

**PATENTED MEDICINE PRICES REVIEW BOARD**

**IN THE MATTER OF the Patent Act R.S.C. 1985, c. P-4 as amended**

**IN THE MATTER OF the Medicines**

**DIFFERIN® (adapalene)**

**DIFFERIN XP® (adapalene)**

**TACTUPUMP® (adapalene/benzoyl peroxide)**

**TACTUPUMP FORTE® (adapalene/benzoyl peroxide)**

**(Collectively, " the Adapalene Medicines" )**

**Sold in Canada by GALDERMA CANADA Inc. (the "Respondent")**

**REPLY TO GALDERMA CANADA INC.'S RESPONSE**

**INTRODUCTION**

1. The same defined terms indicated in Board Staff's Notice of Application apply to this Reply.
2. Board Staff admits the allegations and statements made in paragraphs 3 through 5 of Galderma's Response (the "Response").
3. Galderma admits that
  - a) the PMPRB has jurisdiction over Differin XP under Patent 237, TactuPump under Patent 451 and TactuPump Forte under Patent 237 and Patent 451 (paragraph 9 of the Response);
  - b) Galderma markets the Adapalene Medicines in question in Canada (paragraph 10 of the Response);
  - c) Galderma is required to amend its Form 1 for TactuPump to include reference to Patent 451 and for TactuPump Forte to include reference to the 451 Patent and the 237 Patent (paragraph 18 of the Response).

Board Staff acknowledges and agrees with these admissions by Galderma.

4. Board Staff denies the remainder of the allegations in the Galderma Response.
5. Board Staff disagrees with Galderma's assertion that Patent 237 does not pertain to TactuPump, but will not be pursuing that allegation in the context of these proceedings as

Galderma has at least admitted that the PMPRB has jurisdiction over TactuPump under Patent 451, which expires after Patent 237.

6. Contrary to the allegations in the Response, Board Staff is not seeking to “over-extend” the PMPRB’s jurisdiction. The PMPRB has jurisdiction over the sale of Differin, and Differin XP under both Patent 237 and Patent 451. Consequently, Galderma must provide the information and documents set out in section 80 of the Act, and in sections 3 and 4 of the Regulations as it relates to Differin (DIN 2148749, DIN 2231592 and DIN 2376660), and Differin XP (DIN 2274000).

### **JURISDICTION OVER DIFFERIN**

7. Galderma admits to marketing Differin in Canada, but disputes that the PMPRB has jurisdiction with respect to the sale of Differin on the basis that Patent 451 and Patent 237 do not pertain to Differin.

8. Differin contains adapalene. Patent 237 is entitled “Use of Adapalene for the Treatment of Dermatological Disorders”, and each and every claim set out in Patent 237 includes the use of adapalene. Patent 237 pertains to Differin.

9. Patent 451 is entitled “Composition Comprising a Retinoid and Benzoyl Peroxide” and adapalene is, itself, a retinoid. Claims 9, 17 and 19 of Patent 451 specifically contemplate the use of adapalene as the retinoid in the composition. Patent 451 also pertains to Differin.

### **JURISDICTION OVER DIFFERIN XP UNDER PATENT 451**

10. Galderma admits that Patent 237 pertains to Differin XP, and that the PMPRB has jurisdiction over Differin XP in that respect. However, Patent 451 also pertains to Differin XP.

11. Patent 451 is entitled “Composition Comprising a Retinoid and Benzoyl Peroxide” and adapalene is, itself, a retinoid. Claims 9, 17 and 19 of Patent 451 specifically contemplate the use of adapalene as the retinoid in the composition. Patent 451 also pertains to Differin XP..

### **ANTICIPATED FILINGS**

12. Board Staff has not received the updated and corrected filings from Galderma in respect of TactuPump and TactuPump Forte. At the present time, Galderma is not compliant with

respect to the necessary filings in respect of Differin, Differin XP, TactuPump and TactuPump Forte.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 12<sup>th</sup> day of May, 2016.

Original signature redacted

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