THALOMID is Not an Innovative Drug Eligible for Canadian Data Protection

Mar 4, 2013

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In Canada, drugs that are classified as “Innovative drugs” are eligible for eight years of data protection (data exclusivity). In April 2012, the Federal Court (Trial Division) held that Celgene’s new use of THALOMID for treating multiple myeloma was an “innovative drug” despite the previous approval of the medicinal ingredient thalidomide[1].(For further information please see Scorned Drug Makes Unexpected Comeback that is “Innovative” Enough to Qualify for Canadian Data Exclusivity.) The Minister of Health appealed the Federal Court’s decision, and in a decision released February 15, 2013, the Federal Court of Appeal held that THALOMID is not an innovative drug and overturned the lower Court[2].

Thalidomide has a controversial past: while it was approved in Canada as early as 1960 and prescribed to treat sleeplessness and morning sickness in pregnant woman, it was permanently taken off the market in 1962 when it was discovered that it was associated with severe birth defects.

Research by Celgene in the 1990’s established that thalidomide was useful for treating conditions such as cancer and leprosy. Marketing authorization was issued to Celgene on August 4, 2010, for the use of THALOMID for treating multiple myeloma. However, the government advised Celgene that THALOMID was not eligible for data protection because the medicinal ingredient had been previously approved. Celgene applied for judicial review of the government’s decision and the Federal Court sided with Celgene, holding that the prior thalidomide approval should not stand in the way of data protection of THALOMID.

The Canadian Data Protection Regulations (the Regulations) define an “innovative drug” as a “drug that contains a medicinal ingredient not previously approved by the Minister.[3] Writing for the majority of the Federal Court of Appeal, Justice Gauthier rejected Celgene’s argument that the word “approved” refers to the current status of the drug. Celgene submitted that reading down the definition of an innovative drug in this manner is consistent with the purpose and object of the Regulations and Canada’s international treaty obligations.

The Court of Appeal held that a medicinal ingredient such as thalidomide that once received regulatory approval is "previously approved" for the purposes of the Regulations. Data protection is limited to new medicinal ingredients which means, in this context, submitted for the first time to the appropriate authority. The fact that Celgene had to submit a considerable amount of confidential data gathered at significant cost does not, in and of itself, justify stretching the definition of “innovative drug.” The Court expressed concern that reading in the additional limitation of “currently approved” to the definition of “innovative drug” could open the door to unexpected scenarios whereby drugs may be treated differently depending on why their approval was withdrawn.

The dissenting opinion of Justice Nadon emphasized that after the thalidomide tragedy, the sale of thalidomide in Canada was expressly prohibited by law. As thalidomide was removed from the market by legislation, thalidomide was not “previously approved” but rather the previous approval had been essentially nullified. Justice Nadon rejected any “slippery slope” concerns because the fact situation of thalidomide is highly unusual and any precedent set by the decision is narrow.

No appeal has been filed with the Supreme Court of Canada to date. Overall, the Court of Appeal’s narrow take on what constitutes an “innovative drug” is consistent with recent case of *Takeda Canada Inc. v. Canada (Health)*, where the Court of Appeal held that all enantiomers of previously approved medicinal ingredients were excluded from qualifying as “innovative drugs”, regardless of the amount of clinical data collected on the enantiomer[4] (For further information please see Enantiomers Not Eligible for Data Protection in Canada). Drug manufacturers should take note that the courts are taking a strict approach to the definition of “innovative drug.” This will prevent data protection if there is a previously approved drug or variant, even when an innovator company has expended considerable effort, ingenuity and expense to develop its own drug.

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1 *Celgene Inc. v. The Minister of Health* (2012 FC 154)

[2] *Canada (Health) v. Celgene Inc.* (2013 FCA 43)
[3] Section C.08.004.1 of the *Food and Drug Regulations*
[4] 2013 FCA 13