Court File No.: T-906-20

Court File No.:

FEDERAL COURT

B E T W E E N :

GALDERMA CANADA INC.

Applicant

– and –

PATENTED MEDICINE PRICES REVIEW BOARD and ATTORNEY GENERAL OF CANADA

Respondents

APPLICATION UNDER sections 18.1 and 18.2 of the *Federal Courts Act*, RSC, 1985, c.F-7 (the "*Federal Courts Act*"), and Part V of the *Federal Courts Rules*, 1998, SOR/98-106, as amended (the "*Federal Courts Rules*")

NOTICE OF APPLICATION UNDER SECTIONS 18, 18.1 AND 18.2 OF THE *FEDERAL COURTS ACT*

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED by the applicant. The relief claimed by the applicant appears on the following page.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicant. The applicant requests that this application be heard at 180 Queen Street West, Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the applicant's solicitor, or where the applicant is self-represented, on the applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules* information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

August 11, 2020

Issued by: Alice Prodan Gil
(Registry Officer)

Address of local office: 180 Queen Street West, Suite 200
Toronto, Ontario M5V 3L6

TO: **The Administrator of this Honourable Court**
Federal Court
180 Queen Street West, Suite 200
Toronto, Ontario M5V 3L6

AND TO: **Patented Medicines Prices Review Board**
The Secretary of the Patented Medicines Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

AND TO: **Attorney General of Canada**
Ontario Regional Office
Department of Justice Canada
120 Adelaide Street West
Suite #400
Toronto, Ontario M5H 1T1

APPLICATION

NATURE OF THE APPLICATION

Galderma Canada Inc. (“Galderma”) applies for judicial review under sections 18, 18.1, and 18.2 of the *Federal Courts Act* of the decision of the Patented Medicine Prices Review Board (the “Board”) released on May 7, 2020. In the decision, the Board asserts jurisdiction over the medicine Differin (“Differin 0.1”) and orders Galderma to file prescribed pricing information with the Board for Differin 0.1 for the period between January 1, 2010 and March 14, 2016.

GALDERMA MAKES APPLICATION FOR:

1. an Order in the nature of *certiorari*, quashing and/or setting aside the Board’s order that Galderma file the pricing information for Differin 0.1 for the period between January 1, 2010 and March 14, 2016;

2. a Declaration that the Board does not have jurisdiction over Differin 0.1;

3. an Order granting Galderma its costs of this Application; and

4. such further or other relief as the Applicant requests and the Honourable Court deems just to grant.

THE GROUNDS FOR THE APPLICATION ARE:

Overview

1. The Board was asked by the Federal Court of Appeal ("FCA") to reconsider whether the invention described in Canadian Patent No. 2,478,237 (the "237 Patent") (use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) was "intended or capable of being used for" Differin 0.1 (0.1% adapalene).

2. The 237 Patent discloses an invention restricted solely to use of 0.3% adapalene to treat dermatological disorders and pertains to Differin XP, a medicine that is different and distinct from Differin 0.1 (0.1% adapalene).

3. The patents owned by Galderma disclosing an invention pertaining to Differin 0.1, a drug that uses 0.1% adapalene to treat dermatological disorders, were issued as early as 1990 and expired by the end of 2009.

4. In making its decision ("Reconsideration Decision"), the Board erred in determining: (1) that Differin 0.1 and Differin XP are the same medicine; and (2) that the invention embodied in the 237 Patent (use of a 0.3% concentration of adapalene for treatment of dermatological disorders) is "intended or capable of being used for" Differin 0.1 (0.1% adapalene). The Board erred by concluding that because Differin 0.1 and Differin XP can be used to treat similar clinical conditions and have a shared active substance that the two distinct medicines were the same medicine. The Board failed to consider, and in fact disregarded,

the entire record, including: previous submissions by Board Staff and the Attorney General; expert evidence before the Board; the FCA Decision; the Federal Court Decision; a previous decision of the Board in the same matter; and the treatment of Differin 0.1 and Differin XP as two distinct medicines by Health Canada. These errors in failing to consider the entire record led the Board to incorrectly and unreasonably determine that it had jurisdiction over Differin 0.1; a medicine that Board acknowledged was “off patent”.

Factual Background

5. Galderma markets and sells various pharmaceutical products, including Differin 0.1, an acne medicine containing the active pharmaceutical ingredient 0.1% adapalene.

