Date: 20070405

Docket: A-151-06

Citation: 2007 FCA 140

CORAM: **LÉTOURNEAU J.A.**
SEXTON J.A.
EVANS J.A.

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

THE MINISTER OF HEALTH and
ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED

Respondents

Heard at Toronto, Ontario, on February 15, 2007.

Judgment delivered at Ottawa, Ontario, on April 5, 2007.

REASONS FOR JUDGMENT BY: SEXTON J.A.

CONCURRED IN BY: LÉTOURNEAU J.A.
EVANS J.A.

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REASONS FOR JUDGMENT

SEXTON J.A.

[1] This is an appeal from the decision of O'Keefe J. of the Federal Court in *Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 341, in which he applied issue estoppel to preclude Pharmascience Inc. ("Pharmascience") from relying on the allegations in its second notice of allegation ("NOA") respecting Canadian Patent No. 2,261,732 (the "'732 patent") owned by Abbott Laboratories. In O'Keefe J.'s view, Pharmascience could not attempt to litigate additional questions which it failed to raise in previous litigation before Gibson J. between the same parties and with respect to the same patent.

[2] In this appeal, this Court is called upon to determine whether generic drug manufacturers should be permitted to submit multiple NOAs in respect of a patent, each one alleging that the patent is invalid. I have concluded that generics should in most circumstances be precluded by the doctrine of issue estoppel from alleging for a second time that a patent is invalid, unless the basis relied upon for the subsequent allegation could not be determined with reasonable diligence at first instance, or some special overriding circumstance exists to warrant a judge exercising her discretion not to apply issue estoppel on the facts of the particular case.

[3] As the reasons that follow will explain, no such extraordinary circumstances exist in this case and thus O'Keefe J. was correct to apply issue estoppel. Accordingly, I would dismiss this appeal.

BACKGROUND

[4] The respondents in this appeal are Abbott Laboratories and Abbott Laboratories Limited (collectively, "Abbott"). Abbott Laboratories Limited ("Abbott Canada") manufactures and sells the antibiotic clarithromycin in Canada under the brand name BIAXIN in 250 mg and 500 mg strength tablets pursuant to Notices of Compliance ("NOCs") issued to it on May 8, 1992 and August 25, 1994. Although Abbott did not invent the clarithromycin molecule, Abbott Laboratories, the parent company of Abbott Canada, owns several patents relating to crystalline forms of clarithromycin, methods or processes for their manufacture, and their uses as an antibiotic.

[5] Pharmascience seeks to market a generic version of BIAXIN in Canada. It therefore attempted to obtain regulatory approval for its product by filing an Abbreviated New Drug Submission which makes reference to Abbott's previously approved product, BIAXIN. Pharmascience has also sent three NOAs to Abbott in respect of the patents listed on the patent register for BIAXIN.

[6] The first NOA was directed to the '732 patent. Pharmascience alleged that its product was produced by a process which would not infringe the '732 patent and in the alternative, that the '732 patent was invalid because its claims were broader than the invention disclosed. In response to this NOA, Abbott launched an application pursuant to section 6 of the *Patented Medicines (Notice of Compliance Regulations*, SOR/93-133 (the "*NOC Regulations*") for an order prohibiting the Minister of Health from issuing an NOC to Pharmascience because none of its allegations were justified. The application was heard by Gibson J. who held that Pharmascience's NOA was insufficient in respect of the non-infringement allegations and that in any event, the allegations of invalidity contained in it were not justified (*Abbott Laboratories v. Canada (Minister of Health)*, 2004 FC 1349 ("*Pharmascience I*"). Gibson J.'s decision was upheld by this Court (*Pharmascience Inc. v. Canada (Minister of Health*), 2005 FCA 250).

[7] The second NOA, which is at issue in this appeal, was, like the first NOA, directed to the '732 patent, as well as to five other patents: 2,258,606 (the "'606 patent"), 2,277,274 (the "'274 patent"), 2,386,527, 2,386,534, and 2,387,361. It alleged that these patents were invalid on a number of grounds, including anticipation and obviousness. In response to this second NOA,

Abbott commenced a second application for an order of prohibition. As will be explained more fully below, Justice O'Keefe held that Pharmascience was precluded by the doctrine of issue estoppel from alleging that the '732 patent was invalid. Consequently, he found it unnecessary to consider the allegations concerning the other patents and granted an order of prohibition until the expiry of the '732 patent (*Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 341 ("*Pharmascience II*")).

[8] The third NOA is not at issue in these proceedings. In it, Pharmascience alleged that it would not infringe five of the listed patents. At the Federal Court, Harrington J. found that Pharmascience's allegations in respect of the '274 patent were justified (*Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 120). However, an appeal to this Court was allowed on February 15, 2007 (2007 FCA 73).

