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Docket: T-586-06

Citation: 2007 FC 446

Ottawa, Ontario, April 26 2007

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

PFIZER CANADA INC. and PFIZER INC.

Applicants

and

THE MINISTER OF HEALTH and RATIOPHARM INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] This is a motion by the Respondent, Ratiopharm Inc. (Ratiopharm) brought under section 6(5) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (NOC Regulations). Ratiopharm is seeking to strike out the Applicants' (collectively referred to as "Pfizer") underlying application for an Order prohibiting the Minister of Health (Minister) from issuing a Notice of Compliance (NOC) to Ratiopharm for the manufacture and sale of the heart medication, amlodipine besylate (amlodipine). Pfizer's amlodipine medication is marketed under the trade name "Norvasc®". In the underlying application, Pfizer contends that the issuance of a NOC to Ratiopharm would infringe its

Canadian Patent No. 2,355,493 Patent (the 493 Patent) which is listed against Norvasc® in accordance with section 4 of the NOC Regulations.

[2] On this motion, Ratiopharm asserts that Pfizer's prohibition application is plainly without merit and constitutes an abuse of process and should, therefore, be struck out. In support of its argument, Ratiopharm relies heavily on two recent decisions by Justice Roger Hughes in *Pfizer Canada Inc. and Pfizer Inc. v. The Minister of Health and Pharmascience Inc.*, [2007] F.C.J. No. 274, 2007 FC 188 (*Pharmascience*) and *Pfizer Canada Inc. and Pfizer Inc. v. The Minister of Health and Cobalt Pharmaceuticals Inc.*, [2007] F.C.J. No. 263, 2007 FC 187 (*Cobalt*) where he held that Pfizer's 493 Patent would not be infringed by the provision by the generic manufacturers in those cases of amlodipine medication equivalent to Norvasc®.

Background

[3] In order to better understand some of the issues raised by this proceeding and, in particular, Ratiopharm's abuse of process submission, an outline of the history of the litigation between the parties is advisable.

[4] Pfizer's 493 Patent was filed with the Canadian Patent Office on August 21, 2001, and published on February 23, 2002. It is based on a priority filing of U.K. Patent No. 0020842.1 filed on August 23, 2000. The 493 Patent will expire on August 21, 2021.

[5] On January 23, 2004, Ratiopharm filed with the Minister an abbreviated new drug submission (ANDS) with respect to amlodipine. In its ANDS, Ratiopharm compared its proposed drug to Pfizer's Norvasc® which had received a NOC against which was listed the 493 Patent.

[6] Prior to the filing of the 493 Patent, Pfizer had filed two patents on the Patent Register listed against Norvasc®: Canadian Patent No. 1,253,865 (the 865 Patent) and Canadian Patent No. 1,321,393 (the 393 Patent). The 865 Patent was filed on March 9, 1983 and expired on May 9, 2006 and is not in issue in this proceeding. The 393 Patent was filed on April 2, 1987 and expires on August 17, 2010. The question of the validity of Pfizer's 393 Patent has come up in previous litigation in this Court and in the Federal Court of Appeal. In that earlier litigation, Ratiopharm challenged the validity of the 393 Patent and initially it was successful. In *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2006] F.C.J. No. 273, 2006 FC 220, Justice Konrad von Finckenstein held that Pfizer had failed to disprove Ratiopharm's allegations that the 393 Patent was invalid. However, on June 9, 2006, the Federal Court of Appeal allowed Pfizer's appeal from that decision and prohibited the Minister from issuing a NOC to Ratiopharm until the expiry of the 393 Patent: see *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2006] F.C.J. No. 894, 2006 FCA 214, leave to appeal denied [2006] S.C.C.A. No. 335.

[7] While the litigation concerning Pfizer's 393 Patent was before this Court, Pfizer listed the 493 Patent on the Patent Register with respect to Norvasc®.

