Court File No. (T-906-20)

FEDERAL COURT OF APPEAL

B E T W E E N:

GALDERMA CANADA INC.

Appellant

– and –

ATTORNEY GENERAL OF CANADA

Respondent

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellant. The relief claimed by the appellant appears below.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellant. The appellant requests that this appeal be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the *Federal Courts Rules* and serve it on the appellant's solicitor or, if the appellant is self-represented, on the appellant, WITHIN 10 DAYS after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341B prescribed by the *Federal Courts Rules* instead of serving and filing a notice of appearance.

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 APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

9 February 2024 Issued by: _____
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APPEAL

APPELLANT, Galderma Canada Inc. ("Galderma") appeals to the Federal Court of Appeal from the Judgment ("Judgment") of the Honourable Mr. Justice Fothergill (the "Judge") dated 11 January 2024. The Judgment dismissed Galderma's application for judicial review of a decision of the Patented Medicine Prices Review Board (the "Board") released on 7 May 2020 ("Redetermination Decision").

THE APPELLANT ASKS that:

1. the Judgment be set aside;

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

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

4. costs of this appeal and of the hearing in the Federal Court be awarded to Galderma; and

5. such further and other relief as this Honourable Court deems just.

THE GROUNDS OF APPEAL ARE:

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

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

3. The patents owned by Galderma disclosing an invention pertaining to Differin, Canadian Patent Nos. 1,266,646 (the "646 Patent") and 1,312,075 (the "075 Patent'), were issued as early as 1990 and had expired by the end of 2009.

4. Galderma began selling Differin in Canada in or around May 1996. At that time, the company properly listed Differin on the appropriate Board form ("Form 1") and mentioned the 646 and 075 Patents. Galderma also provided the prescribed pricing information for Differin to the Board from January 1996 until the 075 Patent expired in December 2009.

5. In 2003, Galderma Research & Development filed an application for the 237 Patent, which issued on 12 May 2009 and lapsed on 14 March 2016. Galderma listed the 237 Patent on the Form 1 for Differin XP, a different acne medicine from Differin, containing the active pharmaceutical ingredient adapalene 0.3% (adapalene in a 0.3% concentration formulation).

6. 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% adapalene). As part of the Board Application, the Board sought an order requiring Galderma to: (1) list the 237 Patent on the Form 1 for Differin; and (2) file the prescribed

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

7. The parties agreed that a three-part test articulated in a decision of this Court applied to determine whether the Board had jurisdiction over a patentee in respect of a medicine sold in Canada. The test involves three factors, or questions: (1) is the party a patentee of an invention?; (2) does the invention pertain to a medicine?; and (3) is the medicine being sold in Canada? The parties also agreed that only the second factor - does the invention disclosed and claimed in the 237 Patent pertain to Differin - was at issue.

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

9. The onus is on Board Staff to prove that the invention disclosed and claimed in the 237 Patent is “intended or capable of being used for” Differin.

10. In the 2016 Board Decision, the Board concluded that the 237 Patent was not, on its face, “intended or capable of being used for” the preparation or production of Differin or adapalene. The Board nonetheless held in the 2016 Decision that the 237 Patent was “intended or capable of being used for” Differin.

11. In the 2016 Board Decision, the Board concluded that Canadian Patent No. 2,466,321, entitled "Gel Comprising at Least a Retinoid and Benzoyl Peroxide", and Canadian Patent No. 2,656,451, entitled "Composition Comprising a Retinoid and Benzoyl Peroxide" did not pertain to Differin or Differin XP. The Board held that the Canadian Patent Nos. 2,466,321 and 2,656,451 on their face were for a combination of medicines and there was no rational connection to adapalene as a single agent. The Board stated: “[a] simple reference to the ingredients by itself in the patent is not sufficient to create the required connection or link under subsection 79(2) of the *Patent Act*.”

12. In a decision dated 9 November 2017, the Federal Court quashed the 2016 Board Decision. The Federal Court found that the Board did not have jurisdiction to regulate the price of Differin, that the Panel’s analysis was flawed and unreasonable, and that the invention described in the 237 Patent did not pertain to Differin.

