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Pharma in brief - Canada

Federal Court holds that an ester of a "previously approved medicinal ingredient" is not eligible for data protection

Case: *Photocure ASA v Canada (Health)*, 2015 FC 959 (Court File No. T-1774-14)
Drug: CYSVIEW® (HAL HCl)
Nature of case: Judicial review of Minister of Health's decision to not grant data protection to a compound
Successful party: Health Canada
Date of decision: August 10, 2015

Summary

Photocure ASA (**Photocure**) markets HAL HCl in Canada under the name CYSVIEW® for use as an optical imaging agent in the detection of non-muscle invasive bladder cancer. Photocure sought "innovative drug" status for CYSVIEW® in order to obtain eight years of data protection under section C.08.004.1 of the *Food and Drug Regulations* (***FDA Regulations***). The Minister of Health (**Minister**) refused to grant "innovative drug" status to CYSVIEW® because HAL HCl is an ester of ALA HCl, which was previously approved.

The Federal Court dismissed Photocure's application for judicial review of the Minister's decision. Justice Kane held that: (1) affidavit evidence not before the Minister was inadmissible; (2) the standard of review was reasonableness; and (3) the Minister's decision to not grant "innovative drug" status was reasonable.

Background

Before the Minister, Photocure argued that: (a) HAL HCl is a salt of HAL, which has not been previously approved; and (b) HAL is an ester of ALA, which has not been previously approved. Accordingly, HAL HCl is not an "ester" of ALA HCl within the meaning of "innovative drug" in the *FDA Regulations*. The Minister thought otherwise and refused data protection. Photocure then brought an application for judicial review.

Affidavits not before decision maker struck

Photocure filed an expert affidavit in support of its application for judicial review. This affidavit provided scientific background, argument, and opinion evidence. In response, the Minister filed affidavit evidence from the individual at Health Canada who decided that CYSVIEW® was not an "innovative drug".

In general, the Court will not admit evidence that was not before the decision-maker. Therefore, since Photocure's affidavit did not fit into any of the recognized exceptions, and since the Minister's affidavit was in response to Photocure's, Justice Kane ruled both affidavits inadmissible.

Standard of review is reasonableness

Photocure argued that the standard of review was correctness because, in interpreting the meaning of "innovative drug" under the *FDA Regulations*, the Minister was determining a question of law. In contrast, the Minister argued that the standard of review was reasonableness because it was not interpretting the *FDA Regulations*; rather it was determining the fact of whether CYSVIEW® was an ester of ALA HCl.

Justice Kane agreed with the Minister and held that the standard of review was reasonableness. She found that the issue was a factual determination as to whether one drug is a variation of another. Since the Court has no expertise in determining such matters, it deferred to the decision-maker.

Minister's decision was reasonable

A reasonable decision is one that can withstand a "somewhat probing examination". Justice Kane found that the Minister's decision was based on a thorough comparison of the whole structures of CYSVIEW® and ALA HCl, and determined that CYSVIEW® was an ester of that previously approved drug. Thus, Justice Kane upheld the Minister's decision and dismissed Photocure's application.

Link to decision:

Photocure ASA v Canada (Health), 2015 FC 959

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