[9] For convenience, the following chronology sets out the dates of the events relevant to this appeal:

DATE	**EVENT**
October 22, 2003	Second NOA served on Abbott
December 5, 2003	Notice of application issued by Abbott in respect of second NOA
July 8, 2004	Hearing of application in respect of first NOA before Gibson J.
October 1, 2004	Judgment rendered by Gibson J. in application respecting first NOA
June 29, 2005	Judgment of Gibson J. upheld by the Federal Court of Appeal
July 25, 2005	Abbott Memorandum of Fact and Law filed for application before O'Keefe J. respecting second NOA
September 19-22, 2005	Hearing of application in respect of second

	NOA before O'Keefe J.
March 16, 2006	Judgment rendered by O'Keefe J. in application respecting second NOA

DECISION BELOW

[10] In the court below, O'Keefe J. first reviewed the law of issue estoppel. In particular, he relied upon this Court's decision in *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 467, to conclude that "[t]he case law indicates that a party is required to use reasonable diligence to bring forth in the first instance all points that relate to that issue. In this case, the issue is the invalidity of the '732 patent" (*Pharmascience II* at paragraph 36).

[11] In O'Keefe J.'s view, the invalidity of the '732 patent was put in issue in the previous proceedings before Gibson J. when Pharmascience alleged that the claims of the '732 were broader than the invention disclosed. Therefore, by raising additional arguments to establish the invalidity of the patent in the present litigation, Pharmascience was attempting to raise for a second time the issue of invalidity. Moreover, the decision of Gibson J. had been upheld on appeal to this Court and was final. The parties to the present application were also the same as those to the previous application. Finding no basis for exercising his discretion not to apply issue estoppel, O'Keefe J. concluded that Pharmascience was precluded from relying on its allegations respecting the '732 patent and issued an order pursuant to subsection 6(2) of the *NOC Regulations* prohibiting the Minister from issuing an NOC to Pharmascience.

RELEVANT REGULATORY PROVISIONS

[12] This case engages the requirements set out in the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The pertinent subsections are as follows:

5. (1) Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug,	5. (1) Lorsqu'une personne dépose ou a déposé une demande d'avis de conformité pour une drogue et la compare, ou fait référence, à une autre drogue pour en démontrer la bioéquivalence d'après les caractéristiques pharmaceutiques et, le cas échéant, les caractéristiques en matière de biodisponibilité, cette autre drogue ayant été commercialisée au Canada aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été soumise, elle doit inclure dans la demande, à l'égard de chaque brevet inscrit au registre qui se rapporte à cette autre drogue :
…	[…]
(*b*) allege that	*b*) soit une allégation portant que, selon le cas :
(i) the statement made by the first person pursuant to paragraph 4(2)(*c*) is false,	(i) la déclaration faite par la première personne aux termes de l'alinéa 4(2)*c*) est fausse,
(ii) the patent has expired,	(ii) le brevet est expiré,
(iii) the patent is not valid, or	(iii) le brevet n'est pas valide,
(iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.	(iv) aucune revendication pour le médicament en soi ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites advenant l'utilisation, la fabrication, la construction ou la vente par elle de la drogue faisant l'objet de la demande d'avis de conformité.
…	[…]

6(1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(*b*) or (*c*), 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 allegation.	6. (1) La première personne peut, dans les 45 jours après avoir reçu signification d'un avis d'allégation aux termes des alinéas 5(3)*b*) ou *c*), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer un avis de conformité avant l'expiration du brevet visé par l'allégation.
(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.	(2) Le tribunal rend une ordonnance en vertu du paragraphe (1) à l'égard du brevet visé par une ou plusieurs allégations si elle conclut qu'aucune des allégations n'est fondée.

ISSUES

[13] Three broad issues are raised in this appeal:

1. What is the standard of review?
2. Did O'Keefe J. err by failing to consider the merits of the allegations concerning the '606 and '274 patents?
3. Does issue estoppel apply to prevent Pharmascience from relying on the allegations of invalidity in its NOA?

ANALYSIS

1) Standard of Review

[14] In *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235 ("*Housen*"), the Supreme Court of Canada explained that the standard of review to be applied by appellate courts varies in relation to the nature of the question at issue. For questions of law, a standard of correctness is applied (*Housen* at paragraph 8). For questions of fact, a standard of palpable and overriding error should be used (*Housen* at paragraph 10). For questions of mixed fact and law, a standard of palpable and

overriding error is generally applied, unless an extricable error of law can be identified, in which case a standard of correctness is used (*Housen* at paragraph 27-28).

[15] When the lower court judge has made a discretionary decision, it will usually be afforded deference by the appellate court. However, the latter will be entitled to substitute the lower court judge's discretion for its own if the appellate court determines that the lower court judge has given insufficient weight to relevant factors (*Elders Grain Co. v. Ralph Misener (The)*, [2005] 3 F.C.R. 367 at paragraph 13).

2) '606 and '274 Patents

[16] The first submission made by Pharmascience counsel in oral argument was that O'Keefe J. erred in failing to consider the merits of the allegations concerning the '606 and '274 patents. In her view, subsection 6(2) of the *NOC Regulations* requires the applications judge to substantively consider the allegations against each of the patents targeted by the NOA. When asked why it was necessary to consider those patents once it was decided that Abbott was entitled to an order of prohibition based on the '732 patents, counsel responded that her client Pharmascience might, in the future, be able to utilize a different process not involving the '732 patent but yet engaging the '606 and '274 patents. In those circumstances, she said it would be useful to get an advance ruling on the '606 and '274 patents, thus avoiding duplicative litigation.

