

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
Galderma Canada Inc., (the “Respondent”)
and the medicine “Tactuo”**

STATEMENT OF ALLEGATIONS OF BOARD STAFF

A. INTRODUCTION

1. This Statement of Allegations results from an investigation by Board Staff into the price of Tactuo (DIN 02365871), a patented medicine sold in Canada by Galderma Canada Inc. (“Galderma”).
2. According to publicly available information, Galderma sold Tactuo in 2011 in Canada at a price of \$85.60 per tube (\$1.43/g) and is presently selling Tactuo in 2012 at a price of \$87.60 per tube (\$1.46/g). **Attachment 1**

B. THE MEDICINE

3. Health Canada issued a Notice of Compliance (“NOC”) for Tactuo on March 21, 2011, and Galderma began selling the medicine in Canada in May 2011. **Attachment 2**
4. Tactuo is indicated for the treatment of *acne vulgaris*, characterized by comedones, inflammatory papules/pustules with or without occasional nodules in patients 12 years of age and older. Tactuo is a topical gel sold in a 60 g tube. It is a combination of drugs currently sold in Canada as individual components: adapalene 0.1% and benzoyl peroxide 2.5%. **Attachment 3**

C. THE PATENT

5. Canadian Patent No. 2,466,321 (gel comprising at least a retinoid and benzoyl peroxide) pertains to Tactuo. **Attachment 4**
6. The patent was issued on November 8, 2011 to Galderma Research & Development (France) and will expire on December 9, 2022.

7. Galderma is a patentee within the meaning of subsection 79(1) of the *Patent Act*, as it is entitled to exercise rights in relation to the above-mentioned patent.

D. FACTORS SET OUT IN SUBSECTION 85 (1) OF THE *PATENT ACT*

8. Subsection 85(1) of the *Patent Act* (the “Act”) sets out the factors the Board shall take into consideration in determining whether a medicine is being or has been sold at an excessive price in any market in Canada:

In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

- (a) the prices at which the medicine has been sold in the relevant market;
 - (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
 - (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
 - (d) changes in the Consumer Price Index; and
 - (e) such other factors as may be specified in any regulations made for the purposes of this subsection.
9. To date, no additional factors have been prescribed pursuant to paragraph 85(1)(e).
 10. Board Staff submits that it is appropriate in the case at bar for the Board to give due consideration to its January 2010 Compendium of Guidelines, Policies and Procedures (the “2010 Guidelines”) to establish an approach and methodology in applying the factors set out in subsection 85(1) of the Act to determine if Tactuo is being or has been sold at an excessive price in Canada.

PRICES AT WHICH THE MEDICINE HAS BEEN SOLD IN THE RELEVANT MARKET

11. Paragraph 85(1)(a) of the Act requires the Board to take into consideration the prices at which the medicine has been sold in the relevant market.

12. Pursuant to the 2010 Guidelines (C.11.18), the introductory price is the National Average Transaction Price (“N-ATP”) from the date of first sale to the end of the six-month regulatory reporting period (June 30 or December 31), as long as the period covered is greater than one month. Accordingly, the introductory price for Tactuo is the N-ATP from May to June 2011.
13. Based on the regulatory filings of the patentee, Board Staff calculated the N-ATP of Tactuo in Canada for the introductory period and for each subsequent reporting period. **Attachment 5**

PRICES OF OTHER MEDICINES IN THE SAME THERAPEUTIC CLASS

14. Paragraph 85(1)(b) of the Act requires the Board to take into consideration the prices at which other medicines in the same therapeutic class have been sold in the relevant market.
15. The 2010 Guidelines (C.8.12) state that for combination drug products, such as Tactuo, where each of the elements of the combination drug product are sold in Canada and have the same indication or use, the comparable drug products will be limited to the component parts, unless the Human Drug Advisory Panel (“HDAP”) identifies the new patented drug product as providing therapeutic improvement.
16. Following a scientific review by HDAP, Tactuo was found to provide moderate therapeutic improvement as compared to its component parts, adapalene 0.1% and benzoyl peroxide 2.5%.
17. The 2010 Guidelines (C.11.5) provide that the introductory price of a new drug product providing moderate improvement will be presumed to be excessive if the N-ATP or any Market-Specific Average Transaction Price (MS-ATP) exceeds the Maximum Average Potential Price (MAPP) at introduction as determined by the higher of:
 - (a) The highest non-excessive price of the drug products identified in the Therapeutic Class Comparison (TCC) test; and
 - (b) The mid-point between the TCC test and the Median International Price Comparison (MIPC) test of the drug under review.