[8] In a letter dated February 10, 2006, Ratiopharm sent a Notice of Allegation (NOA) to Pfizer under section 5(3) of the NOC Regulations with respect to the 493 Patent. In that NOA, Ratiopharm made allegations of ineligibility for listing on the Patent Register on the basis that the 493 Patent did not contain claims for the medicine amlodipine and no claim for the use of that medicine. Ratiopharm also made allegations of non-infringement and invalidity. On the same day, Ratiopharm requested the Minister to use his discretion under section 3(2) of the NOC Regulations to delete the 493 Patent from the Patent Register with respect to Norvasc®.

[9] On February 20, 2006, Ratiopharm initiated an application for judicial review of the Minister's decision to list the 493 Patent against Norvasc®.

[10] On March 24, 2006, the Minister informed Pfizer that the 493 Patent would be removed from the Patent Register due to improper listing, subject to any written representations made by Pfizer.

[11] In response to Ratiopharm's NOA concerning the 493 Patent, Pfizer filed the Notice of Application in this proceeding on March 31, 2006. That application sought to prohibit the Minister from issuing a NOC to Ratiopharm at any time before the expiration of the 493 Patent. Pfizer asserted that Ratiopharm's allegations were not justified.

[12] On April 5, 2006, Ratiopharm filed a motion for an Order dismissing Pfizer's application under section 6(5) of the NOC Regulations alleging that the 493 Patent was ineligible for listing on the Patent Register for Norvasc® (the April Motion). Subsequently, the Minister decided to suspend the reconsideration of the eligibility of the 493 Patent for listing until after the conclusion of the April Motion. The Minister informed Ratiopharm that in order for it to proceed with its proposed reconsideration of the filing of the 493 Patent, Ratiopharm would be required to withdraw its April Motion. In the result, Ratiopharm abandoned its April Motion without prejudice to its right to re-assert the allegations in its NOA.

[13] On June 2, 2006, after conducting a re-audit, the Minister determined that the 493 Patent did contain a claim to the medicine amlodipine and, accordingly, the 493 Patent was determined to be properly listed against Norvasc® on the Patent Register.

[14] A few days later, on June 9, 2006, the Federal Court of Appeal allowed Pfizer's appeal from the decision of Justice von Finckenstein with respect to the validity of the 393 Patent and prohibited the Minister from issuing a NOC to Ratiopharm with respect to amlodipine until the expiry of the 393 Patent on August 17, 2010.

[15] On June 22, 2006, Ratiopharm initiated this motion to dismiss Pfizer's 493 prohibition application and on July 6, 2006, Ratiopharm withdrew its application for judicial review of the Minister's decision until this motion was decided.

The 493 Patent

[16] Pfizer's 493 Patent was filed on August 21, 2001, based on a priority date of August 23, 2000. The patent application was laid open to the public on February 23, 2002 and is to be construed as of that date.

[17] The 493 Patent is titled "therapeutic compositions comprising excess enantiomer". The patent discloses that amlodipine is a well-known heart medication used in the treatment of hypertension and angina. Amlodipine is what is called a racemate which is a chemical composition made up of equal amounts of two molecular enantiomers (R+ and S-). It is a matter of prior art that the S- enantiomer of amlodipine had significant and beneficial calcium channel blocking properties and that amlodipine had the ability to release nitric oxide (NO). NO is a potent and beneficial vasodilator and inhibitor of platelet aggregation. The invention claimed by the 493 Patent was the discovery that the R+ enantiomer of amlodipine was responsible for the release of NO. This new knowledge and the corresponding ability to isolate or manipulate the R+ enantiomer may allow for more focussed treatment of patients who require an enhanced NO release.

[18] For the purposes of this proceeding, the parties agree that it is only claim 22 of the 493 Patent that is relevant and which must be construed. That claim reads:

> The R(+) enantiomer of amlodipine or a pharmaceutically acceptable salt thereof for use in the treatment of a condition for which a vascular NO-releasing agent is indicated.

