

**PATENTED MEDICINE PRICES REVIEW BOARD**

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

**AND 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.**

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**NOTICE OF APPLICATION – Failure to File**

**TAKE NOTICE THAT** Board Staff will bring an application before the Patented Medicine Prices Review Board (the "Board") for hearing on a date to be determined by the Board.

**THE APPLICATION IS FOR** an Order pursuant to section 81 of the *Patent Act* (the "Act") requiring the Respondent, Galderma Canada Inc. to provide the information referred to in section 80 of the Act and in sections 3 and 4 of the Patented Medicine Regulations (the "Regulations"), in respect of the medicines Differin, Differin XP, TactuPump and TactuPump Forte on the terms set out in the Draft Order at Appendix I.

**THE GROUNDS FOR THE APPLICATION ARE:**

1. Galderma Canada Inc. has failed to provide the Board with certain prescribed information regarding the medicines Differin, Differin XP, TactuPump and TactuPump Forte<sup>1</sup> as the patentee of at least Canadian Patent Nos. 2,656,451 ("the '451 Patent") and 2,478,237 ("the '237 Patent") (collectively "the Adapalene Patents") which pertain to Differin, Differin XP, TactuPump and TactuPump Forte (collectively, "the Adapalene Medicines"). Galderma Canada Inc. ought to have filed certain information upon issuance of the patents for all sales made after the patents were laid open for public inspection. As such, Galderma Canada Inc. is in breach of the reporting requirements under the Act and Regulations, and the Board ought to make an order compelling Galderma Canada Inc. to comply with those requirements.

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<sup>1</sup> Differin, DifferinXP, TactuPump and TactuPump Forte are identified in Galderma Canada Inc's website as product names or registered trademarks of Galderma S.A., its affiliates, related companies or its licensors.

## The Adapalene Patents and the Patentee

2. Canadian Patent No 2,656,451 is entitled "Composition Comprising a Retinoid and Benzoyl Peroxide." The '451 Patent has 23 claims. Claims 1-18 relate to compositions which include, among other things, a retinoid and benzoyl peroxide. Claims 9-11 and 17-18 relate to the composition where the retinoid is specified to be adapalene. Claim 19 relates to the composition of any of claims 1-16 as a medication. Claims 20-23 relate to the use of the composition of any of the claims 1-18 to prevent and/or treat certain dermatological conditions including acne.
3. The description of the '451 Patent discloses, among other things, that the retinoids that are part of the compositions of the invention include adapalene and that "in particular, adapalene and also its salts will be preferred" ; that the "preferred retinoid concentrations are between 0.0001 and 20% by weight relative to the total weight of the composition" ; and that "the compositions according to the invention are particularly suitable to the treatment, in a preventative and/or curative manner, of acne vulgaris."
4. The '451 Patent has a PCT publication date of January 17, 2008 and issued on January 27, 2015.
5. Canadian Patent No 2,478,237 is entitled "Use of Adapalene for the Treatment of Dermatological Disorders." The '237 Patent has 7 claims. Claims 1-6 relate to the use of adapalene for the treatment of certain dermatological conditions including acne. Claim 7 relates to a pharmaceutical composition comprising, among other things, adapalene.
6. The '237 Patent has a PCT publication date September 18, 2003 and issued on May 12, 2009.
7. The Canadian Intellectual Property Office lists Galderma Research and Development (France) as the Owners and Applicants for the '451 Patent and the '237 Patent.
8. Galderma Canada Inc. was established in 1989 as part of the global organization known as Galderma S.A. which includes Galderma Research and Development and is headquartered in Switzerland. Galderma Canada Inc. markets and sells Galderma products in Canada under the authorization of Galderma S.A.

9. Galderma Canada Inc. as such falls within the definition of "patentee" in respect of the '451 and '237 Patents pursuant to subsection 79(1) of the Act.