[17] A review of section 6 of the *NOC Regulations*, however, reveals no basis for Pharmascience's assertion that the applications judge was obliged to consider the merits of the allegations against the '606 and '274 patents. Subsections 6(1) and (2) provide as follows:

6(1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(*b*) or (*c*), 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 allegation.	6. (1) La première personne peut, dans les 45 jours après avoir reçu signification d'un avis d'allégation aux termes des alinéas 5(3)*b*) ou *c*), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer un avis de conformité avant l'expiration du brevet visé par l'allégation.
(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.	(2) Le tribunal rend une ordonnance en vertu du paragraphe (1) à l'égard du brevet visé par une ou plusieurs allégations si elle conclut qu'aucune des allégations n'est fondée.

[18] Pharmascience counsel argued before us that the use of the imperative "shall" in subsection 6(2) obliges the applications judge to consider the allegations made against each patent referred to in the NOA, even if allegations against one of the patents have already been found to be unjustified, thereby warranting an order of prohibition. However, reading subsection 6(2) in light of subsection 6(1), reveals that the term "shall" has no such purpose. It is the "first person," typically an innovator pharmaceutical company, who initiates the application under subsection 6(1) and asks the court to make an order of prohibition on the basis that the allegations in the NOA are unjustified. Nowhere is the "second person," usually a generic drug company, given the opportunity to demand that the court evaluate the merits of each of its allegations, if, by dismissing one of the allegations, the first person becomes entitled to an order of prohibition.

[19] In the court below, O'Keefe J. determined that Pharmascience was estopped from relying on its allegations of invalidity against the '732 patent. Those allegations were therefore not justified and O'Keefe J. accordingly made an order prohibiting the Minister of Health from issuing an NOC to Pharmascience for its generic version of BIAXIN until the expiry of the '732 patent. The only person who is aggrieved by reason of the failure of O'Keefe J. to deal with the '606 and '274 patents is Abbott. It was Abbott who commenced an application for an order prohibiting Pharmascience from obtaining an NOC because the allegations in the NOA relating to the '606 and '274 patents were not justified. Those two patents expire approximately two years after the '732 patent. Therefore, Abbott could have appealed arguing that it could have had a prohibition order lasting two more years after the prohibition order relating to the '732 patent had expired. Abbott did not appeal and the time for doing so has now expired.

3) Issue Estoppel

[20] The primary issue in this appeal is whether O'Keefe J. correctly applied issue estoppel to preclude Pharmascience from relying on the allegation in its second NOA that the '732 patent is invalid. Pharmascience maintains that the court below should not have had recourse to the doctrine of issue estoppel because Abbott failed to plead estoppel and because O'Keefe J. incorrectly identified and applied the test for issue estoppel. As the analysis that follows will indicate, I am not satisfied that there is any basis for departing from the conclusions of O'Keefe J. on this issue.

a) Failure to Plead Estoppel

[21] The first point raised by Pharmascience in relation to issue estoppel is that O'Keefe J. should not have considered issue estoppel because Abbott failed to plead the doctrine in its notice of application. According to Pharmascience, it was prejudiced by this omission because it was not able to file evidence on this point or to cross-examine Abbott witnesses regarding issue estoppel.

[22] Pharmascience fails to acknowledge, however, that the reasons for judgment in the case relied upon by Abbott to ground its claims of estoppel were released almost ten months after Abbott filed its notice of application in the present proceeding. Abbott commenced this proceeding by notice of application on December 5, 2003; Gibson J.'s reasons in *Pharmascience I* were not released until October 1, 2004 and were not final until the Court of Appeal dismissed Pharmascience's appeal on June 29, 2005. Without the benefit of the decisions of those courts, therefore, Abbott could not be expected to have raised the issue estoppel argument at the time of the notice of application, or indeed up to June 29, 2005. By that time, the only step left for Abbott before the hearing was the filing of its Memorandum of Fact and Law. Abbott did raise the issue in its Memorandum of Fact and Law.

[23] Pharmascience goes on to submit that even if Abbott was not required to plead issue estoppel in its notice of application as originally filed, it should have amended its notice of application after the release of Gibson J.'s reasons. Abbott, however, took the most reasonable step, by raising the matter in its Memorandum of Fact and Law. Upon receiving the Memorandum, Pharmascience became aware that issue estoppel was to be raised by Abbott. Arguably, if

Pharmascience felt this was improper it could have brought a motion under Rule 58 of the *Federal Courts Rules*, SOR 98/106. More importantly, however, Pharmascience, if it really felt prejudiced, should have objected before O'Keefe J., and if it felt it needed an adjournment to deal with the issue, it should have so requested. Pharmascience did not do so. Having failed to contest Abbott's reliance on estoppel at the earliest opportunity, Pharmascience has no grounds to object to it now.

b) Should Issue Estoppel be Applied?

[24] O'Keefe J. was satisfied that all of the elements of the test for issue estoppel were made out, thereby warranting the application of the doctrine. In particular, O'Keefe J. was persuaded that a party must put its best foot forward by raising all arguments with respect to an issue at first instance and that issue estoppel applies to prevent such a party from attempting to raise additional arguments going to that same issue in a subsequent litigation. Because he found that the issue of invalidity of the '732 patent had been raised before Gibson J., O'Keefe J. held that Pharmascience was precluded from raising in the present proceedings additional arguments to support its contention that the '732 patent is invalid, such as obviousness and anticipation. Moreover, he concluded that insufficient circumstances existed to justify invoking his overriding discretion to refuse to apply issue estoppel.

