

## RESOURCE CENTRE

### INTERNATIONAL TRADE LAW



#### If at First You Don't Succeed... October 30, 2006

##### October 2006 Patents

On October 17, 2006, Justice Hughes delivered Reasons for Judgment in *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited*.<sup>[1]</sup> a patent infringement action brought in respect of the drug levofloxacin. Justice Hughes found Canadian Patent No. 1,304,080 (owned by Daiichi and licensed to Janssen-Ortho) valid and infringed by Novopharm's levofloxacin product. This decision is significant for several reasons.

#### LOSE THE NOC PROCEEDING, WIN THE INFRINGEMENT ACTION

The Plaintiffs' success in the infringement action was preceded by their failure to obtain a prohibition order against Novopharm in the context of a proceeding under the *Patented Medicines (Notice of Compliance) Regulations*.<sup>[2]</sup> In the NOC proceeding, Justice Mosley, who did not have the advantage of live witness testimony, found Novopharm's allegation of obviousness to be "justified" and accordingly, declined to grant a prohibition order. Novopharm subsequently obtained a notice of compliance and began selling its levofloxacin product. The Federal Court of Appeal dismissed the innovators' appeal from the NOC proceeding decision on the basis of mootness, as the notice of compliance had been issued by the time of the hearing.<sup>[3]</sup>

Mr. Justice Hughes' decision affirms the notion that a patentee who has been unsuccessful in an NOC proceeding can still be successful in a patent infringement action in respect of the same patent. It also underscores the differing burdens and standards of proof between NOC proceedings and patent infringement actions, and the oft-cited principle that findings in NOC proceedings do not constitute *res judicata* for the purposes of other proceedings.

#### 10 FACTOR TEST FOR OBVIOUSNESS

In his Reasons, Justice Hughes set out a "new" test for obviousness wherein he considered ten factors:

- 1) What is the invention as claimed?
- 2) Who is the person skilled in the art to whom the patent is addressed?
- 3) What body of knowledge and information would the ordinary person skilled in the art be expected to have, or to be reasonably able to obtain, as of the date of the alleged invention?
- 4) What was the climate in the relevant field at the time the alleged invention was made?
- 5) What motivation existed at the time the alleged invention was made to solve a recognized problem?
- 6) What effort and time was involved? Were the efforts randomized or focused?
- 7) Commercial success [a secondary factor].
- 8) Subsequently recognized advantages [a secondary factor].
- 9) Meritorious awards [a secondary factor].
- 10) Hindsight [a secondary and potentially dangerous factor].

Applying these factors to the facts of the case, Justice Hughes determined that Novopharm had failed to prove on a balance of probabilities that the invention was obvious and, accordingly, upheld the validity of



the patent.

## EXPERT TESTIMONY AND THE USE OF LEGALESE

The decision also serves as a caution on the use of legal terminology in expert testimony. Justice Hughes observed that one expert's use of phrases such as "motivated" and "worth a try" negatively affected his assessment of the witness and the weight accorded to that witness's testimony.

## REDUCED AVAILABILITY OF EQUITABLE RELIEF

Mr. Justice Hughes refused to grant an election of an accounting of the Defendant's profits on the basis that a party seeking an equitable remedy, such as profits, must show some basis for the exercise of equity. Justice Hughes found that the Plaintiffs had made no such showing, and reasoned that he had no basis to award such relief. In contrast, in *Wellcome Foundation Ltd. v. Apotex Inc.*,<sup>[4]</sup> Justice MacKay took the position that a successful plaintiff should be allowed to elect an accounting of the defendant's profits unless there is some reason to refuse that election.

Mr. Justice Hughes granted an injunction forcing the Novopharm product off the market, even though the Court had allowed it onto the market in the NOC proceeding. Other relief awarded included damages, pre- and post-judgment interest, destruction/delivery-up (at the choice of the Defendant) and costs.

The parties have until November 17, 2006 to appeal the decision.

Kavita Ramamoorthy

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[1]. 2006 FC 1234.

[2]. *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited and the Minister of Health*, 2004 FC 1631, (2005), 35 C.P.R. (4th) 353.

[3]. *Janssen-Ortho Inc. and Daiichi Pharmaceutical Co., Ltd. v. Novopharm Limited and the Minister of Health*, 2005 FCA 6, (2005), 40 C.P.R. (4th) 1.

[4] (1992), 40 C.P.R. (3d) 361 at 369 (F.C.T.D.), rev'd in part but not on this point 60 C.P.R. (3d) 135 (F.C.A.), leave to appeal to S.C.C. refused 62 C.P.R. (3d) vi.

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The purpose of this document is to provide information as to developments in the law. It does not contain a full analysis of the law nor does it constitute an opinion of Ogilvy Renault LLP or any member of the firm on the points of law discussed.

For further information, please contact one of the following lawyers:

### Toronto

|                      |                |  |
|----------------------|----------------|--|
| Patrick E. Kierans   | (416) 216-3904 | <a href="mailto:pkierans@ogilvyrenault.com">pkierans@ogilvyrenault.com</a>         |
| Donald M. Cameron    | (416) 216-4868 | <a href="mailto:dcameron@ogilvyrenault.com">dcameron@ogilvyrenault.com</a>         |
| Jason C. Markwell    | (416) 216-2977 | <a href="mailto:jmarkwell@ogilvyrenault.com">jmarkwell@ogilvyrenault.com</a>       |
| Kavita Ramamoorthy   | (416) 216-4097 | <a href="mailto:kramamoorthy@ogilvyrenault.com">kramamoorthy@ogilvyrenault.com</a> |
| R. Scott MacKendrick | (416) 216-4090 | <a href="mailto:smackendrick@ogilvyrenault.com">smackendrick@ogilvyrenault.com</a> |

### Montréal

|                    |                |  |
|--------------------|----------------|--|
| Judith M. Robinson | (514) 847-4608 | <a href="mailto:jrobinson@ogilvyrenault.com">jrobinson@ogilvyrenault.com</a> |
| George R. Locke    | (514) 847-4681 | <a href="mailto:glocke@ogilvyrenault.com">glocke@ogilvyrenault.com</a>       |
| Brian R. Daley     | (514) 847-4764 | <a href="mailto:bdaley@ogilvyrenault.com">bdaley@ogilvyrenault.com</a>       |

### Ottawa

|                   |                |  |
|-------------------|----------------|--|
| Kenneth E. Sharpe | (613) 780-8618 | <a href="mailto:ksharpe@ogilvyrenault.com">ksharpe@ogilvyrenault.com</a> |
|-------------------|----------------|--|

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