Date: 20070628

Docket: A-580-06

Citation: 2007 FCA 251

CORAM: **NADON J.A.**
SEXTON J.A.
RYER J.A.

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

ABBOTT LABORATORIES LIMITED, TAP PHARMACEUTICALS INC.,
THE MINISTER OF HEALTH and
TAKEDA PHARMEUTICAL COMPANY LIMITED

Respondents

Heard at Toronto, Ontario, on June 27 and 28, 2007.

Judgment delivered from the Bench at Toronto, Ontario, on June 28, 2007.

REASONS FOR JUDGMENT OF THE COURT BY: NADON J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on June 28, 2007)

NADON J.A.

[1] This is an appeal by the appellant Novopharm Limited from a decision of von Finkenstein J. of the Federal Court, 2006 FC 1411, dated November 21, 2006, who allowed the application of the respondents Abbott Laboratories Limited and TAP Pharmaceuticals Inc. ("Abbott"), under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

("NOC Regulations"), for an order prohibiting the Minister of Health (the "Minister") from issuing a NOC to Novopharm for Lansoprazole (the "drug") in 15mg or 30 mg delayed release capsules for oral administration until after the expiry of Canadian patent no. 2,009,741 (the " '741 patent").

[2] At issue in these proceedings is the drug Lansoprazole in respect of which the respondent Takeda Pharmaceutical Company Limited ("Takeda") obtained Canadian patent no. 1,255,314 (the " '314 patent") which expired on June 6, 2006.

[3] In March 1999, Takeda was issued the '741 patent for a new use of Lansoprazole.

[4] The '314 patent was issued in respect of Lansoprazole to treat excess gastric secretions which were believed to cause gastric and duodenal ulcers. Such use of Lansoprazole is referred to as the "old use".

[5] The subsequent scientific discovery that most ulcers were in fact caused by a bacterium called *Helicobacter pylori* ("H. pylori") led to a new treatment approach based on antibacterial drugs. As a result, the '741 patent was issued in respect of a "new use" for Lansoprazole as an antibacterial agent to treat and prevent infectious diseases, i.e. ulcers caused by H. pylori.

[6] A NOC for the new use of Lansoprazole under the name PREVACID was issued to Abbott on April 7, 1998.

[7] Because it was seeking the issuance of a NOC for its generic formulation of delayed release capsules in 15mg and 30mg strengths, in regard to which it claimed bioequivalence to PREVACID, which would allow the sale thereof in Canada, Novopharm was obliged, pursuant to subsection 5(1) of the Regulations, to serve on the respondent Abbott a Notice of Allegation (a "NOA") wherein it alleged that its formulation of Lansoprazole, NOVO-LANSOPRAZOLE, would not infringe the '741 patent. Specifically, Novopharm asserted that its drug would not be made, constructed, used or sold as an antibacterial composition or for the treatment of H. pylori infections.

[8] Following the service of Novopharm's NOA, Abbott commenced the application which resulted in von Finkenstein J. concluding that Novopharm's allegations of non infringement were not justified and that, hence, an order of prohibition should be issued in respect of Novopharm's NOVO-LANSOPRAZOLE until the expiry of the '741 patent.

[9] In making his order, the judge construed the '741 patent, as he was bound to, and made a number of findings regarding the issue of infringement.

[10] First, he construed the patent and, in particular, claim 16 thereof. After a brief review of the Supreme Court of Canada's decisions in *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, and *Free World Trust v. Electrosanté Inc.*, [2000] 2 S.C.R. 1024, in which the Supreme Court sets out the principles relevant to claim construction, the judge turned to the expert evidence adduced by the parties which he assessed in the light of their respective submissions.

[11] This led the judge to conclude that claim 16 was a claim for the antibacterial use of Lansoprazole alone or in combination with other drugs to prevent infectious diseases caused by H. pylori.

[12] The judge then turned to the question of infringement, i.e. whether Novopharm would infringe claim 16 if it made, constructed, used or sold its NOVO-LANSOPRAZOLE.

[13] After a careful review of the evidence and, in particular of Novopharm's proposed product monograph for its NOVO-LANSOPRAZOLE and its proposed bottle label, the judge concluded, *inter alia*, that:

- Novopharm's product monograph will induce and encourage physicians to prescribe NOVO-LANSOPRAZOLE to treat ulcers caused by H. pylori.
- Novopharm's bottle label will induce or encourage physicians to prescribe NOVO-LANSOPRAZOLE to treat ulcers caused by H. pylori.