[25] In this appeal, Pharmascience submits that O'Keefe J. erred in identifying and applying the test for issue estoppel. As the discussion that follows will illustrate, I am not persuaded by Pharmascience's arguments in this regard.

i) The Test for Issue Estoppel

[26] On a number of occasions the Supreme Court of Canada has had the opportunity to explain the doctrine of issue estoppel. In *Toronto (City) v. Canadian Union of Public Employees (C.U.P.E.), Local 79*, [2003] 3 S.C.R. 77 at paragraph 23, Arbour J. described issue estoppel as "a branch of *res judicata* (the other branch being cause of action estoppel), which precludes the relitigation of issues previously decided in court in another proceeding."

[27] In *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460 at paragraph 33 ("*Danyluk*"), Binnie J. explained that there is a two-step analysis governing issue estoppel:

> The first step is to determine whether the moving party (in this case the respondent) has established the preconditions to the operation of issue estoppel set out by Dickson J. in *Angle*, *supra*. If successful, the court must still determine whether, as a matter of discretion, issue estoppel ought to be applied.

[28] The pre-conditions to the operation of issue estoppel referred to in *Danyluk* are those from Lord Guest's decision in *Carl Zeiss Stiftung v. Rayner & Keeler Ltd. (No. 2)*, [1967] 1 A.C. 853, which were cited with approval by a majority of the Supreme Court of Canada in *Angle v. Canada (Minister of National Revenue)*, [1975] 2 S.C.R. 248 at 254 ("*Angle*"):

> …(1) that the same question has been decided; (2) that the judicial decision which is said to create the estoppel was final; and, (3) that the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies…

[29] In *Danyluk* at paragraph 33, Binnie J. stressed that this test is not to be mechanically applied:

> The rules governing issue estoppel should not be mechanically applied. The underlying purpose is to balance the public interest in the finality of litigation with the public interest in ensuring that justice is done on the facts of a particular case. (There are corresponding private interests.)

[30] Pharmascience does not dispute that Gibson J.'s decision was final or that the parties to the present proceeding are the same as in the earlier litigation. It does dispute, however, O'Keefe J.'s findings with respect to the first precondition for issue estoppel, by arguing that the issues to be decided in the present proceeding differ from those in the previous proceeding, that the question of invalidity of the '732 patent was not fundamental to the decision of Gibson J., and that Pharmascience was not required in the earlier proceeding to put forward all its arguments going to the invalidity of the '732 patent. Pharmascience also argues that even if O'Keefe J. properly considered the preconditions to issue estoppel, he should have exercised his overriding discretion not to apply estoppel on the facts of the present case.

ii) Similarity of Issues to those Before Gibson J.

[31] Pharmascience argues that for issue estoppel to apply, the same issue must be raised in both proceedings. It submits that Gibson J.'s decision considered only the issue of the sufficiency of the infringement allegations in the NOA; it did not resolve whether the '732 patent was invalid. According to Pharmascience, Gibson J.'s comments about the validity of the patent were *obiter* and therefore collateral to the main issue decided.

[32] In determining whether a question was decided in a previous proceeding, the Supreme Court of Canada in *Angle* held that the court must determine whether the question was fundamental to the earlier decision:

> It will not suffice if the question arose collaterally or incidentally in the earlier proceedings or is one which must be inferred by argument from the judgment. That is plain from the words of De Grey C.J. in the *Duchess of Kingston's case* [(1776), 20 St. Tr. 355, 538n.], quoted by Lord Selborne L.J. in *R. v. Hutchings* [(1881), 6 Q.B.D. 300.], at p. 304, and by Lord Radcliffe in *Society of Medical Officers of*

> *Health v. Hope* [[1960] A.C. 551.]. **The question out of which the estoppel is said to arise must have been "fundamental to the decision arrived at" in the earlier proceedings:** per Lord Shaw in *Hoystead v. Commissioner of Taxation* [[1926] A.C. 155.]. The authors of Spencer Bower and Turner, *Doctrine of Res Judicata*, 2nd ed. pp. 181, 182, quoted by Megarry J. in *Spens v. I.R.C.* [[1970] 3 All. E.R. 295.], at p. 301, set forth in these words the nature of the enquiry which must be made:
>
> > **... whether the determination on which it is sought to found the estoppel is "so fundamental" to the substantive decision that the latter cannot stand without the former. Nothing less than this will do**. [Emphasis added.]

[33] It is undeniable that Pharmascience raised the issue of the invalidity of the ’732 patent in the earlier proceedings. At paragraph 4 of his reasons, Gibson J. paraphrased the allegations in the first NOA, specifically highlighting the claim made by Pharmascience that the ’732 patent is invalid because its claims are broader than the invention disclosed:

> …Pharmascience’s Notice of Allegation alleges that its form II clarithromycin is produced by a process that does not infringe Canadian Letters Patent No. 2,261,732 and that, alternatively, if its clarithromycin is covered by claims 16 to 21 of the Patent, **then those claims are broader than the invention made and disclosed and thus the Patent is invalid**. [Emphasis added.]