18. The 2010 Guidelines (C.11.13) set out the introductory price review procedure and the price sources which may be relied upon by Board Staff for purposes of conducting the TCC test:

C.11.13 Board Staff will use public sources for the prices of the drug products used for comparison purposes. The sources of prices which Board Staff will consult are (in alphabetical order): the Association québécoise des pharmaciens propriétaires (AQPP); IMS Health; McKesson Canada; Ontario Drug Benefit (ODB) Programs; PPS Pharma; and the Régie de l'assurance maladie du Québec (RAMQ). Board Staff will select the lowest public price from these sources for each of the drug products identified for comparison purposes. If no price is available for a comparator from these sources, Board Staff will explore additional sources until a public price is found.

19. In conducting the TTC test for Tactuo, Board Staff relied on the public price sources listed in C.11.13. Where none of the six public price sources were available for a given comparator, Board Staff did not consider as appropriate any retail prices for such drug products based on the mark-ups associated with retail prices.
20. In this case, the TCC test compared the price of Tactuo with the price of its constituent elements adapalene 0.1% and benzoyl peroxide 2.5% which resulted in a price of \$1.1857 per gram.
21. Tactuo's mid-point was calculated using the MIPC test for Tactuo of \$0.8088 per gram based on the publicly available ex-factory prices available in France, Germany, Italy, Switzerland, the United Kingdom and the United States and the TCC test of \$1.1857 per gram which resulted in a price of \$0.9973 per gram.
22. Accordingly, the MAPP for Tactuo was determined to be \$1.1857 per gram based on the TCC test. Therefore the introductory N-ATP of Tactuo failed the TCC test as it exceeded its MAPP. **Attachment 6**

PRICES AT WHICH THE MEDICINE AND OTHER MEDICINES IN THE SAME THERAPEUTIC CLASS HAVE BEEN SOLD IN COUNTRIES OTHER THAN CANADA

23. Paragraph 85(1)(c) of the Act requires the Board to take into consideration:
- i) prices at which the medicine has been sold in countries other than Canada; and
 - ii) prices at which other medicines in the same therapeutic class have been sold in countries other than Canada.

24. In accordance with the 2010 Guidelines, Board Staff compared the N-ATP of Tactuo to the publicly available prices of Tactuo sold in the comparator countries listed in Schedule 1 to the *Patented Medicines Regulations* (“the Regulations”).
25. From May 2011 to December 2011, Tactuo was sold in six of the seven comparator countries (France, Germany, Italy, Switzerland, the United Kingdom and the United States).
26. For the period from January 2012 to June 2012, Tactuo was sold in all seven comparator countries.
27. The results of the International Price Comparison (“IPC”) test for the introductory period and for each subsequent period indicate that the price of Tactuo in Canada was the second highest price internationally for all periods and was above the MIPC test for all periods. **Attachment 7**
28. Board Staff also considered the international prices of the comparator medicines (“ITCC”) in the seven countries listed in the Regulations. The 2010 Guidelines articulate two approaches to considering this factor:
 - a) Under the straight class approach, the N-ATP of Tactuo is compared to the median international price of the comparator medicines.
 - b) Under the ratio approach, the ratio between the price of Tactuo and the price of comparator medicines are determined for each combination within each comparator country. The median of the resulting ratios is then applied to the N-ATP of Tactuo.
29. The results of the International TCC Test for Tactuo at introduction were as follows: **Attachment 8**

International TCC Test	As of date of first sale May 2011
Straight Class Approach	Fail
Ratio Approach	Pass

CHANGES IN THE CONSUMER PRICE INDEX (“CPI”)

30. Paragraph 85(1)(d) of the Act requires the Board to take into consideration changes in the CPI.

31. The 2010 Guidelines recognize that the prices of patented medicines should be entitled to increase in accordance with the CPI. Specifically, the 2010 Guidelines permit patentees to bank CPI increases for a period of up to three years, subject to a maximum yearly price increase corresponding to 1.5 times the forecast change in the annual CPI.
32. Because the introductory price of Tactuo was excessive, Board Staff increased the maximum allowable price, referred to as the National-Non-Excessive Average Price (N-NEAP) in 2012 by an amount equal to the change in CPI. **Attachment 5**