[14] By reason of these findings, the judge concluded that claim 16 of the '741 patent would be infringed if the Minister issued a NOC to Novopharm for its NOVO-LANSOPRAZOLE.

[15] In a postscript to his Reasons, the judge pointed out that following the hearing of the prohibition application, Novopharm referred him to the Supreme Court of Canada's recent decision in *Astrazeneca Canada Ltd. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, in support of the proposition that since the new use of Lansoprazole, i.e. as an antibacterial agent, was not an

approved use of PREVACID, it did not incorporate the invention found in the ‘741 patent. Consequently, in Novopharm’s view, it had not “early worked” the ‘741 patent in submitting its Abbreviated New Drug Submission (“ANDS”) and, as a result, the NOC Regulations did not require it to make reference to the ‘741 patent.

[16] The judge held that Novopharm’s submissions would not be considered because the point had not been raised by Novopharm in its NOA nor, for that matter, in its Memorandum of Fact and Law.

[17] Novopharm challenges the judge’s decision on a number of counts. First, it says that the judge erred in law in failing to properly construe claim 16 in that:

1. he omitted an essential element of the claim, i.e. its antibacterial use and, as a result, he construed to claim to cover the *per se* use of Lansoprazole to prevent an ulcer caused by excess gastric secretions (the old use), and
2. he incorrectly construed the claims of the patent to include the use of Lansoprazole when administered with other drugs.

[18] In our view, the judge made no such error. At paragraph 23 of his Reasons, he adopted the point of view put forward by Dr. Armstrong, one of Abbott’s expert witnesses, who said;

> [23] Point a) is conclusively dealt with by the testimony of Abbott’s witness, Dr. Armstrong, who observed:
>
> > 27. In 1990 there were no data, and there are none today, to support any suggestion that taking Lansoprazole can prevent a patient from acquiring an H. pylori infection. This is an important medical fact which given background to the meaning

> of "treating and preventing". No person of ordinary skill in the art, reading the patent in 1990, would have concluded that Lansoprazole was being described for use in preventing an H. pylori infection. For this reason, among others, such a person would also understand, necessarily, that claim 16 cannot be directed at preventing or treating H. pylori infections (as Dr. Graham has it) but is clearly directed at preventing the diseases that such infections cause – ulcers.
>
> 28. A person with ordinary skill in the art reading the patent as a whole would understand that the invention relates to the antibacterial ability of Lansoprazole to prevent the diseases caused by H. pylori and that it is not limited to eradication of H. pylori or directed to the prevention of H. pylori infections from occurring.
>
> (Reply Affidavit of Dr. David Armstrong, AR, Vol III at 527.)

[19] This makes it clear that the judge's construction of the claim is that it pertains to the use of Lansoprazole as an antibacterial agent to prevent the diseases caused by H. pylori and that he did not confuse the old use of Lansoprazole found in the '314 patent with its new use found in the '741 patent.

[20] In our view, the judge also made no error in holding that the claim did not exclude the use of Lansoprazole with other drugs. In so holding, he relied, *inter alia*, on the evidence of Drs. Sekar and Saibil, two of Novopharm's expert witnesses, and on that of Dr. Fass, an Abbott expert witness.

[21] The judge clearly understood the principles of claim construction and he applied them, correctly in our view, in the light of the expert evidence available to him. As a result, we fail to see how it can be said that the judge's construction is in error.

[22] Consequently, we conclude that the judge properly construed the patent. Novopharm's submissions on this point are therefore dismissed.

[23] With respect to the judge's findings that its product monograph and its bottle label will cause or induce infringement to occur, Novopharm makes the following points. It says that the judge made an unreasonable or incorrect application of this Court's decisions in *A.B. Hassle, Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 229, and *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2006 FCA 357, which required him to examine the intentions and activities of the generic manufacturer so as to determine whether there was inducement to infringe. In our view, the judge clearly understood the principles set by these cases and made no error in applying them.

[24] Novopharm also says that there was no evidence before the judge which could lead him to conclude that its product monograph and bottle label would induce or encourage physicians to prescribe NOVO-LANSOPRAZOLE to patients for the new use. First, Novopharm says that its product monograph does not include, contrary to that of PREVACID, any reference to H. pylori or triple therapy, i.e. the new use.

[25] Second, it says that there is nothing in its product monograph that could influence physicians to prescribe its NOVO-LANSOPRAZOLE as an antibacterial agent for the prevention of H. pylori. To the contrary, it submits that its product monograph makes it clear that the conditions to be treated with its drug product are limited to conditions pertaining to the reduction of gastric acid secretions.