[34] A review of Gibson J.’s reasons reveals that when he decided that the first NOA was insufficient, he concluded that he could have disposed of the case on that basis. However, he went on to consider the merits of the allegations of invalidity made in the NOA, ultimately finding them to be unjustified. With respect to the invalidity argument, Gibson J. held as follows at paragraph 122:

> Given the foregoing, I am satisfied that an interpretation of the disclosure of the '732 Patent in a manner that extends to include the process utilized or proposed to be utilized by Pharmascience's supplier is reasonably open and does not result in the claims of that patent that are here in issue exceeding the scope of the disclosure on which those claims are based. In the result, to put it another way, **I am satisfied that, on the evidence before the Court, Pharmascience has failed to discharge the evidentiary burden on it to justify the allegation of invalidity of the Claims 16 to 21 of '732 Patent on the basis of over breadth**. [Emphasis added.]

[35] The question that arises is whether the issue of invalidity was “fundamental” to Justice Gibson’s decision. Although Gibson J. uses language which might indicate that his findings on the merits of Pharmascience’s invalidity allegations were *obiter*, in fact they were fundamental to his decision. Applications under section 6 of the *NOC Regulations* are commenced by first persons for the purpose of having the court issue an order prohibiting the Minister of Health from issuing an NOC to a second person. According to the text of subsection 6(2) of the regulations, an order will only be made in respect of a patent if *none* of the allegations relating to that patent in the NOA are justified. Gibson J. concluded only that the allegations in the first NOA with respect to *non-infringement* were insufficient. He made no equivalent holding about the allegation of invalidity. Therefore, in order to meet the criteria in subsection 6(2) for granting a prohibition order, Gibson J. was required to consider the merits of the invalidity allegation. It was only after he found Pharmascience’s allegation that the ’732 patent was invalid to be unjustified that he could have issued the prohibition order sought by Abbott preventing Pharmascience from marketing its clarithromycin product until the expiry of the ’732 patent. His assessment of the merits of the invalidity allegation was therefore a fundamental component of his decision.

[36] Pharmascience also argues that in the context of the *NOC Regulations*, a second person is permitted to serve multiple NOAs alleging invalidity of a single patent. In its submission, each ground of invalidity, be it overbreadth, anticipation, obviousness or inutility, constitutes a separate issue for the purpose of issue estoppel. Therefore, because only the question of overbreadth was raised before Gibson J., the other grounds of invalidity, such as anticipation and obviousness, which are raised in the second NOA, cannot be precluded by issue estoppel.

[37] O'Keefe J. rejected this argument on the basis that the law requires litigants to put their best foot forward at the first opportunity, a principle that was accepted by the Supreme Court of Canada in *Danyluk*. At paragraph 18, Binnie J. made the following broad statements about issue estoppel:

> **The law rightly seeks a finality to litigation. To advance that objective, it requires litigants to put their best foot forward to establish the truth of their allegations when first called upon to do so. A litigant, to use the vernacular, is only entitled to one bite at the cherry.** The appellant chose the ESA as her forum. She lost. An issue, once decided, should not generally be re-litigated to the benefit of the losing party and the harassment of the winner. **A person should only be vexed once in the same cause. Duplicative litigation, potential inconsistent results, undue costs, and inconclusive proceedings are to be avoided**. [Emphasis added.]

[38] Later, at paragraph 54, he explained that issue estoppel "extends to the issues of fact, law, and mixed fact and law that are necessarily bound up with the determination of that "issue" in the prior proceeding."

[39] In *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, [2004] 2 F.C.R. 85 at paragraph 25 (F.C.A) ("*P&G*"), Rothstein J.A. (as he then was), speaking for this Court, approved the following passage from page 9 of Lord Denning's decision in *Fidelitas Shipping Co. Ltd. v. V/O Exportchleb*, [1965] 2 All E.R. 4 (C.A.):

> But within one cause of action, there may be several issues raised which are necessary for the determination of the whole case. The rule then is that, once an issue has been raised and distinctly determined between the parties, then, as a general rule, neither party can be allowed to fight that issue all over again. The same issue cannot be raised by either of them again in the same or subsequent proceedings except in special circumstances. . . . **And within one issue, there may be several points available which go to aid one party or the other in his efforts to secure a determination of the issue in his favour. The rule then is that each party must use reasonable diligence to bring forward every point which he thinks would help him. If he omits to raise any particular point, from negligence, inadvertence, or even accident (which would or might have decided the issue in his favour), he may find himself shut out from raising that point again, at any rate in any case where the self-same issue arises in the same or subsequent proceedings**. [Emphasis added.]

[40] What, then, is the "issue" decided by Gibson J.? Is it the broad question of invalidity, or the more specific question pertaining to overbreadth? This question must be governed by the wording of the *NOC Regulations*, which set out the following requirements at paragraph 5(1)(*b*):

5. (1) Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug,	5. (1) Lorsqu'une personne dépose ou a déposé une demande d'avis de conformité pour une drogue et la compare, ou fait référence, à une autre drogue pour en démontrer la bioéquivalence d'après les caractéristiques pharmaceutiques et, le cas échéant, les caractéristiques en matière de biodisponibilité, cette autre drogue ayant été commercialisée au Canada aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été soumise, elle doit inclure dans la demande, à l'égard de chaque brevet inscrit au registre qui se rapporte à cette autre drogue :
…	[…]
(*b*) allege that	*b*) soit une allégation portant que, selon le cas :
(i) the statement made by the first person pursuant to paragraph 4(2)(*c*) is false,	(i) la déclaration faite par la première personne aux termes de l'alinéa 4(2)*c*) est fausse,
(ii) the patent has expired,	(ii) le brevet est expiré,
(iii) the patent is not valid, or	(iii) le brevet n'est pas valide,
(iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.	(iv) aucune revendication pour le médicament en soi ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites advenant l'utilisation, la fabrication, la construction ou la vente par elle de la drogue faisant l'objet de la demande d'avis de conformité.