6. Galderma began selling Differin 0.1 in Canada in or around May 1996. At that time, the company properly listed Canadian Patent Nos. 1,266,646 and 1,312,075 on the appropriate Board form (“Form 1”) for Differin 0.1. Consistent with reporting obligations to the Board, Galderma also provided the prescribed pricing information for Differin 0.1 to the Board from January 1996 until Canadian Patent No. 1,312,075 expired in December 2009.

7. In 2003, Galderma Research & Development filed an application for the 237 Patent, which issued on May 12, 2009 and lapsed on March 14, 2016. Galderma listed the 237 Patent on the Form 1 for Differin XP, which is a different acne

medicine from Differin 0.1, containing the active pharmaceutical ingredient adapalene 0.3% (adapalene in a 0.3% concentration formulation).

8. Differin 0.1 and Differin XP are different medicines containing separate and distinct active pharmaceutical ingredients and with different uses. Differin 0.1 contains 0.1% adapalene whereas Differin XP contains 0.3% adapalene.

9. The Board issued a Notice of Application in February 2016 (the "Board Application"), alleging, among other claims, that the 237 Patent pertained to Differin 0.1.

10. As part of the Board Application, the Board sought an order requiring Galderma to:

    a. list the 237 Patent on the Form 1 for Differin 0.1; and

    b. file the prescribed information relating to Differin 0.1 for the period between January 1, 2010 and March 14, 2016 (the term during which the 237 Patent remained in force),

even though the invention described and claimed in the 237 Patent does not pertain to Differin 0.1.

11. The parties agreed that the three-part test to determine whether the Board has jurisdiction over a patentee in respect of a medicine being sold in Canada involved the following three factors:

    a. Is the party a patentee of an invention?

b. Does the invention pertain to a medicine?

c. Is the medicine being sold in Canada?

12. The parties agreed that only the second factor (does the invention claimed and described in the 237 Patent pertain to Differin 0.1) was at issue in the proceeding.

13. To properly apply its jurisdiction under section 79(2) of the *Patent Act,* the Board must find that the ***invention*** described in the 237 Patent is intended or capable of being used for Differin 0.1 (0.1% adapalene) or for the preparation or production of Differin 0.1 (0.1% adapalene).

14. The onus is on Board Staff to prove that the invention described and claimed in the 237 Patent is "intended or capable of being used for" Differin 0.1.

15. In a previous decision dated December 19, 2016, the Board incorrectly and unreasonably concluded that the 237 Patent is capable of being used for Differin 0.1. In doing so, the Board also erred in concluding that the 237 Patent pertains to Differin 0.1. The Board held that the "237 ***patent*** pertains to the use of adapalene to treat dermatological disorders" (emphasis added) and ordered Galderma to file prescribed pricing information for Differin 0.1 for the period between January 1, 2010 and March 14, 2016. In the previous decision, the Board also held that the 237 Patent is not, "on its face, intended to, or capable of being used to prepare or produce the molecule adapalene."

16. In a decision dated November 9, 2017, the Federal Court quashed the Board's previous decision. The Federal Court found that the Board did not have jurisdiction to regulate the price of Differin 0.1, that the Panel's analysis was flawed and unreasonable, and that the invention described in the 237 Patent did not pertain to Differin 0.1.

17. In a decision released on June 28, 2019, the FCA set aside the Federal Court judgment, quashed the Board's decision and returned the matter to the Board for redetermination. The FCA held that the invention described in the 237 Patent was the use of a 0.3% concentration of adapalene for treatment of dermatological disorders. The FCA also held that the medicine at issue was Differin 0.1, a medicine with a 0.1% concentration of adapalene, and not adapalene in and of itself.

18. The FCA suggested that the Board may consider what kind of "clinical similarities" would support a finding that the invention of a patent was intended or capable of being used for that medicine. The only issue, however, for redetermination by the Board was whether the invention of the 237 Patent (the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) is "*intended or capable of being used for*" Differin 0.1 (0.1% adapalene). [Emphasis added].

19. The Board asked the parties to file written submissions in response to the FCA decision. The Board issued its Reconsideration Decision on May 7, 2020.

20. The Reconsideration Decision incorrectly and unreasonably determines that Differin 0.1 and Differin XP are the same medicine and that the invention of the 237 Patent (the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) also pertains to Differin 0.1. On this basis, the Board ordered Galderma to file pricing information for Differin 0.1 for the period between January 1, 2010 and March 14, 2016.

