceedings were initiated. The Respondent, Minister of Health takes no position with respect to either motion.

[2] In another proceeding taken by the same Applicants against the Minister and a different Respondent, Cobalt Pharmaceuticals Inc. T-768-06, a similar motion was brought by the Applicants to add Pfizer Limited as a party to these proceeding and a similar motion was brought by Cobalt to strike those proceedings as against the ‘393 patent. Again, the Minister took no position.

[3] For the reasons that follow, I am adding Pfizer Limited as a party Applicant in each proceeding and I am dismissing the motion of each of Pharmascience and Cobalt to dismiss their respective proceedings as to the ‘393 patent.

[4] Both the T-768-06 (Cobalt) and T-899-06 (Pharmascience) proceedings are brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulation* SOR/93-133 as amended (NOC). The presently named Applicants are the same, Pfizer Canada Inc. and Pfizer Inc. In both proceedings the Applicants have put in issue two Canadian Patents, being those numbered 1,321,393 (‘393 patent) and 2,355,493 (‘493 patent). It is common ground that the ‘493 patent was issued and granted to one of the presently named Applicants, Pfizer Inc. and, as for as the record shows, that entity remains as owner. The ‘493 patent is not the subject of the motions presently under consideration.

[5] The record indicates that the ‘393 patent was issued and granted to Pfizer Limited (not Pfizer Inc.) on August 17, 1993. It appears that Pfizer Limited remains as owner (patentee) of that patent. Pfizer Limited has not been named as a party to either the Cobalt or Pharmascience proceedings.

[6] The NOC Regulations are unusual, their history and purpose was discussed recently by the Supreme Court of Canada in *Apotex Inc. v. AstraZeneca Canada Inc.* (2006), 52 C.P.R. (4th) 145, 2006 SCC 49. The general scheme of the NOC Regulations is to create a patent registry with the Department of Health in which innovator drug companies may list patents relevant to their various drug submissions for regulatory approval. A generic drug company who wishes to enter the market before the expiry of such patents must challenge the validity or applicability of the patents by way of a notice of allegation sent to the party listing the patents. This notice will generally trigger an application to this Court seeking to prohibit the Minister from issuing an approval to the generic to market the drug, the issue being whether the allegations of the generic are justified.

[7] The application to this Court is to be made under section 6(1) of the NOC Regulations by a "first person" who is defined in section 2 of those Regulations by reference to section 4(1) of those Regulations as "a person who files, or has filed a submission for, or has been issued a notice of compliance". It can be seen that such a person is not necessarily the patentee. A "patentee" is defined in the *Patent Act* R.S.C. 1985, c. P-4 section 2 as "the person for the time being entitled to the benefit of the patent", the "benefit" is the grant of the patent monopoly as set out in section 42 of the post October 1, 1993 and 1996 versions of the *Act* and section 44 of the pre October 1, 1989 version of that *Act*. In this case, the '393 patent was granted to Pfizer Limited, not currently a party to these proceedings. As far as we know, Pfizer Limited remains the grantee, that is the owner, of that patent.

[8] Section 6(4) of the NOC Regulations provides that where the "first person" is not the "owner of each patent" that is the subject of the proceedings, the owner shall be made a party.

[9] In the two proceedings at issue the owner of the '393 patent, Pfizer Limited, was not a named party in the Notice of Application, however, it seeks to become a party now. The reasons for the omission of Pfizer Limited as a named Applicant is set out in paragraph 15 of the Nicola affidavit sworn June 21, 2006. It was a matter of inadvertence and oversight, she as one of the solicitors acting for the Applicants swears that the instructions were at all times that Pfizer Limited should be a named Applicant. It appears that shortly after the error was noticed, the solicitors for Pharmascience and Cobalt were contracted and asked to consent to the addition of Pfizer Limited as a party Applicant. They refused. It appears from the evidence of the Ms Nicola that a similar error was made in other proceedings respecting the same patent but against other generics. It seems that other generics consented to the addition of Pfizer Limited as a party Applicant. This is irrelevant to the matter now before me, as the matter here is contested.