[41] What the *NOC Regulations* require the second person to establish is, *inter alia*, that the patent is invalid or that it would not be infringed. In other words, the "issue" to be addressed is invalidity or non-infringement. The specific grounds on which the second person wishes to demonstrate invalidity, whether that be by obviousness, anticipation, overbreadth or lack of sound prediction, do not constitute separate issues for the purpose of issue estoppel but are merely different bases on which the second person may address the issue of invalidity. Consequently, multiple NOAs from the same generic relating to a particular pharmaceutical and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. As a majority of this Court identified in *P&G* at paragraph 22, an exception to the application of this rule might be made in cases where facts material to the issue could not have been discovered with reasonable diligence at the time of the first litigation. No such exception applies in the present case, however. Pharmascience does not deny that it could have raised additional grounds of invalidity in the first NOA, but merely contends that splitting its claims is permissible within the scheme of the regulations.

[42] None of the cases relied upon by Pharmascience necessitate a departure from the foregoing principles. Pharmascience advances these cases in an effort to show that previous decisions of this Court and the Federal Court have endorsed the use of successive NOAs alleging invalidity. However, in my view, Pharmascience misreads the holdings in these cases. A proper review of them reveals that they are entirely consistent with the conclusion that multiple NOAs alleging invalidity will generally not be permitted. In *AB Hassle et al. v. Apotex Inc. et al.* (2005), 38 C.P.R. (4th) 216 (F.C.), aff'd 2006 FCA 51, at paragraphs 73 and 76 ("*AB Hassle*"), Layden-Stevenson J.

appropriately summarized the jurisprudence developed in cases such as those cited in the present case by Pharmascience:

> The general rule, stated in *P & G*, *supra*, is that a party in one proceeding is estopped from raising an issue that it could and should have raised in a previous proceeding between the parties. Although this form of estoppel is of the weaker variety, when the conditions are met, it is a matter of discretion as to whether the party should not be estopped…
>
> …
>
> As I understand it, the jurisprudence holds that a subsequent NOA is permissible when a previous NOA has been withdrawn due to difficulties in meeting regulatory requirements or where the subsequent NOA is separate and distinct from the previous one (such as a new formulation) or where a procedural defect with respect to the previous NOA opens the door for the transmission of a subsequent NOA.

[43] One case cited by Pharmascience in support of its argument is *Bayer AG v. Apotex Inc.*, [1998] F.C.J. No. 1593, in which Gibson J. was called upon to determine whether a fifth NOA made by a generic was an abuse of process. In his reasons, Gibson J. reviewed a line of cases standing for the proposition that it is not an abuse of process for more than one NOA to be brought before the court by the same generic, provided each is separate and distinct from the others. The critical point that Pharmascience fails to appreciate in reviewing the case, however, is Gibson J.'s analysis of what is to be considered "separate and distinct." He concluded that the fifth NOA was not separate and distinct because it was merely an attempt to bolster the allegations in the fourth NOA through new evidence. Moreover, he apparently accepted the principle set out above that generics are required to raise in their NOAs all material facts which they could have uncovered with reasonable diligence. Because no sufficient explanation was given to explain why the new evidence was not referred to in the earlier NOA, Gibson J. ruled the fifth NOA to be an abuse of process.

[44] Pharmascience also relies on *Bayer AG v. Apotex Inc.*, 2003 FC 1199, a later decision of Gibson J. between the same parties. In oral argument, Pharmascience counsel referred to this case, but did not indicate the relevant portion. Upon a review of the reasons, I fail to see how it assists the appellant. At paragraph 28, Justice Gibson explains that although issue estoppel was forecasted by the relief sought in the originating notice of motion, it was not referred to in the applicant's memorandum of fact and law and was not argued before the court. Consequently, issue estoppel was not considered in the reasons for judgment.

[45] Another case cited by Pharmascience is the decision of this Court in *AstraZeneca AB v. Apotex Inc.*, 2005 FCA 183 ("*AstraZeneca*"). There it was alleged that a second NOA submitted by a generic was an abuse of process. In deciding the issue, Evans J.A. began by restating the principle that "it is an abuse of process for a second person to repeat an allegation in a second NOA, unless the legal and factual bases are separate and distinct from those supporting its earlier application" (*AstraZeneca* at paragraph 21). He then went on to evaluate the two NOAs at issue and concluded that the allegations contained in them were separate and distinct such that the second was not an abuse of process. However, two crucial differences exist between that case and the one at present that prevent its application to the present facts. First, in *AstraZeneca*, Apotex Inc. withdrew the first NOA because it was having difficulty complying with regulatory standards for safety and effectiveness with the formulation of its drug product. The prohibition proceeding launched by AstraZeneca AB was therefore discontinued and, significantly, there was no hearing of the merits of the allegations in the NOA. This scenario is in stark contrast to the present proceedings where the

first NOA proceeded to a hearing before Gibson J. after which he ruled on the merits of the allegations.