[19] Pfizer has framed the construction issue in this proceeding at para. 34 of its Responding Motion Record as follows:

> 34. Section 4(2)(b) provides that a patent is eligible to be listed on the patent register if it contains a "claim for the medicine itself or a claim for the use of the medicine." There is no doubt that claim 22 of the 493 Patent is a claim for the R(+) enantiomer of amlodipine. The relevant question is whether the fact that it is *only* for the R(+) enantiomer, and not both the R(+) and S(-) enantiomers, means that it cannot be listed against Norvasc®.

[20] For its part, Ratiopharm says that claim 22 does not encompass the racemate amlodipine and, therefore, cannot be listed against Norvasc®. Put another way, it asserts that a generic version of Norvasc® cannot infringe claim 22 because that claim is limited to the single R(+) enantiomer and does not include the R(+) enantiomer as constituted in the racemate form.

[21] The construction issue thus framed by the parties is identical to the issue that was before the Court in *Pharmascience*, above, and in *Cobalt*, above. It is argued on behalf of Ratiopharm that the principle of judicial comity applies to Pfizer's underlying prohibition application and that I should, therefore, follow the decisions made by Justice Hughes in *Pharmascience* and in *Cobalt*. Both of those earlier cases involved applications brought by Pfizer for prohibition orders to prevent the issuance of NOC's to generic manufacturers (Pharmascience and Cobalt) where Pfizer asserted that its 493 Patent was properly listed against its heart medication, Norvasc®. In both cases, it was only the construction of claim

22 of the 493 Patent that required judicial consideration and, specifically, whether that claim included the use of the R+ enantiomer in the racematic formulation (ie. amlodipine). Justice Hughes found for the generic manufacturer in both cases and drew the following common conclusion found at para. 64 of the *Pharmascience* decision:

> The analysis as to "medicine" has been conducted based on the patent itself, its description and claims, and uncontradicted evidence. There is no serious controversy as to the law. While the analysis has been lengthy for clarity purposes the result is plain and obvious, the 493 patent should not be listed under the provisions of section 4(1) of the NOC Regulations as against the notice of compliance in question.

[22] Pfizer contends that, because the evidentiary record before me is different, I am not bound to apply the principle of comity to my construction of claim 22. For example, counsel for Pfizer points out that the Minister's decision by which it was determined that the 493 Patent was properly listed against Norvasc® was not before Justice Hughes. She also points to differences in the expert evidence tendered in those earlier cases from that which is before me. Comity, it was argued, is applied "only in relation to a pure question of law that is not informed by the evidence on the record".

[23] In considering whether the principle of comity applies, it is, therefore, necessary to examine the decisions from *Pharmascience*, above, and *Cobalt*, above.

The *Pharmascience* and *Cobalt* Decisions

[24] As in this case, the generic challengers in *Pharmascience*, above, and *Cobalt*, above, sought relief under section 6(5)(a) of the NOC Regulations. The Court was required to consider the standard of proof which applies to such a motion and, specifically, whether it required a finding that it was "plain and obvious" that the underlying prohibition application was futile or, alternatively, a finding that accorded with some lower standard. After reviewing the relevant authorities Justice Hughes defined the standard as follows at para. 16 in the *Pharmascience* decision:

> [16] Taking these matters into consideration I find that a section 6(5)(a) motion should be considered on the basis that if a determination can be made based on law and the application of uncontroverted relevant evidence or admissions or plain and obvious findings on the evidence, then the Court should proceed to make a determination. Section 6(5)(a) must have a purpose that is not trivial. However, if the Court finds itself determining the matter on disputed relevant evidence or having to weight the merits of competing expert opinion, the matter should be left to the hearing at trial. It is difficult to sum this up as simply "plain and obvious", it goes beyond that, but where the law can be applied to admissions and relevant evidence that is quite reasonably found to be undisputed or "plain and obvious" then the Court has a duty to make a determination.