Standard of Review

21. The Board's Reconsideration Decision is both incorrect and unreasonable. The Board failed to consider the evidence, the parties' previous submissions, and the decisions of the Federal Court and FCA. The Board also failed to apply the appropriate legal test to determine whether the invention of the 237 Patent (the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) is "intended or capable of being used for" Differin 0.1 (0.1% adapalene).

22. The Reasons for the Reconsideration Decision are not internally coherent, do not present a rational chain of analysis, and are not justified in relation to the relevant law and facts.

23. These errors result in an incorrect and unreasonable outcome based on an incorrect and unreasonable application of the *Patent Act* that improperly extends the Board's jurisdiction to a medicine that has been "off patent" since 2009.

The Board Failed To Find That The Invention Does Not Pertain To Differin 0.1

24. The Board failed to consider all of the evidence when it unreasonably determined that the invention of the 237 Patent (the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) is “intended or capable of being used for” Differin 0.1 (0.1% adapalene).

25. The Board unreasonably determined that the invention of the 237 Patent (the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) is “intended or capable of being used for” Differin 0.1 (0.1% adapalene) by comparing “clinical similarities” of Differin 0.1 and Differin XP, which are two different medicines.

26. The Board unreasonably concluded that Differin 0.1 and Differin XP are the same medicine. This conclusion failed to properly consider: differences between Differin 0.1 and Differin XP; the Board Staff and Attorney General’s previous submissions; expert evidence before the Board; the Federal Court Decision; the FCA Decision; the Board’s previous decision; and the treatment of Differin 0.1 and Differin XP as two distinct medicines by Health Canada. All of this evidence demonstrates that Differin 0.1 and Differin XP are not the same medicine. Indeed, there was no evidence before the Board that the invention, use of 0.3% adapalene as a pharmaceutical composition in the form of a gel or cream, was intended or capable of being used for Differin 0.1.

27. The Board unreasonably concluded that Differin 0.1 and Differin XP are the same medicine, because of the clinical similarities caused by their shared active substance, adapalene. The FCA explicitly held that the medicine at issue was Differin 0.1 and not the active substance, adapalene *per se*.

28. The Board unreasonably relied on the existence of a shared Product Monograph and its contents to conclude that Differin 0.1 and Differin XP are the same medicine.

29. The Board unreasonably relied upon the language required by Health Canada to be included in the Product Monograph, including the use of drug in the singular form, to conclude that Differin 0.1 and Differin XP are the same medicine.

30. The Board has acted incorrectly and unreasonably by expanding its jurisdiction to include an off patent medicine. The *Constitution Act* and the *Patent Act* limit the Board's jurisdiction to *patented medicines*, i.e., medicines covered by a patentee's monopoly.

31. The Board has acted incorrectly and unreasonably by relying upon its consumer protection mandate to grant itself jurisdiction over an off patent medicine. As noted repeatedly, Differin 0.1 has been off patent since 2009.

32. The Board has misapplied the legal test in s. 79(2) of the *Patent Act* and related jurisprudence, including *ICN Pharmaceuticals Inc. v. Canada (Patented, Medicine Prices Review Board)* (1996), 68 CPR (3d) 417 (FCA).

Suspension Period

33. The Federal Court suspended all deadlines due to the COVID-19 pandemic on March 16, 2020. The Board released the Reconsideration Decision on May 7, 2020 during the Suspension Period. The Suspension Period for Ontario proceedings, including the deadline for judicial review proceedings under section 18.1(2) of the *Federal Courts Act*, ended on July 14, 2020 and deadlines began to run again as of that date. The Applicant filed this Notice of Application by the prescribed deadline of August 13, 2020.

Relief Requested

34. Galderma requests that the Court quash the Board Order and substitute its own decision to declare that the Board does not have jurisdiction over Differin 0.1 and that Galderma is not required to file the prescribed pricing information.

THE APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

1. The material filed at the hearing before the Board;

2. Affidavits filed pursuant to the Rules; and

3. Such further and other material as counsel may adduce and this Honourable Court admit.

Date: August 11, 2020

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– Applicant –		– Respondents –

FEDERAL COURT

PROCEEDING COMMENCED AT TORONTO

NOTICE OF APPLICATION

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