

# Federal Court Decision on HMRC Judicial Review Applications

## *Hoechst Marion Roussel Canada Inc. v. Attorney General of Canada* 2005 FC 1552

On November 17, 2005, the Federal Court issued a decision with respect to two judicial review applications filed by Hoechst Marion Roussel Canada Inc. (“HMRC”). HMRC was seeking to set aside the decisions of the Patented Medicine Prices Review Board (“PMPRB”) on the basis that the PMPRB was without jurisdiction to inquire into the pricing of the Nicoderm patch because:

- (1) The overlapping functions of the PMPRB as investigator, prosecutor and adjudicator create a reasonable apprehension of bias;
- (2) The manner in which the PMPRB proceeded by making determinations prior to the issuance of the Notice of Hearing denied the Respondent a reasonable opportunity to be heard and gives rise to a reasonable apprehension of bias;
- (3) Nicoderm is not a medicine for the purposes of section 83 of the *Patent Act*;
- (4) Patent No 1,331,340 (“’340 Patent”) and Patent No 1,338,700 (“’700 Patent”) do not pertain to the medicine;
- (5) The PMPRB cannot assert jurisdiction on the basis of Canadian Patent Applications.

On the issues dealing with the structure and manner of proceeding of the PMPRB, the Federal Court found that the PMPRB, as an administrative tribunal with economic regulatory functions, must be accorded a degree of flexibility and as such may perform multiple overlapping functions without creating a reasonable apprehension of bias. Furthermore, the Federal Court was of the view that the Board ought to be granted “a considerable degree of flexibility” in respect of its

procedural requirements and as such found that natural justice and procedural fairness had been respected.

With respect to the issue of whether Nicoderm is a medicine, the Federal Court, relying on the Federal Court of Appeal in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 (F.C.A.) (“ICN”), found that, as the word “medicine” was to be interpreted broadly and in its ordinary meaning, Nicoderm fell within the definition of “medicine”. The Federal Court, again relying on ICN, found that both Patents ‘700 and ‘340 did pertain to the medicine when applying the “merest slender thread” interpretation as articulated by the Federal Court of Appeal, and that a patent may pertain to the medicine even though it is not being used.

The Federal Court, however, dealing with the issue of patent applications found that, as a patent application gives rise only to a potential grant of patent, the PMPRB was not authorized to assert jurisdiction until the patent issued.

No appeal having been filed in the Federal Court of Appeal, this matter will be remitted to the Board. The Federal Court decision is available on our Web site under Publications; Hearings; Nicoderm.

Patentees will be interested to know that the HMRC decision does not affect the Board’s present policy on patent pending, which is to assert jurisdiction retroactively to review the price at which the medicine was sold during the pre-grant infringement period, **once the patent issues.** ■

The Board issued a Notice of Hearing in April 1999 in the matter of Hoechst Marion Roussel Canada and its medicine Nicoderm. HMRC brought a motion for an order that the Board rescind the Notice of Hearing on the grounds that the Board was without jurisdiction to inquire into the matter raised in the Notice. The Board issued its decisions on the matters raised on August 3, 1999 and August 8, 2000 respectively. HMRC brought two judicial review applications seeking to set aside both of the Board’s decisions.

Nicoderm is a transdermal nicotine patch. It is indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.