The substantive issue before the Court in *Pharmascience* and in *Cobalt* was whether Pfizer's 493 Patent was properly listed on the Patent Register for Norvasc® in conformity with section 4 of the NOC Regulations. As in this case, Pfizer asserted only claim 22 of the 493 Patent in support of its infringement position.

[25] Justice Hughes was able to construe claim 22 without resorting to any extrinsic evidence and it was, accordingly, unnecessary for him to weigh the merits of the competing opinions of the expert witnesses. In *Pharmascience*, above, at para. 33, he duly noted that the issue of patent construction was a matter of law for the Court and he described the role of experts in the following terms:

> [33] It is apparent that in any seriously contested patent matter the parties will marshal experts on one side and the other, whose views as to construction of the claims will differ, favouring one party or the other. The Court will seek assistance from experts when needed to explain terms not readily apparent and to provide background, where needed, as to the concepts to be considered in the patent. In the final analysis however construction is a matter for the court alone, taking into consideration the whole of the description and claims and avoiding a strict "dictionary" approach to a claim.

[26] After a thorough analysis of the language of the 493 Patent, Justice Hughes reached the following conclusion at para. 54 of the *Pharmascience* decision:

> [54] To return to the construction of claim 22 which says:
>
> > The R(+) enantiomer of amlodipine or a pharmaceutically acceptable salt thereof for use in the treatment of a condition for which a vascular NO-release agent is indicated.
>
> and having in mind that principles expressed by the Supreme Court in *Whirlpool*, *supra*, it is plain and obvious that claim 22 does not refer to the racemate. Considering claim 22 in light of the description and the rest of the claims, as is required by *Whirlpool*, it is plain and obvious that what is claimed in claim 22 is a composition that comprises essentially only the R(+) enantiomer and that it is therapeutically effective in treating a condition in which NO-release is indicated. The patent expressly teaches away from

> the use of the racemate for treatment of a condition in which NO-release is indicated.
>
> [55] From the foregoing analysis it can be seen that whereas the uncontradicted evidence shows that the notice of compliance for NORVASC is directed to the racemate, claim 22 is directed to one of the enantiomers contained in the racemate, the R(+) enantiomer.

Judicial Comity

[27] The is no dispute that this case raises an identical issue of patent construction to the issues before the Court in *Pharmascience*, above, and in *Cobalt*, above, albeit that some of the extrinsic evidence bearing on the construction issue before me may differ somewhat from the evidence placed before Justice Hughes in those earlier proceedings. The question, then, is whether there is sufficient uniformity between the issues raised and resolved by Justice Hughes and the issues arising in this case to justify the application of the principle of judicial comity.

[28] The issue of judicial comity has arisen in the context of NOC proceedings. In *Aventis Pharma Inc. v. Apotex Inc.*, [2005] F.C.J. No. 1559, 2005 FC 1283 aff'd [2006] F.C.J. No. 208, 2006 FCA 64, Justice Anne Mactavish considered and applied the principle for the reasons set out at paras. 362 to 365:

> 362 In this case, Schering and Aventis urge me to follow Justice Snider's decision in *Pharmascience* as a matter of judicial comity. As was noted by Justice Richard, as he then was, in *Glaxo Group Ltd. v. Minister of National Health and Welfare* [1995] F.C.J. No. 1430, 64 C.P.R. (3d) 65 where he quoted the decision of the British Columbia Court of Appeal

in *Bell v. Cessna Aircraft Co.*, [1983] 149 D.L.R. (3d) 509 at p. 511, 36 C.P.R. 115:

