

Pharma in brief - Canada

PMPRB explores application of the “patent pertaining” analysis to formulations and combination drugs in failure-to-file application

Case:	<i>In the matter of Galderma Canada Inc and the medicines containing “adapalene”</i>
Drug:	Differin [®] (adapalene 0.1% w/w) & Differin XP [™] (adapalene 0.3% w/w)
Nature of case:	Application by Board staff to the Patented Medicine Prices Review Board (PMPRB or the Board) pursuant to the <i>Patent Act</i> , RSC 1985, c P-4
Successful party:	Divided
Date of decision:	December 19, 2016

Summary

Galderma markets adapalene in Canada for the treatment of acne as a monotherapy under the trade names Differin[®] (0.1% adapalene) and Differin XP[™] (0.3% adapalene). The PMPRB Board staff brought an application before a panel seeking an order requiring Galderma to address three additional patents owned by Galderma, but which Galderma argued did not pertain to its adapalene monotherapy products.

The panel agreed with Galderma that two of the patents did not pertain to the adapalene monotherapy products because they provided for the use of a combination of medicines, which can include adapalene as one of the two active ingredients. These two combination patents, the panel held, were not intended or capable of being used to make an adapalene monotherapy on the basis that a simple reference to adapalene in the patents was insufficient to establish the necessary rational connection. The panel also held that the third patent, which was directed to an adapalene monotherapy formulation, pertained to Differin[®] and issued an order accordingly in respect of that patent.

Background

Differin[®] contains 0.1% adapalene. Differin XP[™] contains a higher concentration of adapalene — 0.3%. Galderma has marketed Differin[®] products in Canada since June 1996 and reported price and sales data to the PMPRB for them with respect to certain patents until December 2009. Galderma has also marketed Differin XP[™] in Canada since July 2007 and reported corresponding price and sales data to the PMPRB until the lapse of Canadian Patent No. 2,478,237 (the **237 Patent**), on March 14, 2016. In this case, the Board staff argued that the 237 Patent also pertained to Differin[®]. In addition, the Board staff argued that Canadian Patents No. 2,466,321 (the **321 Patent**) and 2,656,451 (the **451 Patent**) pertain to both Differin[®] and Differin XP[™].

The PMPRB allowed the Board staff’s application in respect of Differin[®] and the 237 Patent, but dismissed it in respect of the 321 and 451 Patents in respect of Differin XP[™] and Differin[®].

The 237 Patent pertains to Differin[®]

The 237 Patent relates to the use of adapalene to treat dermatological disorders. There was no dispute that the 237 Patent is not intended or capable of being used to make the molecule adapalene. Galderma, however, argued that

the 237 Patent is not intended or capable of being used to make Differin[®] — a 0.1% adapalene formulation — because on its face, the patent is specific to 0.3% adapalene formulations (such as Differin XP[™]).

The panel held that while the abstract of the 237 Patent refers to 0.3% adapalene, it is not clear that it pertains *exclusively* to 0.3% adapalene. The panel found that the title and first paragraph of the 237 Patent do not mention 0.3% adapalene and, on its face, the use of 0.3% adapalene may be one (but not the only one) of the patent's objectives. On a balance of probabilities, the panel found the requisite connection exists between Differin[®] and the 237 Patent; it therefor exercised its discretion to find that the patent "pertains to" Differin[®] and ordered Galderma to file the necessary information up to the lapse date of the 237 Patent.

The 321 and 451 Patents pertain to neither Differin[®] nor Differin XP[™]

The 321 and 451 Patents provide for the use of a combination of medicines, which can include adapalene as one of the two active ingredients. The Board staff argued that on the "merest slender thread" standard established in a previous case (*ICN Pharmaceuticals, Inc. v Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 FCR 32), these two patents pertain to the adapalene-only drugs, Differin[®] and Differin XP[™], because each patent refers to adapalene as one of the two possible medicinal ingredients. Galderma argued that the 321 and 451 Patents pertain to its combination products, but not the Differin[®] monotherapies.

The panel agreed with Galderma that on their faces, neither the 321 nor the 451 Patent is intended or capable of being used to make an adapalene monotherapy. The panel held that the Board staff had incorrectly reversed the analysis, asking whether the medicine pertained to the patent instead of whether the patent pertained to the medicine. A simple reference to adapalene in the patent is insufficient to establish the necessary rational connection.

No lack of procedural fairness

The panel rejected Galderma's argument that the Board denied it procedural fairness and violated the principle of legitimate expectations in asserting jurisdiction over Differin[®] on the basis of the 237, 321, and 451 Patents.

Since the hearing before the panel is *de novo* and there was no issue regarding the composition of the panel or Galderma's ability to present its case in this forum, there could be no lack of procedural fairness. Similarly, since the doctrine of legitimate expectations cannot give rise to substantive rights, the panel held that it was irrelevant whether or to what extent the Board staff made representations regarding the 237 Patent and Differin[®].

Link:

[Board Order](#).

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