Enantiomers Not Eligible for Data Protection in Canada

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Authors: Noel Courage and Ainslie Parsons

Takeda Canada Inc. v. Canada (Health), 2013 FCA 13

In Canada, innovative drugs are eligible for eight years of data exclusivity under section C.08.004.1 of the *Food and Drug Regulations* (the "Regulations")[1]. Data exclusivity prevents competitors from relying on an innovator company's clinical trial data to take a shortcut to get regulatory approval without generating their own data. The definition of what qualifies as an "innovative drug" and entitled to data protection has been before the courts on a number of recent occasions. An "innovative drug" is defined in the Regulations as a drug that contains a medicinal ingredient not previously approved by the Minister and that is "not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph"[2]. In April 2012, we reported a decision of the Federal Court (Trial Division) holding that Celgene's new use of THALOMID for treating multiple myeloma was an "innovative drug" despite the previous approval of the medicinal ingredient thalidomide[3]. (For further information please see Scorned Drug Makes Unexpected Comeback that is "Innovative" Enough to Qualify for Canadian Data Exclusivity.) The Celgene case was encouraging to brand name companies because it indicated that the courts may be willing to approach the definition of an "innovative drug" with some flexibility.

The more recent Federal Court of Appeal case of *Takeda Canada Inc. v. Canada (Health)*[4], took a narrow view. At issue in *Takeda* was whether an enantiomer of a previously approved drug is an innovative drug eligible for data protection. If it is a mere "variation" of a previously approved drug, it will not be eligible for data protection. Takeda had filed for approval of the enantiomer drug, DEXILANT, in a new drug submission, for treatment of gastroesophageal reflux disease. Typically Health Canada permits a reduced clinical package for an enantiomer of a previously approved drug. In this case Takeda was likely relying in part on studies and comparisons with respect to Takeda's previously approved drug, lansoprazole (PREVACID).

In *Takeda*, the majority of the Federal Court of Appeal affirmed the Minister of Health's refusal to grant data protection to Takeda's drug DEXILANT. The Court held that the ordinary wording of the Regulations excludes all enantiomers of previously approved medicinal ingredients from qualifying as "innovative drugs." Further, the government's Regulatory Impact Analysis Statement which accompanied the Regulations focused on the specific issue of whether data protection should be extended to enantiomers and the like and concluded that it should not. The amount of clinical data collected on the enantiomer as part of the NDS is irrelevant to eligibility. Unfortunately, the Court did not try to reconcile this case with the prior lower court decision on THALOMID.

The dissenting opinion was reflective of Takeda's arguments in favour of data protection. Justice Stratas held that a drug that contains an enantiomer of a previously approved medicinal ingredient should not be automatically excluded from data protection. Rather, the listed substances in the definition of innovative drugs should only be treated as examples of substances that may be variations depending on the circumstances. In Justice Stratas' opinion, if regulatory approval for a drug requires the submission of confidential data generated by considerable effort and the medicinal ingredient has qualities of safety and efficacy materially different from a previously approved medicinal ingredient, then it is not a variation of that previously approved ingredient.

There is not a high likelihood that the Supreme Court of Canada will hear an appeal, if one is filed. Unless the case is overturned or limited by a future Appeal Court decision, pharmaceutical companies should expect that going forward, any new drug that is a salt, ester, enantiomer, solvate, or polymorph of a previously approved medicinal ingredient will not likely be eligible for data protection.

Update: An application for leave to appeal this case to the Supreme Court of Canada was dismissed (2013 CanLII 33948 (SCC)).

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[1] SOR/2006-241.

[2] Section C.08.004.1, *Food and Drug Regulations*

[3] (2012 FC 154, Appeal heard November 27, 2012)

[4]2013 FCA 13