> The principle of judicial comity has been expressed as follows:
>
> > The generally accepted view is that this court is bound to follow a previous decision of the court unless it can be shown that the previous decision was manifestly wrong, or should no longer be followed: for example, (1) the decision failed to consider legislation or binding authorities which would have produced a different result, or (2) the decision, if followed, would result in a severe injustice. The reason generally assigned for this approach is a judicial comity. While doubtless this is a fundamental reason for the approach, I think that an equally fundamental, if not more compelling, reason is the need for certainty in the law, so far as that can be established. Lawyers would be in an intolerable position in advising clients if a division of the court was free to decide an appeal without regard to a previous decision or the principle involved in it. [at p. 511]

363 Apotex submits that I should not follow Justice Snider's decision in *Pharmascience*, arguing that her decision was not one made *in rem*, and was dependent upon the nature of the evidence that was adduced before her. Rather, Apotex says, I should decide the double patenting issues before me on the basis of the evidence that was placed before me in this case.

364 I have carefully considered Apotex's argument as to why I should not follow Justice Snider's decision in *Pharmascience*. In considering this question, it is, I think, necessary to distinguish between Justice Snider's conclusions of law, which may be subject to the principle of comity, and her findings of fact, which will be dependent upon the nature of the evidence that was adduced before her.

> 365 In this case, Justice Snider found, as a matter of law, and evidently as a matter of first impression, that the operation of the concept of obviousness-type double patenting was not limited to cases involving the same patentees or inventors. While I have carefully considered the arguments advanced by Apotex in this regard, Apotex has not persuaded me that the decision of Justice Snider in this regard was manifestly wrong, and I proposed [sic] to follow it.

[29] In *Abbott Laboratories v. Canada (Minister of Health)*, [2006] F.C.J. No. 256, 2006 FC 120 rev'd on other grounds [2007] F.C.J. No. 233, 2007 FCA 73, Justice Sean Harrington also discussed the principle of judicial comity in the NOC context:

> [65] Judicial comity suggests that a judge of a lower court should exercise restraint when faced with a legal point previously decided by another member of that same Court. It is not an application of the rule of *stare decisis*, but a recognition that decisions of the Court should be consistent, so that there be some predictability. Mr. Justice Richard (as he then was) reviewed the authorities in the context of NOC proceedings in *Glaxo Group Ltd. v. Minister of National Health and Welfare et al.* (1995) 64 C.P.R. (3d) 65, supra, at paragraph 40. So did Madam Justice Dawson more recently in *Alfred v. Canada (Minister of Citizenship and Immigration)* 2005 FC 1134, [2005] F.C.J. No. 1391. She referred to Re *Hansard Spruce Mills Ltd.*, [1954] 4 D.L.R. 590 (BCSC), where Mr. Justice Wilson said:
>
> > "...I have no power to overrule a brother Judge, I can only differ from him, and the effect of my doing so is not to settle but rather to unsettle the law, because, following such a difference of opinion, the unhappy litigant is confronted with conflicting opinions emanating from the same Court and therefore of the same legal weight."
>
> [66] Mr. Justice Richard was of the view that previous decisions should be followed unless the Judge considered them to be clearly wrong. Madam Justice Dawson said she

> would only go against the decision of another Judge if a) a subsequent decisions have affected the validity of the impugned judgment; b) it has been demonstrated that some binding authority in case law and relevant Statute was not considered; or c) the judgment itself was unconsidered i.e. given where the exigencies required an immediate decision.

[30] I agree with counsel for Pfizer that the principle of judicial comity may not be readily applicable to prohibition proceedings brought under section 6(1) of the NOC Regulations. That can be so because even in cases which involve a common generic product and challenges to an identical patent, the allegations set out in the respective NOA's of the generic challengers, or the evidence the parties present, may be sufficiently different that disparate judicial outcomes are possible. This point is recognized in the recent decision in *Sanofi-Aventis Canada Inc. v. NovoPharm Limited et al.,* 2007 FCA 163, where, in a discussion concerning abuse of process, Justice Edgar Sexton observed at para. 50:

> … Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. However, where one generic has made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give rise to the possibility of an inconsistent result, this concern is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate.

