

Gilead Leave to Appeal to Supreme Court of Canada dismissed re: FCA Decision Not to List Patent on Register Due to Lack of Product Specificity Under PM(NOC) Regulations

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In *Gilead Sciences Canada Inc. v. Canada (Minister of Health)*, 2012 FCA 254, the Federal Court of Appeal (FCA) dismissed Gilead's appeal of the Minister's decision not to list Canadian Patent No. 2,512,475 (the '475 Patent) on the patent register. In the Minister's view, the '475 Patent failed to meet the requirements of the *Patented Medicine (Notice of Compliance) Regulations* (PM(NOC)) because it did not specifically claim all the medicinal ingredients in the New Drug Submission (NDS).

The '475 Patent specifically claimed two of three medicinal ingredients, but claimed the third as an unnamed agent selected from a class, rather than the actual ingredient. In his final decision, the Minister wrote, "a patent containing claims for a formulation cannot 'match' the approved formulation [in the NDS or NOC] unless both formulations explicitly contain all of the same medicinal ingredients." Classes of ingredients therefore failed to meet the "matching requirement" due to a lack of product specificity, and the '475 Patent could not be listed. This decision was upheld by Justice Mosley of the Federal Court under paragraph 4(2)(b) of the PM(NOC).

The FCA held that Justice Mosley should have construed the '475 Patent claims and then interpreted paragraphs 4(2)(a) and (b) of the PM(NOC) to determine under what paragraph the claims best fit. The FCA concluded that paragraph 4(2)(a) was the most appropriate, as the claims were for a new combination of chemically-stable medicinal ingredients. Citing *Purdue Pharma v. Canada (Attorney General)*, 2011 FCA 132, the Court noted that without specific and exact matching between patent claims and an approved NOC, a patent will not be eligible for listing on the register due to a lack of product specificity as required by paragraph 4(2)(a) of the PM(NOC). The Court dismissed Gilead's appeal. Gilead's leave to appeal to the Supreme Court of Canada has been dismissed without costs.