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. and the medicines containing "adapalene"

REASONS FOR DECISION ON REDETERMINATION ORDERED BY THE FEDERAL COURT OF APPEAL ON JUNE 28, 2019

Introduction

1. The only issue in this proceeding is whether the Respondent is required to file with the Board certain prescribed sales and financial information with respect to its product Differin for the period between January 1, 2010 and March 14, 2016.

2. In its decision dated December 19, 2016, the Board concluded that the Respondent was required to file this information. That decision was set aside by the Federal Court and the Federal Court's decision was appealed to the Federal Court of Appeal. On June 28, 2019, the Federal Court of Appeal returned this matter to the Board for redetermination.

3. The Federal Court of Appeal has ordered the Board to determine whether the invention of Patent No. 2,478,237 (the 237 patent) pertained to the medicine in question, i.e., Differin, on the basis that the invention of the 237 patent is the use of a 0.3% concentration of adapalene for the treatment of dermatological disorders.[1]

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[1] *Canada (Attorney General) v Galderma Canada Inc*, 2019 FCA 196 [*Galderma FCA*] at para 75.

4. By virtue of sections 79 to 81 of the Patent Act, the answer to this question determines whether the Respondent is required to file the prescribed sales and financial information for Differin.

5. For the reasons set out below, the Board concludes that the 237 patent pertains to Differin and orders Galderma to file the prescribed sales and financial information for Differin for the period between January 1, 2010 and March 14, 2016.

Federal Court of Appeal Decision

6. The background to this proceeding is set out in the Board's decision dated December 19, 2016 (the "Initial Decision")[2], the decision of the Federal Court dated November 9, 2017[3], and the decision of the Federal Court of Appeal dated June 28, 2019[4], and will not be repeated in these reasons. The Board will set out in this section those aspects of the Federal Court of Appeal's decision that pertain to the Board's task on this redetermination.

7. The Federal Court of Appeal determined what the invention of the 237 patent is. In particular, the Court concluded that the invention of the 237 patent is "a pharmaceutical composition having a concentration of 0.3% adapalene to be used in the treatment of dermatological conditions with an inflammatory or proliferative component, such as common acne".[5]

8. After having identified the invention of the 237 patent, the Federal Court of Appeal considered whether that invention pertained to the medicine which is at issue in this proceeding, and concluded that determining this issue required the consideration of three questions.

9. First, what is the medicine at issue, adapalene or Differin?

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2 *Re Galderma Canada Inc* (2016), Ottawa (Patented Medicine Prices Review Board).

3 *Galderma Canada Inc v Canada (Attorney General)*, 2017 FC 1023.

4 *Galderma FCA*.

5 *Galderma FCA* at para 50.

10. The Federal Court of Appeal concluded that the Board in the Initial Decision had determined that the medicine is Differin. The Court concluded that given that Differin was on the market and adapalene *per se* was not, it was not unreasonable for the Board to reach this decision.[6]

11. Second, what is the meaning of the phrase “pertains to a medicine” as used in section 79(2) of the *Patent Act*?[7]

12. The Federal Court of Appeal concluded that the Board must be guided by the statutory definition in section 79(2) of the *Patent Act*. Section 79(2) states that “an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.” The Court stated that since the Board concluded in the Initial Decision that the 237 patent could not be used to prepare or produce adapalene, the relevant question for the Board is whether the invention of the 237 patent is intended or capable of being used for Differin.[8]

13. Third (and the sole issue for the Board on this redetermination), does the invention of the 237 patent pertain to the medicine in question?

14. The Federal Court of Appeal noted that, in the Initial Decision, the Board made repeated references to the fact that the 237 patent did not relate exclusively to a 0.3% concentration of adapalene and, as such, the Board may have reasoned that since the 237 patent did not relate exclusively to 0.3% adapalene, there was a possibility that it also related to 0.1% adapalene so that, in the circumstances, the invention of the 237 patent could be “used for” Differin as well as Differin XP. The Court concluded that if the possibility that the invention of the 237 patent pertained to Differin rests solely on this premise, the Initial Decision was unreasonable because the only reasonable

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6 *Galderma FCA* at para 61.