The concern expressed above does not, however, apply where the issue for determination is one of patent construction. Inasmuch as this is an issue of law for the Court to decide, there should, in theory at least, be only one correct answer regardless of the expert evidence brought to bear upon it. This is particularly evident when one considers that the experts are speaking objectively for the notional person skilled in the art.

[31] In a case like this one, the principle of comity does apply because Justice Hughes' decisions in *Pharmascience*, above, and *Cobalt*, above, turn solely on his construction of claim 22 of the 493 Patent without any reliance upon or reference to the expert opinions offered by the parties. Justice Hughes was able to construe the patent by examining only its language and, in so doing, he has made a determination on an issue of law which is deserving of deference. In such a context it does not matter if the evidentiary record before me is different from that which was placed before Justice Hughes. If he was able to construe the patent without resorting to extrinsic evidence then comity dictates that I do the same, absent a finding that Justice Hughes was "manifestly wrong".

[32] I need not decide whether comity would apply if Justice Hughes had construed the patent with the aid of extrinsic evidence that differed from the record before me. But even in such a case, it seems to me that the Court should be cautious and generally loath to adopt an inconsistent construction of the same patent. The need for predictability and consistency with respect to construction questions dictates such an approach. Therefore, even if the principle of comity does not strictly apply, the need for consistency and predictability

remains. This point was made by Justice Judith Snider in *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2004), 32 C.P.R. (4th) 224, 2004 FC 204, [2004] F.C.J. No. 374 at para. 19:

> [19] As noted, the '376 patent has already been the subject of litigation between P&G and Genpharm prior to these proceedings. Accordingly, it seems appropriate to consider how this patent was construed in these previous decisions. Indeed:
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> > Where the Court has previously construed the same patent, particularly a construction upheld on appeal, the Court, in another proceeding involving different alleged infringers, would require strong argument to come to a different view. [Roger T. Hughes and John H. Woodley, "Patented Medicines -- Notice of Compliance" CD-ROM: Hughes and Woodley on Patents, Release 19, July 2003 (Markham: LexisNexis Canada Inc.) at s. 18A]

In *Almecon Industries Ltd. v. Anchortek Ltd.* (2001), 17 C.P.R. (4th) 74, 2001 FCT 1404, [2001] F.C.J. No. 1956 Justice Frederick Gibson made a similar point at para. 29:

> [29] In *Alsop Process Co. of Canada v. J.P. Friesen & Son*,12 (1917), 35 D.L.R. 353 (Ex. Ct.).12 Mr. Justice Cassels wrote at page 355:
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> > While the defendants in the present case may not be technically bound by the decisions in the cases to which I have referred, except as to questions of law, it would require a strong argument to induce me to come to a different view as to the construction of the specifications from that held by the House of Lords and these eminent Judges.

The same concern about the need to avoid repetitious litigation over identical issues in NOC prohibition proceedings was expressed by Justice Marshall Rothstein in *Hoffman-La Roche Ltd. v. Canada (Minister of Health)* (1998), 158 F.T.R. 135, [1998] F.C.J. No. 1706, where he dismissed the application on the ground of abuse of process.

[33] I have carefully considered the arguments advanced by Pfizer in an effort to convince me that the decisions made by Justice Hughes in *Pharmascience*, above and *Cobalt*, above were "manifestly wrong". While there is certainly another construction which could have been given to claim 22 of the 493 Patent, the interpretation adopted by Justice Hughes is sound and certainly not manifestly wrong.

[34] I also do not accept Pfizer's argument that Justice Hughes' decisions are wrong because they conflict with the Minister's policy of allowing a patent holder to list a patent on the Register for a single drug against a combination medicine, including the listing of an enantiomer against a racemate which contains it. If, as Justice Hughes has found, the subject patent does not, as a matter of construction, include a claim for the combination medicine, the patent should not be listed. This is not a question of whether the Minister may list a patent containing a single drug against a combination medicine. It is clear that the Minister may do so in appropriate cases. The question here (and the one before Justice Hughes) is whether the Minister's listing policy should have been applied to Patent 493 based on its proper construction.

