BEWARE OF OVERCLAIMING, FEDERAL COURT OF CANADA WARNS

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INTRODUCTION

The Applicant's application for a writ of prohibition preventing the Canadian Minister of National Health and Welfare from issuing a Notice of Compliance to the Respondent in respect of anti-depression medication was denied, the Court having ruled that the Respondent's allegations that the proposed drug would not infringe the Applicant's patents were sufficient. (*Biovail Pharmaceuticals Inc. et al v. Minister of National Health and Welfare at al*, (2005) F.C.J. No. 7, Harrington J., January 6, 2005)

BACKGROUND

This case relates to the Patented *Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("NOC Regulations").

When a generic drug manufacturer wishes to obtain a Notice of Compliance ("NOC"), it can, instead of filing a New Drug Submission, compare its proposed drug to an existing drug. In the present case, the Applicant, Biovail, had obtained a NOC for its anti-depression drug Wellbutrin® SR and the Respondent, Novopharm, compared its proposed drug, also for the treatment of depression, to Biovail's Wellbutrin® SR drug.

Biovail had previously filed a list of its patents relating to Wellbutrin® SR pursuant to the NOC Regulations. In accordance with said NOC Regulations, Novopharm had no alternative but to file a Notice of Allegation ("NOA") in respect of all of Biovail's disclosed patents, failing which the Minister of National Health and Welfare ("Minister") would not issue a NOC. In its NOA,

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Novopharm alleged, in respect of Biovail's patents, that its proposed drug did not infringe said patents, and that the patents were not valid. Biovail in turn filed an application to the Federal Court of Canada for a writ of prohibition to prevent the Minister from issuing a NOC to Novopharm.

As in all cases relating to patents, the Court must first interpret the patent(s) in suit to determine the scope of the invention. The Court will then decide whether the first drug manufacturer's application for a writ of prohibition is substantiated. It should be noted that in such NOC proceedings, the Court's finding of infringement and/or invalidity does not constitute *res judicata*. A patentee is therefore always free to litigate a "regular" patent infringement action against the generic drug maker if the latter is allowed to commercialize the generic drug.

THE FACTS

Biovail's drug contains an ingredient, HPMC, which serves in the release of the medicine; Novopharm's proposed drug contains a different ingredient, HPC, a derivative of HPMC that serves the same purpose. In its application for a writ of prohibition, Biovail argued that Novopharm's NOA was insufficient and that the proposed generic drug would infringe its patents. Novopharm in addition alleged that Biovail's patents were invalid.

The Court therefore had to decide the following: "The only question is whether the Court should grant an order prohibiting the Minister from issuing Novopharm a NOC until after the expiration of one or both of the two underlying patents". In other words, if the Court found the patents to be valid and infringed, then a NOC cannot issue. However, if the Court found that the patents are not infringed or invalid, then a NOC may be issued to Novopharm.

THE FEDERAL COURT JUDGEMENT

Justice Harrington began his analysis by interpreting the patents in suit, in accordance with the teachings of the Supreme Court of Canada concerning the proper way to construe patent claims (*Free World Trust v. Électro-Santé Inc.*, (2000) 2 S.C.R. 1024 and *Whirlpool Corp. v. Camco Inc.*, (2000) 2 S.C.R. 1067).

In respect of the first patent, the Court was asked to determine whether HPMC, the substance used by Biovail for the controlled release of the medicine, was essential to the working of the invention, or if a variant could

be substituted without making any material difference. After hearing the expert evidence of the parties, the Court concluded that HPMC, the substance described in Biovail's first patent, was an essential element of the invention and that no variant, such as HPC used in Novapharm's drug, had been contemplated by the inventor. The Court ruled that a literal interpretation of the claims excluded HPC as a permissible variant, and in addition, the intent of the inventor showed that HPMC was essential and therefore, all variants would fall outside of the claims. The Court ruled that the first Biovail patent would not be infringed if a NOC was issued to Novopharm. Justice Harrington therefore concluded that Biovail's assertion that the allegations of Novopharm's NOA in respect of that patent were insufficient should fail.

In respect of the second patent, which related generally to a chemical composition allowing the release of the active ingredients of the drug, Novopharm had alleged in its NOA that not only was this patent not infringed, but also that the patent was so broad in scope that it was invalid. The Court, in order to construe the claims in an informed and purposive way, referred to the disclosure. Justice Harrington, with the assistance of the expert evidence, concluded hat the inventor intended only one means of release of the medicine, namely through "an osmotic pressure system". The process described in Novopharm's drug submission was a "hydrogel process" which, according to Justice Harrington, and all of the experts, was a completely different system than the one described in the patent and therefore, Biovail's second patent was not infringed.

However, the Court also ruled that if the claims were to be interpreted more broadly, i.e. that Novopharm's "hydrogel process" could be included in Biovail's "osmotic process", then Biovail's second patent would be invalid for "covetous claiming". Justice Harrington writes: "If the inventor claims more than he should, he loses everything. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. (…) The disclosure teaches us nothing about sustained release through a hydrogel process, the process to be used by Novopharm."

In light of its findings, the Court dismissed Biovail's application for a writ of prohibition, with costs.

CONCLUSION

Although this decision relates to the particulars of a NOC proceeding, the Court's thorough application of the Supreme Court teachings is of much interest to patent agents and attorneys alike. Patent construction is of the

utmost importance and the Courts will not hesitate to consider a patent unenforceable if its claims are too broad in scope.

As stated by the Supreme Court of Canada: "The claims are to be read in an informed and purposive way to permit a fairness and predictability and to define the limits of the monopoly. Ingenuity of the patent lies not in the identification of the desired result but in teaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desired result" (*Free World Trust v. Électro-Santé Inc.*, (2000) 2 S.C.R. 1024, paragraphs 31-32).