[10] The provisions of section 6(4) of the NOC Regulations are similar to the provisions of section 55(3) of the *Patent Act* post October 1, 1996, (section 55(3) of the Post October 1, 1993 and pre October 1, 1989 versions) namely, that the patentee shall be or be made a party to any action for infringement of a patent. Infringement proceedings can be brought by the patentee but also by "all persons claiming under the patentee" as provided in section 55(1) as it appears in all versions of the *Patent Act*. The jurisprudence establishes that both exclusive and non-exclusive licensees are "persons claiming under the patentee" and can bring an action for infringement (*Armstrong Cork*

Canada Ltd. v. Domco Industries Ltd., [1982] S.C.R. 907 at 917-920). In an infringement action when the patentee was not named as a party to the action as filed, the action is not a nullity, the patentee can be added at a later time (*American Cyanamid Company v. Novopharm Ltd.*, [1972] FC 739 at 761 and 769 (FCA)).

[11] Proceedings under the NOC Regulations are different in many respects. They are started by a "first person" who is not necessarily the patentee. The "first person" is the person who seeks or has a notice of compliance from the Minister. Section 6(1) of the Regulations provides the proceedings are to be commenced by the first person, no other person is named as a party entitled to bring the application. Section 6(1) states that the purpose of the application is to seek an "order prohibiting the Minister from issuing a notice of compliance until the expiration of a patent that is the subject of the application". Thus the Minister is the appropriate named Respondent in the application. No express provision is made for the addition of the generic, described as the "second person" in the NOC Regulations as a respondent. However, Federal Court Rule 303(1)(a) requires that every person "directly affected" by the order sought shall be a named respondent thus clearly the generic should be a named respondent.

[12] The NOC Regulations, section 6(4), state that a patentee "shall be made a party to the application". Rule 303(1)(b) of this Court states that person who is required to be named as a party under an Act of Parliament pursuant to which the application is brought shall be a named respondent. There is a difference between an Act and a Regulation, however, the Regulation is

clear and nothing in Rule 303(1)(b) prohibits a party whose presence is required by Regulation from being a party.

[13] The generics, here Pharmascience and Cobalt, argue that the effect of the NOC Regulations is that the patentee shall be named as a party from the outset in the Notice of Application or, at the very least, added within the 45 day period stipulated for commencing an application provided for in section 6(1) of the NOC Regulations. They argue that the Regulations require strict compliance, failing which an application is a nullity and the patentee and others claiming under it are left to their remedies in an ordinary infringement action.

[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. Section 6(4) of the Regulations require that a patentee "shall be made party to the application". If the only opportunity for doing so was to be at the outset of the proceeding, then section 6(1) would have provided for the patentee to be named at the that time. The separate provision in section 6(4) indicates that while becoming a party is mandatory for a patentee, the timing is not that of section 6(1) but rather is to be governed by the practice and procedure of the Court in this case Rule 303 requiring joinder of certain parties and Rules 103 and 104 which

provided that a claim shall not be defeated by reason of misjoinder or nonjoinder of a party and the Court may order joinder subject to appropriate directions.

[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.

[16] The Respondent generics, Cobalt and Pharmascience, say that they will be prejudiced by the addition of the patentee since, in their view, the proceedings are a nullity and ought to be struck out. Once struck out, given the timing provided for in the Regulations, these proceedings could not be brought anew. This argument presupposes that the proceedings are a nullity. They are not. The patentee may be joined as a party after the proceedings are begun.

[17] Therefore, I find that in each of these proceedings T-768-06 and T-899-06 Pfizer Limited shall be added as a party Applicant and the style of cause amended accordingly. Pfizer Limited is to be represented by the same solicitors as to the present Applicants and shall not be entitled to adduce any evidence or conduct cross-examinations on its own behalf beyond that already adduced or to be adduced and conducted or to be conducted by the present Applicants. It shall not be entitled to make argument separate from that of the present Applicants. Since the error arose through the inaction or inadvertence of the Applicants' solicitors, I award costs to the Respondent, Pharmascience. The Minister was not represented and shall not be entitled to costs.

ORDER

FOR THE REASONS PROVIDED HEREIN:

THIS COURT ORDERS that:

1. Pfizer Limited shall be added as a party Applicant to each of T-768-06 and T-899-06. It shall be represented by the same solicitors as the other Applicants and shall not adduce evidence or conduct cross-examinations or make argument other than as together with the other Applicants;

2. The style of cause in each proceeding shall be amended accordingly;

3. The Respondent, Pharmascience, is entitled to its costs; and

4. The motion by Pharmascience to dismiss the application in respect of Canadian Patent 1,321,393 is dismissed without costs.

"Roger T. Hughes"
Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-899-06
STYLE OF CAUSE:	Pfizer Canada Inc. et al. v. Pharmascience et al.
PLACE OF HEARING:	Toronto, Ontario
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APPEARANCES:

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SOLICITORS OF RECORD:

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