[35] Pfizer also argued that Justice Hughes erred in law by failing to consider the expert evidence that had been tendered to assist with the construction of claim 22. It says that expert evidence is "essential" to the construction of all patent claims. For this, it relies upon a statement from *Novartis Pharmaceuticals Canada Inc. v. RhoxalPharma Inc.*, [2005] 3 F.C.R. 261, [2005] F.C.J. No. 283, 2005 FCA 11, where Justice Alice Desjardins said the following at para. 45:

> 45 Expert evidence, although essential to the construction of a claim, does not govern the construction of a claim. Claims construction is a question of law for the judge who is even entitled to adopt a construction of the claims that differs from that put forward by the parties (*Whirlpool Corp. v. Camco Inc. (Whirlpool)*, [2000] 2 S.C.R. 1067, at para. 61; *Canamould Extrusions Ltd. v. Driangle Inc.* (2004), 237 D.L.R. (4th) 157 , at para. 3, per Stone J.A.; *Nekoosa Packaging Corp. v. AMCA International Ltd.* (1994), 172 N.R. 387, at paras. 12, 13 and 14, per Robertson J.A.).
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> [Emphasis added]

I do not interpret this passage in the manner suggested by Pfizer. If the construction of a patent claim is a matter of law for the presiding judge who is entitled to adopt a construction that differs from that put forward by the parties and their experts, it stands to reason that the judge, in appropriate cases, can construe a claim without relying upon such evidence.

[36] I also think it likely that if Justice Desjardins had something more in mind on this issue, she would have given it more attention than is reflected in the above statement. My view of this is supported by the more limited interpretation of this passage which is set out in the dissenting decision of Justice Denis Pelletier at para. 65:

> 65 I agree with my colleague Desjardins J.A. that the construction of a patent is a task reserved to the trial judge, as opposed to the experts. Like her, I am bound by the jurisprudence which holds that the judge must construe the patent as it would be by a person skilled in the art and, to that end, the judge can hear evidence as to the meaning, to a person skilled in the art, of the words used in the patent. See *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, 2000 SCC 67, at para. 53 cited in para. 52 of my colleague's reasons.
>
> [Emphasis added]

[37] In short, I do not accept that Justice Hughes erred in law by construing claim 22 of the 493 Patent without resorting to the evidence of the expert witnesses.

[38] In the result, I find that the principle of comity applies and I would adopt the conclusion reached by Justice Hughes in his earlier decisions. Pfizer's 493 Patent should not be listed against Norvasc® and Ratiopharm's motion to dismiss Pfizer's application for a prohibition Order is granted.

Abuse of Process

[39] Ratiopharm also contends that Pfizer has abused the regulatory scheme by bringing its application for prohibition in this proceeding and it is seeking an Order to dismiss that application under section 6(5)(b) of the NOC Regulations. It is also on this basis that Ratiopharm seeks an enhanced Order for costs.

[40] Ratiopharm argues that Pfizer's application is devoid of merit and that it represents an abuse of process because it has blocked Ratiopharm's "right" to an earlier NOC for its generic version of Norvasc® after its initial successful challenge to the validity of Pfizer's 393 Patent before Justice von Finckenstein in *Pfizer Canada Inc. and Pfizer Limited v. Minister of Health and Ratiopharm Inc.*, above. But for the statutory stay favouring Pfizer obtained by bringing this proceeding, Ratiopharm says that it would have been on the market with its generic version of Norvasc® and the appeal of Justice von Finckenstein's decision would have been dismissed for mootness. Instead, the Federal Court of Appeal was able to consider the appeal from Justice von Finckenstein's decision on the merits and, in doing so, reversed that decision and upheld the validity of Pfizer's 393 Patent. That result prevents the issuance of a NOC to Ratiopharm for amlodipine until the expiry of the 393 patent in 2010.