CONCLUSION

33. Board Staff submits that where the introductory price is at issue, the price review factors which ought to be accorded the most weight are:
 - the Canadian prices of other medicines in the same therapeutic class, and
 - the prices of the medicine under review in the seven countries identified in the Regulations.
34. In accordance with the 2010 Guidelines, Board Staff further submits that while the ITCC Test can provide information in the context of a hearing into the price of a patented medicine, it ought to be accorded minimal weight in the present case. In comparison to the other factors identified in subsection 85(1) of the *Patent Act*, the ITCC test is the furthest removed from the drug product under review as it considers the prices of comparator medicines in foreign countries.
35. For the period May 2011 to the June 30, 2012, sales of Tactuo at prices above the MAPP/N-NEAP generated excess revenues in the amount of \$ [REDACTED].
36. Board Staff respectfully submits that, when considering the applicable factors in subsection 85(1) of the Act, there are grounds for the Board to conclude that, pursuant to section 83 of the Act, Galderma is selling or has sold the medicine known as Tactuo in Canada at prices which are or were excessive.

ORDER REQUESTED

37. Board Staff seeks the issuance of an Order against Galderma, the terms of which are as follows:
- a) The MAPP of Tactuo in Canada for the period May 2011 to June 2011 and the N-NEAPs for Tactuo from July 2011 to December 2012 shall be as set out in **Attachment 5**, Calculation of Excess Revenues.
 - b) The N-NEAPs for Tactuo for all subsequent reporting periods shall be calculated in accordance with the 2010 Guidelines.
 - c) In accordance with subsection 83(1) of the Act, Galderma shall cause the maximum price at which it sells Tactuo in Canada to be reduced to the N-NEAP effective on or before 30 days from the date of the Board's Order.
 - d) In accordance with subsection 83(2) of the *Patent Act*, Galderma shall offset the amount of excess revenues estimated to have been derived by Galderma from the sale of Tactuo at excessive prices from May 2011 until the date on which the price reduction referred to in paragraph c) above comes into effect as follows:
 - i) With respect to the period from May 2011 to June 30, 2012, Galderma shall pay to Her Majesty in right of Canada, within 30 days of the date of the Board's Order, \$ [REDACTED]; and
 - ii) With respect to the period from July 1, 2012 to the date on which the price reduction referred to in paragraph c) comes into effect, Galderma shall pay to Her Majesty in right of Canada, a further amount equal to the amount of excess revenues estimated by the Board to have been derived by Galderma from the sale of Tactuo at an excessive price and make the payment within 30 days of receipt of a notification from the Board of its estimate of excess revenues based on the information filed in response to paragraph e) below.
 - e) Galderma shall, within 30 days of the date of the Board's Order:
 - i) Notify federal/provincial/territorial ministers of health or their representatives and all customers of the price decrease as required by the Board's Order (a copy of which shall be included in such notifications) and the effective date of such price decrease;

- ii) Submit copies of the above-noted notifications and any other notice to the Board; and
- iii) Provide to the Board information concerning the quantity of Tactuo sold and either the average price per package or the net revenue from sales of Tactuo in Canada, in the same form as required by subsection 4(1) and section 7 of the *Regulations* for the period July 1, 2012 to the date on which the price reduction referred to in paragraph c) comes into effect.

OTHER

- 38. Board Staff reserves the right to make such other allegations and submissions and introduce such other additional documents as counsel to Board Staff may advise and the Board may permit.
- 39. In accordance with section 86 of the Act, Board Staff submits that any hearing conducted by the Board into the price of Tactuo should be held in public and, subject to orders of the Board, all information and documents filed as part of the proceeding should form part of the public record.

Dated at Ottawa this 24th day of September 2012.

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LIST OF ATTACHMENTS

Attachment 1	July 2011 and May 2012 Association québécoise des pharmaciens propriétaires (AQPP) publicly available pricing information for Tactuo (DIN 02365871)
Attachment 2	Notice of Compliance (NOC) for Tactuo manufacturer Galderma Canada Inc.
Attachment 3	Product Monograph for Tactuo
Attachment 4	Canadian Patent No. 2,466,321 pertaining to Tactuo
Attachment 5	Tactuo Calculation of Excess Revenues
Attachment 6	Tactuo Introductory Price Test
Attachment 7	Tactuo International Price Comparison (IPC) Test
Attachment 8	Tactuo International Therapeutic Class Comparison (ITCC) Tests