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

14. In its decision, the Federal Court of Appeal stated that the Board could consider what kind of “clinical similarities” might “support a finding that the invention of a patent was intended or capable of being used for” a medicine. The only issue for re-determination by the Board was whether the invention of 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% adapalene).

15. The Board issued its Redetermination Decision on 7 May 2020. The Redetermination Decision concluded that Differin went off-patent on 29 December 2009. The Redetermination Decision held that Differin and Differin XP are the same medicine and that the invention of the 237 Patent (use of a 0.3% concentration of adapalene for treatment of dermatological disorders) therefore pertains to Differin (which uses a 0.1% concentration of adapalene). Based on the finding, the Board ordered Galderma to file pricing information for Differin for the period between 1 January 2010 and 14 March 2016.

16. Galderma sought judicial review of the Redetermination Decision. The Judge dismissed Galderma’s application.

17. The Judge erred in finding that the Board had jurisdiction over Differin, 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. Expanding the Board’s jurisdiction to an off-patent medicine is an unconstitutional result that is incorrect, cannot fall within the range of acceptable outcomes that are defensible and reasonable based on the facts and law, and is not supported by an internally coherent and rational chain of analysis.

18. The Judge erred in the interpretation of the jurisprudence, including *ICN Pharmaceuticals Inc. v. Canada (Patented, Medicine Prices Review Board)* (1996), 68 CPR (3d) 417 (FCA) ["*ICN*"] and *Merck Canada inc c Procureur général du Canada*, 2022 QCCA 240.

19. The Judge erred in his finding that "the relationship between a patented invention and an off-patent medicine may be tenuous" yet still provide jurisdiction. The Board's jurisdiction is limited to *patented* medicines, and not "tenuous" connections between a patented medicine and an off-patent medicine. The Board simply has no jurisdiction to regulate prices of medicines that are "off-patent". The test is whether the invention of a patent "pertains to" the medicine at issue, which necessarily involves whether the "invention is intended or capable of being used" for the medicine at issue within the meaning of s.79(2) of the *Patent Act*. The Judge's expansion of the Board's jurisdiction is an error of law and contrary to the *Constitution Act* and *Patent Act.*

20. The Judge further erred in finding that that it was "clear from the jurisprudence that the mere existence of a patent gives rise to a presumption of market power due to distortion of the competitive process" and in concluding:

> "Where it appears that a patent confers exclusivity with respect to a portion of the market relating to the medicine being sold in Canada, there is a presumption that its mere existence confers market power by distorting the competitive process and competitors are dissuaded from entering the marketplace. There is no need for Board Staff to demonstrate actual market distortion, and no opportunity for a patentee to prove the contrary."

21. No jurisprudence cited by the Judge supported such a presumption. Furthermore, Board Staff had the onus to establish the Board's case on a balance of probabilities yet they provided no evidence whatsoever that the 237 Patent (use of a 0.3% concentration of adapalene for the treatment of dermatological disorders) conferred any exclusivity, provided any market power, or distorted the competitive process in relation to Differin (0.1% adapalene). In the absence of precedent or evidence, it was therefore an error for the Judge to conclude that the 237 Patent created any monopoly or market power for, or distorted the competitive process in relation to, Differin.

22. The mere existence of the 237 Patent did not provide a basis for a finding of market power in relation to Differin. Indeed, the Judge and Board were at a loss to articulate how the 237 Patent could provide any market power over Differin or how the invention of the 237 Patent was "intended or capable of being used" for Differin.

23. When properly interpreted, it is clear from its face that the 237 Patent does not, and cannot, provide Galderma any exclusivity or market power in relation to Differin.

24. Furthermore, while Galderma denies that any presumption applies or arises in this case, the Judge erred in not providing Galderma an opportunity to rebut any presumption that the 237 Patent pertains to Differin, or that the invention of the 237 Patent confers any commercial exclusivity (i.e. a monopoly) or market power with respect to Differin.