[41] It seems to me that Ratiopharm's argument that Pfizer's conduct amounts to an abuse of process is somewhat incongruous resting, as it does, upon a decision that was later found to be wrong. In any event, I do not believe that a litigant can be faulted for taking full advantage of strategic advantages that are conferred by statute. Although the statutory stay that arises upon a section 6 prohibition application brought by a patent holder has been described as "draconian", that effect, by itself, cannot be the basis for criticism. The right of a patent holder to initiate such a prohibition application is also dependant upon its ability to convince the Minister to first accept the patent for listing and to keep it there. The Minister has no obligation to list a patent and presumably would not do so if it was believed that the

listing was frivolous or clearly contrary to the regulatory objectives. Even where a patent has been listed, it remains subject to removal if the generic manufacturer can make a convincing case for doing so. Here Ratiopharm did attempt to have the 493 Patent removed from the Patent Register for Norvasc® but ultimately it was unsuccessful. Having failed to convince the Minister, Ratiopharm filed a NOA and Pfizer responded with a prohibition application. Up to that point, it was not obvious that the listing of the 493 Patent against Norvasc® was legally untenable and certainly the Minister seems not to have thought so. It is largely with the benefit of hindsight and the delivery of Justice Hughes' reasons for dismissing Pfizer's prohibition applications in *Pharmascience*, above, and in *Cobalt*, above, that Ratiopharm argues that Pfizer's prohibition application is frivolous and an abuse of process.

[42] Even though Justice Hughes' reasons are persuasive, I do not believe that his conclusion is so obviously compelling that no other result could have been reasonably contemplated on the record before him or before me. In order to reach such a threshold, I believe that Ratiopharm would have to meet the test expressed by Justice Louis Pratte in *Creaghan Estate v. Canada*, [1972] F.C. 732 (T.D.) at page 736 or para. 6(3):

> 6(3) Finally, in my view, a statement of claim should not be ordered to be struck out on the ground that it is vexatious, frivolous or an abuse of the process of the Court, for the sole reason that in the opinion of the presiding judge, plaintiff's action should be dismissed. In my opinion, a presiding judge should not make such an order unless it be obvious that the plaintiff's action is so clearly futile that it has not the slightest chance of succeeding, whoever the judge may be before whom the case could be tried. It is only in such a situation

> that the plaintiff should be deprived of the opportunity of having "his day in Court".

In my view, Ratiopharm has not established that Pfizer's prohibition application would fairly fit within the above test when it was initiated. Even with the benefit of Justice Hughes' decisions on point, the fact that Pfizer continued its prohibition application is insufficient to establish an abuse of process. Pfizer has appealed those decisions and presumably it will do so in this case in an attempt to preserve its claim. In the face of those outstanding appeals, Pfizer was well within its rights to have this matter resolved on the merits as well.

[43] Finally, I would note that both parties have actively made use of the regulatory scheme whenever it might advance their respective commercial interests. Given the adversarial nature of the process and the highly competitive nature of this business, the judicial conduct of one party will inevitably carry adverse implications for the other. Such are the expected consequences of NOC litigation but it is only in the clearest of cases that such litigation conduct will warrant a finding of abuse of process. Accordingly, I reject Ratiopharm's argument that Pfizer's conduct in this proceeding represents an abuse of process.

[44] In conclusion, this motion is allowed. Pfizer's application for prohibition is struck out with costs payable to Ratiopharm.

ORDER

THIS COURT ORDERS that:

1. Ratiopharm's motion is allowed;

2. Pfizer's proceedings as they relate to Canadian Patent No. 2,355,493 are struck out; and

3. Ratiopharm is entitled to its costs.

"R. L. Barnes"
Judge

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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