[46] The second difference between *AstraZeneca* and the present case is of vital importance. In *AstraZeneca*, the NOAs at issue both alleged non-infringement, rather than invalidity. As Layden-Stevenson J. explained in *AB Hassle*, where different formulations of the generic drug are at issue, multiple NOAs alleging non-infringement may be permissible. It is intuitive that if a generic makes material changes to its formulation in an attempt to avoid infringing the listed patent, it may submit a new NOA alleging non-infringement by the new product. Similarly, if it was the process for making the generic drug that infringed the patent, a new process adopted by the generic may give rise to a subsequent NOA alleging non-infringement of the patent. That is not to say that minor variations to the formulation or process will be sufficient to permit a new NOA. Only where the change is of significance might a new NOA be permitted. Multiple NOAs alleging invalidity, in contrast, are not permissible because the factual basis does not change depending on the circumstances of the generic. Unless a material fact could not be uncovered by reasonable diligence at the time of the first NOA, subsequent NOAs alleging invalidity will generally not be permitted. In *AstraZeneca*, Evans J.A. appreciated this distinction. From his reasons, it appears that Apotex made a significant change to the formulation of its drug product between the first and second NOAs. The second NOA was therefore permitted because the factual basis for the allegations in it was separate and distinct from that in the first NOA.

[47] Pharmascience also referred us to *AB Hassle v. Canada (Minister of Health and Welfare)* (1997), 71 C.P.R. (3d) 129 (F.C.T.D.). In that case, a number of applications by innovator pharmaceutical companies seeking similar relief against Apotex Inc., a generic, were heard together by MacKay J. In each proceeding, Apotex had served successive NOAs on the innovators in respect of the same patents. The innovators therefore brought an interlocutory motion seeking to have the NOA declared void and, alternatively, to have the proceedings stayed on the basis of *res judicata*. MacKay J. declined both requests. With respect to the former, he followed the decision of this Court in *Pharmacia Inc. v. Canada (Minister of Health)* (1994), 58 C.P.R. (3d) 209 at pages 214-216, to the effect that interlocutory motions are to be discouraged in the context of proceedings under the *NOC Regulations* in favour of having the court hearing the section 6 application assess the weight or significance to be ascribed to a subsequent NOA. The present case is, of course, distinguishable because the question of issue estoppel was raised before the applications judge. With respect to the latter request, MacKay J. determined that the subsequent NOAs were sufficiently distinct from their predecessors to prevent the application of *res judicata*. The NOAs at issue before MacKay J. alleged non-infringement on various grounds. As has already been explained, the situation of NOAs directed to non-infringement is distinguishable from the situation of NOAs directed to invalidity. Because infringement is a factual circumstance that varies depending on the formulation of the drug made by the generic and the process used by the generic for making the drug, among other things, multiple non-infringement NOAs may be permitted. Multiple NOAs alleging invalidity, on the other hand, will rarely be acceptable.

[48] In addition, Pharmascience points to *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1504, in which Tremblay-Lamer J. refused to find a second NOA alleging invalidity of a patent to be an abuse of process on that basis that a previous NOA alleging non-infringement had proceeded to a decision. That case is of no assistance here, however, where both NOAs alleged invalidity.

[49] In sum, Justice O'Keefe was correct to conclude that the preconditions to the operation of issue estoppel have been made out in the present case. Unless Pharmascience can satisfy this Court that O'Keefe J. erred in refusing to exercise his discretion not to apply estoppel, this appeal must be dismissed.

iii) Discretion Not to Apply Issue Estoppel

[50] Pharmascience's next contention relates to the judge's overriding discretion, in cases where issue estoppel is pleaded, to refuse to apply the doctrine. It argues that sufficient circumstances exist in this case such that O'Keefe J. should have exercised his discretion not to apply estoppel. I disagree.

[51] The starting point is the statement of the Supreme Court of Canada in *Danyluk* wherein at paragraph 62 it stressed that in the context of judicial decisions, the circumstances in which this discretion should be exercised are rare:

> The appellant submitted that the Court should nevertheless refuse to apply estoppel as a matter of discretion. There is no doubt that such a discretion exists. In *General Motors of Canada Ltd. v. Naken*, [1983] 1 S.C.R. 72, Estey J. noted, at p. 101, that **in the context of court proceedings "such a discretion must be very limited in application"**. In my view the discretion is necessarily broader in relation to the prior decisions of administrative tribunals because of the enormous

> range and diversity of the structures, mandates and procedures of administrative decision makers. [Emphasis added.]

[52] In *P&G* at paragraph 28, Rothstein J.A. added that "[t]he limited application of such discretion is of very long standing. In earlier jurisprudence, the discretion not to apply the doctrines of *res judicata* was limited to "special circumstances.""

[53] In *Danyluk* at paragraph 67, Binnie J. explained that this overriding discretion is intended to ensure that issue estoppel is not applied unfairly in the circumstances of a given case: "[t]he objective is to ensure that the operation of issue estoppel promotes the orderly administration of justice but not at the cost of real injustice in the particular case." According to Binnie J., the factors which may be relevant in applying this discretion will differ from case to case.

