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Pharma in brief - Canada

Federal Court dismisses Apotex's application for judicial review of Health Canada decision rejecting ANDS for Apo-Progesterone

Case: *Apotex Inc v Minister of Health*, 2017 FC 127 (Court File No. T-1516-16)
Drug: Apo-Progesterone (referencing PROMETRIUM®)
Nature of case: Judicial review of minister's refusal to issue Abbreviated New Drug Submission (ANDS) to Apotex.
Successful party: Minister of Health
Date of decision: February 1, 2017

Summary

Health Canada rejected Apotex's ANDS for a generic version of PROMETRIUM® (progesterone) due to high levels of sodium lauryl sulfate (**SLS**). Apotex applied for judicial review of the decision on grounds of procedural fairness and substantive unreasonableness. The court dismissed Apotex's application.

Background

Apo-Progesterone contains levels of SLS that Health Canada found to be unusually high. Apotex recognized that the amount of SLS would be an issue for Health Canada and provided information regarding US Food and Drug Administration (**FDA**) approval of a different Apotex product containing even higher levels of SLS and other evidence relating to the toxicology of SLS.

Health Canada engaged in a series of communications with Apotex and ultimately denied the ANDS. Apotex filed a request for reconsideration, and a panel concluded there was insufficient evidence to support allowing an increased limit of SLS. The panel determined that the evidence relating to the toxicology of SDS, including the evidence put forward by Apotex, was of "low quality," incomplete, sometimes unpublished, and did not comply with Good Laboratory Practice. The panel also concluded that the FDA approval was not sufficient to support Apotex's contention that its SLS levels for Apo-Progesterone were safe and effective as the claim was missing documentation and excipient levels are not approved in Canada based solely on the fact that such levels had been approved by foreign regulatory agencies. The panel report was ultimately accepted by Health Canada, and the ANDS was again denied.

Apotex subsequently attempted to obtain another reconsideration, including by Apotex's CEO directly contacting the director general of the Therapeutic Products Directorate. The request for reconsideration was denied, and Apotex applied for judicial review.

Apotex's application for judicial review

Justice Phelan dismissed the application, holding that Apotex was afforded a fair procedure and the decision was reasonable.

Apotex's delay. The minister argued that Apotex had failed to bring the application for judicial review within the 30-day time limit.

In the application, Apotex "suggested that it was somehow led on" by the director general to think that the second reconsideration might occur and implied that Health Canada was "somehow antagonistic" to Apotex based on two recent judgments of Justice Manson (reported here). Justice Phelan held that this was "an unfair and unreasonable interpretation" of the director general's words and actions, the two decisions were irrelevant, and the decisions and the record in the application did not establish such antagonism. He found that at best Apotex's CEO had an "honest but mistaken belief" that his request for a second reconsideration would be accepted and characterized Apotex's suggestion as a "desperate plea" to excuse Apotex's failure to file its application on time.

Justice Phelan did note that if Apotex had filed for judicial review the reconsideration would end, there had been a continued intention to dispute the conclusion, and there was significant public interest in decisions relating to public health. He therefore granted Apotex an extension of time.

Procedural fairness. Apotex argued that an external rather than an internal panel should have been used, the panel had demonstrated bias by circulating a draft memorandum showing a closed mind, the panel did its own research and raised new studies at the hearing depriving Apotex of the opportunity to respond, and the panel made legal conclusions it was not entitled to make.

Justice Phelan ruled against Apotex on all four arguments. He held that the guidelines allowed for an internal panel provided it was independent and impartial, the evidence did not show that the panel had decided the matter before hearing from Apotex, Apotex knew what the issue was and had sufficient opportunity to respond, and it was a mischaracterization of the reasons to state the panel had made legal conclusions.

Decision was reasonable. Apotex argued that the panel failed to consider the FDA approval of a different Apotex product containing even higher levels of SLS. Justice Phelan found that throughout the process Health Canada had "continually raised the issue of the SLS levels and offered multiple opportunities for Apotex to provide evidence to establish that high levels of SLS could be accepted," including seeking details of the FDA approval. Further, Health Canada had made it clear that approval was not based solely on the fact that a foreign regulatory agency had accepted higher levels of SLS. He found nothing unreasonable in the panel's decision that Apotex had not justified its reliance on the FDA approval.

Link:

Apotex Inc v Minister of Health, 2017 FC 127.

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