**The Adapalene Medicines**

10. Galderma Canada Inc. is approved to sell medicines that contain adapalene in Canada as follows:

DIN	Brand Name	Dosage	Date of first NOC	Year of First Sale
2148749	Differin	0.1% adapalene gel	1995-01-24	1996
2231592	Differin	0.1% adapalene cream	1997-06-24	1998
2274000	Differin XP	0.3% adapalene gel	2005-12-20	2007
2376660	Differin	1 mg/g adapalene lotion	2011-11-25	
2365871	TactuPump	Gel 0.1% adapalene and 2.5% benzoyl peroxide	2011-03-21	2011
2446235	TactuPump Forte	Gel 3mg/g adapalene and 25 mg/g benzoyl peroxide	2015-09-16	

11. The NOCs for the Adapalene Medicines identified above were issued pursuant to a New Drug Submission, pursuant to section C.08.002 of the FDA Regulations.
12. The Adapalene Medicines are generally indicated for the treatment of acne. The specific authorized indications are identified in the Product Monographs for each product attached to this Notice.

**PMPRB Jurisdiction**

13. The basis for the PMPRB's jurisdiction with respect to Galderma Canada Inc.'s sales of the Adapalene Medicines in Canada, is as follows:
- a. Galderma Canada Inc. is a patentee pursuant to subsection 79(1) of the Act.

- b. in respect of at least one invention pertaining to adapalene, and
- c. Galderma Canada Inc. has sold that medicine in a market in Canada.

**Applicable Regulations**

14. The Act and the Regulations impose, inter alia, the following reporting requirements on patentees of inventions pertaining to a medicine:

a. Paragraph 80(1)(a) of the Act and subsection 3(1) of the Regulations require the patentee to provide to the PMPRB prescribed information identifying the medicine. Pursuant to subsection 3(2) of the Regulations, the prescribed information shall be provided if a NOC has been issued with respect to the medicine, or if the medicine is being offered for sale in Canada. Pursuant to subsection 3(3) of the Regulations, the prescribed information shall be provided within the earlier of 30 days after the first NOC is issued, or 30 days after the date on which the medicine is first offered for sale in Canada.

b. Paragraph 80(1)(b) of the Act and subsection 4(1) of the Regulations require the patentee to provide to the PMPRB prescribed information identifying the medicine and concerning the price of the medicine. Pursuant to subsections 4(2) and 4(3), this information shall be provided within 30 days following the date of the first sale in Canada of the medicine, and within 30 days after each six month period commencing on January and July 1 of each year.

**Failure to Report**

15. The table below summarizes the information that Galderma has failed to file.

DIN	Brand Name	Dosage	Form 1	Form 2
2148749	Differin	0.1% adapalene gel	Amended Form 1 to report the '451 and '237 patents	Semi-annual filing starting with January to June 2010 (when Galderma stopped filing Form 2) to present
2231592	Differin	0.1% adapalene cream	Amended Form 1 to report the '451 and '237 patents	Semi-annual filing starting with January to June 2010 (when Galderma stopped filing Form 2) to present

2274000	Differin XP	0.3% adapalene gel	Amended Form 1 to report the '451 patent (Galderma has already reported the '237 patent for this product)	Continue to file Form 2 (Galderma is currently filing Form 2 under other patents, the latest of which expires on December 3, 2023, but once the '451 and '237 patents are added to Form 1, the Form 2 obligation will be extended to July 11, 2027)
2376660	Differin	1 mg/g adapalene lotion	Original Form 1 to report at least the '451 and '237 patents	File Form 2 when sales commence
2365871	TactuPump	Gel 0.1% adapalene and 2.5% benzoyl peroxide	Amended Form 1 to report the '451 and '237 patents	Continue to file Form 2 (Galderma is currently filing Form 2 under other patents, the latest of which expires on December 9, 2022, but once the '451 and '237 patents are added to Form 1, the Form 2 obligation will be extended to July 11, 2027)
2446235	TactuPump Forte	Gel 3mg/g adapalene and 25 mg/g benzoyl peroxide	Amended Form 1 to report the '451 and '237 patents	File Form 2 when sales commence

16. Galderma Canada Inc. has not complied with the above of its obligations and as such, Galderma Canada Inc. is in breach of the reporting requirements under the Act and Regulations.

**THE FOLLOWING DOCUMENTARY EVIDENCE** will be used at the hearing of the application:

1. One or more affidavits to be sworn;
2. The pleadings and proceedings herein; and
3. Such further and other documentary evidence as counsel may advise and the Board may permit.