

**FEDERAL COURT HOLDS THAT FORMULATION PATENTS MUST CLAIM ALL MEDICINAL INGREDIENTS IN ORDER TO BE ELIGIBLE FOR LISTING [YAZ (DROSPIRENONE/ETHINYL ESTRADIOL)]**

<b>CASE:</b>	<i>Bayer Inc. v. Canada (Minister of Health) et. al. (Federal Court)</i>
<b>DRUG:</b>	<i>YAZ (drospirenone/ethinyl estradiol)</i>
<b>NATURE OF CASE:</b>	<i>PM(NOC) Regulations: Patent Listing – s. 4(2)(b)</i>
<b>SUCCESSFUL PARTY:</b>	<i>Minister of Health</i>
<b>DATE OF DECISION:</b>	<i>November 17, 2009</i>

**SUMMARY:**

On November 17, 2009, Justice Russell of the Federal Court dismissed Bayer Inc.'s application for judicial review of the Minister of Health's decision that Canadian Patent No. 2,194,979 (the "979 Patent") was ineligible for listing on the Patent Register. The Court held that where the approved product contains a formulation with more than one medicinal ingredient, only patents which claim formulations containing all of the approved medicinal ingredients may be listed on the Patent Register pursuant to s. 4(2)(b) of the *PM(NOC) Regulations* (the "*Regulations*").

Bayer filed a New Drug Submission for its product YAZ, a "combination oral contraceptive", which contains a low dose of the progestin drospirenone and a low dose of the estrogen ethinyl estradiol. Bayer sought to list the '979 Patent against YAZ on the Patent Register pursuant to s. 4(2)(b) of the *Regulations*. The '979 Patent claims compositions containing ethinylestradiol which help prevent the degradation of ethinylestradiol. The '979 Patent does not claim any compositions which include drospirenone. Nonetheless, Bayer provided evidence that the YAZ formulation would fall within the claims of the '979 Patent and the addition of drospirenone to the claimed composition would not alter or affect the composition.

On March 11, 2009, the Minister rendered a final decision that the '979 Patent was ineligible for listing as it did not claim a formulation containing all of the medicinal ingredients which were approved through the issuance of the NOC. Bayer then commenced an application for judicial review on the basis that the Minister erred in its interpretation of s. 4(2)(b) of the *Regulations*. Specifically, Bayer argued that the Minister's interpretation of s. 4(2)(b) is inconsistent with the Minister's interpretation of s. 4(2)(a). In particular, the Health Canada Guidance Document regarding the *Regulations* explains that, pursuant to s. 4(2)(a), a compound patent claiming one medicinal ingredient can be listed against a drug that contains that medicinal ingredient in combination with other medicinal ingredients. Bayer further submitted that the Minister's interpretation is inconsistent with the prevention of patent infringement, which is a fundamental objective of the *Regulations*.

In upholding the Minister's interpretation, Russell J. found that the plain and obvious meaning of s. 4(2)(b) is that the claimed formulation must contain all of the medicinal ingredients as it is the formulation which must have been approved. Justice Russell further found that no inconsistency exists between the Minister's interpretation of s. 4(2)(a) and s. 4(2)(b) of the *Regulations*. As "the essence of a compound patent is the medicinal ingredient" and "the essence of a formulation patent is the mixture of ingredients", different approaches must be taken when matching a patent with an approved product under each subsection. Finally, Russell J. dismissed Bayer's arguments concerning patent infringement as it is fully recognized that not all patents will be protected by the operation of the *Regulations* and that some patent infringement may occur.

**LINK TO DECISION:**

[Bayer Inc. v. Canada \(Minister of Health\), 2009 FC 1171.](#)

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