[54] O'Keefe J.'s reasons reveal little evidence of the factors he considered in refusing to exercise his discretion not to apply estoppel. His only comments on this question are made at paragraph 43:

> The respondent submitted that even if issue estoppel does apply, I should exercise my discretion and hear the application. I do not agree. There are not sufficient factors present to cause me to exercise my discretion to hear the case.

[55] In most cases, a discretionary decision is to be afforded deference and an appellate court will not be permitted to substitute its own exercise of discretion for that of the judge in the lower court (*Elders Grain Co. v. Ralph Misener (The)*, [2005] 3 F.C.R. 367 at paragraph 13 (F.C.A.)). However, in cases such as the one at present, where the reasons explaining the lower court judge's

discretionary decision are inadequate, a more searching analysis will be conducted by the appellate court:

> Where, as here, the judge has given no meaningful reasons for the decision, this Court's duty is "to consider the record to determine whether there was material before the motion judges which could have formed a basis for their exercise of discretion consistently with legal principles and the requirements of justice". (*Sark v. Abegweit Band Council*, [1996] F.C.J. No. 532 (F.C.A.))

[56] In *Reynolds v. Canada (Minister of Foreign Affairs)*, [1995] F.C.J. No. 1612 at paragraph 4 (F.C.A.), the Court described this principle in the following terms:

> Since these were discretionary decisions, all that this Court can do is consider the record to determine whether there was material before the motion judges which could have formed a basis for their exercise of discretion consistently with legal principles and the requirements of justice.

[57] In oral argument, Pharmascience stressed two factors which it says mandate an exercise of discretion in its favour. First, it maintains that it was caught by surprise because issue estoppel was not pleaded by Abbott. In those circumstances, Pharmascience claims that it would suffer an injustice if Abbott were permitted to succeed with its issue estoppel argument.

[58] Pharmascience's reliance on Abbott's failure to plead issue estoppel in its notice of application has already been considered and rejected. Abbott could not have pleaded estoppel in its notice of application when originally filed because the event giving rise to issue estoppel, namely, the release of Gibson J.'s reasons, had not yet occurred, let alone having been made final. Moreover, Pharmascience had an obligation to object to Abbott's attempt to raise the issue estoppel argument as soon as possible after it became aware that it had not been pleaded. Having failed to assert any

prejudice from these circumstances in front of O'Keefe J., Pharmascience cannot now maintain that it is deserving of a discretionary decision not to apply issue estoppel.

[59] The second important factor relevant to this exercise of discretion, according to Pharmascience, is that at the time that it served the second NOA, the law permitted multiple NOAs addressing the same issue. Pharmascience submits that even if the law has now changed to preclude successive NOAs on the basis of issue estoppel, it should not be penalized for relying on the law as it existed at the time.

[60] Contrary to Pharmascience's assertion, there has not been a change in the law from a position where multiple NOAs alleging invalidity were permissible to a position where such conduct gives rise to issue estoppel. As explained in the preceding section, Pharmascience has failed to show us any such cases endorsing the issuance of multiple NOAs alleging invalidity. This Court and the Federal Court have permitted successive NOAs only in cases where the allegations contained in them can be considered separate and distinct, such as where the generic seeks to rely on a new formulation or process for making a drug, or where the previous NOA was withdrawn before proceeding to a hearing.

[61] Issue estoppel is a long-standing concept in the common law. The fact that no decision has specifically considered the question before us in this appeal does not mean that this decision changes the applicable law. Indeed, as the foregoing analysis has illustrated, the holding in this appeal is completely consistent with the existing state of the law.

[62] Consequently, Pharmascience has provided insufficient support for its contention that O'Keefe J.'s decision not to exercise his discretion to refuse to apply issue estoppel was not open to him.

CONCLUSION

[63] For the foregoing reasons, I am not persuaded that O'Keefe J. erred in his reasons. Accordingly, I would dismiss this appeal with costs.

"J. Edgar Sexton"
J.A.

"I agree
Gilles Létourneau J.A."

"I agree
John M. Evans J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-151-06
APPEAL FROM AN ORDER OF THE HONOURABLE MR. JUSTICE O'KEEFE, FEDERAL COURT, DATED MARCH 16, 2006, T-2295-03	
STYLE OF CAUSE:	PHARMASCIENCE INC. v. THE MINISTER OF HEALTH and ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 15, 2007
REASONS FOR JUDGMENT BY:	SEXTON J.A.
CONCURRED IN BY:	LÉTOURNEAU J.A. EVANS J.A.
DATED:	APRIL 5, 2007

APPEARANCES:

Carol Hitchman Paula Bremner	FOR THE APPELLANT
Andrew J. Reddon Steven G. Mason	FOR THE RESPONDENTS, ABBOTT LABORATORIES AND ABBOTT LABORATORIES LIMITED
Frederick G. Woyiwada	FOR THE RESPONDENT, MINISTER OF HEALTH

SOLICITORS OF RECORD:

HITCHMAN & SPRIGINGS Barristers & Solicitors Toronto, ON	FOR THE APPELLANT
McCARTHY TÉTRAULT LLP Barristers & Solicitors Toronto, ON	FOR THE RESPONDENTS, ABBOTT LABORATORIES AND ABBOTT LABORATORIES LIMITED
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENT, MINISTER OF HEALTH