[26] The judge did not accept Novopharm's contentions. At paragraphs 40 to 42 of his Reasons, after a careful review of the evidence, including the expert evidence, he sets out his rationale for concluding that Novopharm's product monograph would induce infringement:

> [40] Admittedly, Dr. Graham also points out that: a) physicians rarely look at a PM when making a prescription; and b) that a pharmacist might, when filling out the prescription, note that Novo-Lansoprazole has no indication for triple therapy use. This however, does not detract from the fact that the Novopharm PM is set up in such a way that, by his own admission, it can be seen to be a prescription of Novo-Lansoprazole for triple therapy which would be an encouragement to infringe claim 16 of the 741 patent.
>
> [41] Given the expert testimony that ulcers caused by something other than H. pylori, NSAID's or Zollinger-Ellison Syndrome are extremely rare, it is hard to understand why the reference to duodenal and gastric cancer is on the Novopharm PM and why it occupies the first two bullets.
>
> [42] Accordingly, I find, based on the testimony of Novopharm's most renowned witness, that on a balance of probabilities the Novopharm PM would induce a physician to prescribe Novo-Lansoprazole for a triple therapy to fight H. pylori-caused infections.

[27] In our view, this conclusion was open to the judge on the evidence before him and Novopharm has not persuaded us that in so finding, the judge made an overriding and palpable error.

[28] Novopharm makes a similar argument regarding the judge's finding with respect to the bottle label. It says that there was no evidence to support a finding that by reason of the information appearing on its bottle label, it would induce infringement by physicians or anyone else.

[29] The judge carefully examined the label and the evidence of the experts and, in particular, the evidence of Drs. Sekar and Armstrong. This led him to the following conclusion at paragraph 47 of his Reasons:

> [47] The Court is driven to the conclusion that the inclusion of the amount, the frequency and the duration of the dosage for triple therapy on the label for Novo-Lansoprazole under the rubric 'Adult dosage' and the absence of any other clinically indicated use for that dosage, on the balance of probabilities, will have the effect of inducing or encouraging physicians to prescribe Novo-Lansoprazole for triple therapy.

[30] Novopharm says that that conclusion is untenable and that it constitutes an overriding and palpable error. We cannot agree. We are satisfied that, on the evidence before him, it was open to the judge to conclude as he did.

[31] In the end, what Novopharm is really asking us, in effect, is to reassess the evidence in a light more favourable to it. That we cannot do, absent an overriding and palpable error on the part of the judge.

[32] Two further matters remain for consideration.

[33] The first one is an issue of unfairness. Novopharm says that the issue of inducement by reason of its product monograph and bottle label was not pleaded nor put in play by Abbott in its Notice of Application. It says that the issue only appeared when Abbott, following the cross-examinations of the experts, raised it for the first time in its written submissions to the judge.

[34] Although Novopharm protested against this in its written submissions, it never argued or took the position that allowing Abbott to raise the issue at a late stage was prejudicial and that it required, if the issue was allowed to proceed, leave to adduce additional expert evidence in response.

[35] We are all agreed that it is now too late for Novopharm to take the position that the judge erred in allowing Abbott to raise the issue and, accordingly, in deciding the matter on Abbott's behalf on the ground of inducement.

[36] The last issue arises by reason of the Supreme Court of Canada's decision in *Astrazeneca*, *supra*. It will be recalled that Novopharm submitted that decision to the judge prior to the rendering of his decision and that the judge refused to consider Novopharm's arguments.

[37] Novopharm says that the judge erred in so deciding, since *Astrazeneca* was determinative of the matter. We do not agree.

[38] First, whether Novopharm was obliged by the NOC Regulations to compare its drug to PREVACID and to address the patents listed in regard to the relevant NOC was a matter for the Minister. Consequently, Novopharm ought to have raised the issue with the Minister and, if met with an unfavourable decision, it was open to it to challenge the Minister's decision by way of judicial review.

[39] Second, if it was open to Novopharm to raise the issue in the proceedings commenced by Abbott, we, like the judge, are of the view that Novopharm was obliged to raise the matter in its NOA, which it did not. We are therefore satisfied that the judge made no reviewable error on this point.

[40] Consequently, notwithstanding Mr. Godfrey's most forceful arguments, Novopharm's appeal will be dismissed with costs.

"M. Nadon"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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