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)
Sold in Canada by GALDERMA CANADA Inc.

GALDERMA CANADA INC.'S RESPONSE TO THE NOTICE OF APPLICATION OF BOARD STAFF

Overview

1. Respondent Galderma Canada Inc. ("Galderma") acknowledges the allegations in paragraphs 2, 3, 4, 5, 6, 7, 8, 10, 11, and 12 of the Notice of Application of Board Staff ("Application").

2. Galderma denies the allegations in the remainder of the Application.

3. The Application relates to four medicines marketed in Canada by Galderma, including Differin, Differin XP, TactuPump and TactuPump Forte (the "Medicines").

4. Board Staff alleges that Canadian patent numbers 2,656,451 ("451 Patent") and 2,478,237 ("237 Patent")(collectively, the "Patents") "pertain" to each of the Medicines.

5. Board Staff further asserts that Galderma, which is a patentee under the *Patent Act* (the "*Act*"), has sold the Medicines in Canada and failed to provide the Board

with information required under section 80 of the *Act* and sections 3 and 4 of the Patented Medicine Regulations (the "Information").

6. Contrary to assertions made by Board Staff, Galderma has fully complied with its obligations, except where noted herein, to provide Information relating to any of the Medicines over which the Board has jurisdiction.

7. In the Application Board Staff seek to over-extend the Board's jurisdiction by misconstruing the test for determining when sales of a medicine are considered to fall within the jurisdiction of the Board.

8. The correct application of this test means that the Board's jurisdiction extends only to those Medicines that pertain to an invention (as described in a patent). The chart below describes each of the Medicines and whether the invention described in the 451 Patent or the 237 Patent pertains to the applicable Medicine:

Medicines	**DIN**	**Formulation**	**Does the invention described in the 451 Patent (compositions of adapalene and benzoyl peroxide) pertain to the medicine?**	**Does the invention described in the 237 Patent (compositions containing 0.3% adapalene) pertain to the medicine?**
Differin	2148749	0.1% adapalene gel	NO	NO
Differin	2231592	0.1% adapalene cream	NO	NO
Differin	2376660	1mg/g adapalene lotion	NO	NO
Differin XP	2274000	0.3% adapalene gel	NO	YES

Medicines	DIN	Formulation	Does the invention described in the 451 Patent (compositions of adapalene and benzoyl peroxide) pertain to the medicine?	Does the invention described in the 237 Patent (compositions containing 0.3% adapalene) pertain to the medicine?
TactuPump	2365871	0.1% adapalene and 2.5% benzoyl peroxide gel	YES	NO
TactuPump Forte	2446235	0.3% adapalene and 2.5% benzoyl peroxide gel	YES	YES

Note: Galderma has filed the Information for Differin XP, TactuPump and TactuPump Forte.

9. As is evident from the table, the Board only has jurisdiction over Differin XP (with respect to the 237 Patent only), TactuPump (with respect to the 451 Patent only) and TactuPump Forte (with respect to both patents). None of the 'Differin' medicines (other than Differin XP) are subject to the jurisdiction to the Board.

The Relevant Medicines and Patents

10. Galderma markets the Medicines, which are all indicated for the treatment of *acne vulgaris*, in Canada as follows:

    (a) Differin (0.1% adapalene): was introduced in the 1990s and is available as a gel, cream or lotion. Galderma's patent pertaining to this concentration of Differin expired in June 2010, when Galderma stopped filing the prescribed information with the Board;

    (b) Differin XP (0.3% adapalene): is an improved version of Differin with a higher concentration of adapalene. Galderma began marketing Differin XP, and filing prescribed information in Canada in 2007;

(c) TactuPump (0.1% adapalene and 2.5% benzoyl peroxide): is a combination medicine containing two medicinal ingredients. Galderma began marketing TactuPump and filing prescribed information in Canada in 2013; and

(d) TactuPump Forte (0.3% adapalene and 2.5% benzoyl peroxide) is a newer version of TactuPump that also contains two medicinal ingredients. Galderma obtained marketing approval for TactuPump Forte, and began filing prescribed information in Canada in 2015.

11. The 451 Patent, which expires on July 11, 2027, is entitled, "Composition Comprising a Retinoid and Benzoyl Peroxide." The 451 Patent describes the invention as relating to "a composition comprising, in a physiologically acceptable medium, at least one retinoid, dispersed benzoyl peroxide and a gelling system comprising at least two particular categories of compounds." Adapalene is a topical retinoid.

12. The 237 Patent, which expires on July 12, 2023, is entitled, "Use of Adapalene for the Treatment of Dermatological Disorders." The 237 Patent is limited to compositions, and uses, of inventions comprising 0.3% adapalene. The disclosure mentions the previously marketed 0.1% adapalene compositions, then notes that the applicant has found that 0.3% compositions are an improvement.

The Board's Jurisdiction over the Medicines

13. Before the Board can require any party selling a medicine in Canada to provide Information, the Board must establish jurisdiction over sales of the medicine. Jurisdiction can only be established in circumstances where the Board can establish that:

(a) a party is a patentee of an invention;

(b) a patentee's invention (i.e., the claims set out in the applicable patent) pertains to the medicine under review; and

(c) the patentee is selling the medicine in any market in Canada.

14. Galderma does not dispute Board Staff's assertion in the Application that Galderma is a patentee of an invention and that it is selling the Medicines in Canada. Board Staff misconstrue, however, the second part of the test by asserting [in paragraph 13(b) of the Application] that Board Staff have satisfied this requirement because Galderma is a patentee "in respect of at least one invention pertaining to adapalene".

15. The second element of this test stipulates that a "patentee's invention must pertain to a medicine", which requires a "rational connection between the invention and the pharmaceutical end product". Contrary to the position taken by Board Staff, the "inventions" described in the Patents do not pertain to adapalene as the "pharmaceutical end product".

Application of the Rational Connection Test to the Medicines

16. The proper application of the second criterion of the test for jurisdiction requires that the invention described in each of the Patents must be reviewed to determine if it has a rational connection with each of the Medicines. The results of this review are as follows:

(a) **451 Patent**: pertains to combination compositions and uses of, *inter alia*, adapalene and benzoyl peroxide. Therefore, there is a rational connection *only* to TactuPump and TacuPump Forte, which contain these combination compositions. The balance of the Medicines do not contain benzoyl peroxide and therefore do not pertain to the invention described by the 451 Patent.

(b) **237 Patent**: pertains to compositions comprising 0.3% adapalene. Consequently, it is *only* applicable to Differin XP and TactuPump Forte. The balance of the Medicines only contain 0.1% adapalene and the invention described by the 237 Patent does not therefore apply to these Medicines.

17. Galderma has already fully reported to the Board and filed all required Information relating to: (a) Differin XP, under the 237 Patent; (b) TactuPump, under Canadian patent number 2,466,321 (the "321 Patent"), which expires on December 9, 2022; and (c) TactuPump Forte, under the 321 Patent.

18. Galderma acknowledges the requirement to amend its Form 1 for: (a) TactuPump to include reference to the 451 Patent; and (b) TactuPump Forte to include reference to the 451 Patent and the 237 Patent. It will make these amendments to ensure it is in full compliance with its obligations under the *Act*. Not including reference to these patents to date, however, has had no impact on any of the Information that Galderma has filed, or was required to file, with the Board.

19. Once Galderma effects these minor changes, it will be in full compliance with all of its reporting requirements with respect to any of the Medicines over which the Board has jurisdiction. Accordingly, this Application must be dismissed.

Dated: 22 April 2016

Original signature redacted

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