25. The Judge erred in finding that if, on its face, a "patent" is "intended or capable of being used" for an off-patent medicine, that finding is sufficient to establish the Board's jurisdiction. The test to be applied under s. 79(2) of the *Patent Act* is whether an "invention is intended or capable of being used for medicine", not whether "the patent is intended or capable of being used" for an off-patent medicine. (Emphasis added).

26. The Judge erred in finding that the "Board reasonably found that the clinical similarities between Differin XP and Differin supported the conclusion that the 237 Patent pertained to Differin for the purposes of s. 79(2) of *the Patent Act*."

27. The Board and Judge misapplied this Court's direction to 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" by failing to consider whether the invention of the 237 Patent was in fact "intended or capable of being used" for Differin. As this Court said, the only test is within s. 79(2) of the *Patent Act*. The Board: misapplied the direction of this Court; exceeded its jurisdiction; and wrongly seeks to control the price of an off-patent medicine in contravention of the *Patent Act.*

28. The Judge also erred in finding the Board's interpretation of a shared Product Monograph for Differin and Differin XP supported a finding that the invention of the 237 Patent "is intended or capable of being used" for Differin. This amounted to a finding that Differin and Differin XP are the same medicine merely because both products contain a common ingredient - adapalene. Furthermore, the Board unreasonably relied upon language required by Health Canada to be included in the Product Monograph to conclude that Differin and Differin XP are the same medicine. There was simply no

evidence to support the Board's reliance on language in the Product Monograph that Health Canada required.

29. The Judge erred in finding the Board's interpretation of the 237 Patent to be reasonable. The Board unreasonably relied the description of the 237 Patent, including the comparison of the invention, Differin XP (0.3% adapalene), to the prior art, Differin (0.1% adapalene), as supporting the conclusion that the invention of the 237 Patent pertains to Differin.

30. The Judge erred in finding the Board's interpretation of the evidence of clinicians to be reasonable. The Board unreasonably disregarded expert evidence demonstrating clinical differences between Differin and Differin XP and that the medicines are not considered interchangeable (i.e., substitutable) by clinicians, dermatologists, or pharmacists.

31. The Judge erred in finding that the connection between Differin and the 237 Patent was stronger than the nexus between the patented invention and Virazole, the product at issue in *ICN*. The patents at issue in *ICN* related to one compound, ribavirin, that was the only ingredient in Virazole. The relevant facts of *ICN* are entirely distinguishable from the facts before the Board in this case.

32. The Judge erred in finding that the Board's conclusion that "Differin and Differin XP are the same medicine, albeit in different concentrations" was "reasonably supported by evidence". The Board failed to consider: the differences between Differin and Differin XP; the Board Staff and Attorney General's previous submissions; expert evidence before the Board; the Federal Court Decision; this Court's previous Decision; the Board's

previous decision; and the treatment of Differin and Differin XP as two distinct medicines by Health Canada. The Board unreasonably concluded that Differin and Differin XP are the same medicine because of a shared active ingredient, adapalene.

33. The Judge erred by finding that the only policy consideration relied upon by the Board was its mandate "to ensure that the statutory monopoly granted to patentees of medicines is not abused by excessive pricing of those medicines". Throughout the Redetermination Decision, the Board refers to its "consumer protection mandate" as the policy consideration underpinning the decision. The Board acted incorrectly and unreasonably by relying upon a purported consumer protection mandate to grant itself jurisdiction over an off-patent medicine. Furthermore, in the absence of any evidence of a "statutory monopoly" created for Differin by the 237 Patent, it is incorrect, and unconstitutional, to conclude that the 237 Patent could be "abused" in relation to Differin.

34. The Judge erred in finding that the Board reasonably concluded that the invention of the 237 Patent pertained to, or could be used for, Differin, an off-patent medicine.

35. The *Patent Act,* RSC, 1985, c. P-4 at s. 79-103.

36. The *Patent Rules*, SOR/2019-251 at s. 56.

37. The *Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR/2012-247.

38. The *Constitution Act*, 1867, RSC 1985, App. II, No. 5, s. 91 and 92.

39. The *Federal Courts Act,* RSC, 1985, c. F-7 ss. 27(1) and 52.

40. Such further and other grounds as counsel may submit and this Court hear.

Dated at Toronto on 9 February 2024

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