7 RSC 1985, c P-4 (as amended).

8 *Galderma FCA* at para 65.

interpretation of the 237 patent, read as a whole, is that the invention of that patent is the use of a 0.3% concentration of adapalene to treat dermatological conditions.[9]

15. The Federal Court of Appeal went on to say that the Board referred to other factors in its decision which, if they had been considered, may have influenced the Board's decision. Those other factors included that in Differin and Differin XP the same molecule is used for the same purpose and the invention of the 237 patent is the use of adapalene to treat dermatological disorders. The Federal Court of Appeal also noted that there was evidence before the Board (including the 237 patent itself, the product monograph for Differin and Differin XP and evidence from clinicians) about the clinical similarities and differences between Differin and Differin XP.[10]

16. The Federal Court of Appeal concluded as follows:

> "In cases such as this, where the question is whether an invention pertains to a specific medicine, 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 Board did not address these questions, perhaps because of its view that the 237 patent did not pertain exclusively to 0.3% adapalene. It should be allowed to do so.
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> These questions involve policy considerations "that we presume the legislature desired *the administrative decision maker* […] to make": McLean at paras. 32-33 (emphasis in original). Given that it is the Board who must decide whether the 237 patent pertains to Differin, the matter must be returned to it so that it can complete its inquiry on the basis of a proper understanding of the invention of the 237 patent."[11]

Issue

17. As directed by the Federal Court of Appeal, the sole issue for the Board in this redetermination is whether the invention of the 237 patent (being a pharmaceutical

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9 *Galderma FCA* at paras 68-69.

10 *Galderma FCA* at paras 70-72.

11 *Galderma FCA* at paras 73-75.

composition having a concentration of 0.3% adapalene to be used in the treatment of dermatological conditions with an inflammatory or proliferative component, such as common acne) pertains to (e.g., is intended or capable of being used for) Differin.

18. As directed by the Federal Court of Appeal, when answering this question, the Board will consider the evidence of the clinical similarities and differences and take into account any relevant policy considerations.

Submissions of the Parties

19. On July 11, 2019, the Board asked the parties to provide written submissions on the impact of the Federal Court of Appeal's decision on the Board's redetermination of this matter. Written submissions and reply submissions were filed by the parties on July 31 and August 9, 2019, respectively.

20. The Board has reviewed and considered these submissions, as well as the evidence and submissions filed by both parties for purposes of the initial hearing before the Board in September 2016. The following is intended to be a non-exhaustive summary of the parties' positions that are relevant to this redetermination.

21. Board Staff's position is that the invention of the 237 patent does pertain to Differin. Board Staff submits that there is a sufficiently strong connection between the invention of the 237 patent and Differin. Despite the different adapalene concentrations in the invention of the 237 patent and Differin, both the invention of the 237 patent and Differin use the same molecule and same mechanism of action to treat the same condition, with similar clinical efficacy and side effects.[12] Accordingly, the invention of the 237 patent is intended or capable of being used for Differin.

22. Relying on the Supreme Court of Canada's decision in *Celgene Corp v Canada (Attorney General)*,[13] Board Staff submits that the Board must be guided by its consumer protection mandate and its responsibility to ensure that the monopoly that accompanies

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12 Board Staff Written Submission dated July 31, 2019 (Board Staff Written Submission) at para 2.

13 [2011] 1 SCR 3.

the granting of a patent is not abused to the detriment of Canadian patients and their insurers.[14]

23. In particular, Board Staff argues that policy considerations relating to the Board's overarching consumer protection mandate, including the Board's obligation to balance the monopoly power held by the patentee of a medicine with the interests of purchasers of those medicines, to protect Canadian consumers and their insurers from the impact of a patent on the market for medicines with close clinical similarities, and to ensure that patentees should not be able to evade the Board's regulatory oversight by marketing a core drug product through various line extensions, further support the conclusion that the invention of the 237 patent pertains to Differin.[15]

24. The Respondent, Galderma, submits that for an invention to pertain to a medicine, the invention must encompass the medicine that a patentee is selling in Canada. The invention must be capable of being used for the medicine at issue. The issue is not whether Differin XP has clinical similarities to Differin. The only issue is whether the invention of the 237 patent is intended or capable of being used for Differin.[16]

25. The Respondent's position is that the invention of the 237 patent does not pertain to Differin, because there are clinical differences between the invention of the 237 patent and Differin, such that the invention of the 237 patent is not intended for or capable of being used for Differin.[17] The Respondent argues that the invention of the 237 patent (the use of 0.3% adapalene) cannot be used for Differin (which uses 0.1% adapalene). The different concentrations of adapalene result in differences in effectiveness, tolerance and side effects and are treated as distinct and different medicines in the 237 patent, the product monograph and by prescribing clinicians.[18]

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14 Board Staff Written Submission at paras 21-23.

15 Board Staff Written Submission at paras 29-39 and Board Staff Written Reply Submission dated August 9, 2019 (Board Staff Written Reply) at paras 28-29.

16 Galderma Written Submission dated July 31, 2019 (Galderma Written Submission) at paras 37 and 42.

17 Galderma Written Submission at para 4.

18 Galderma Written Submission at paras 4 and 60-66.

26. Finally, the Respondent argues that Board Staff's position should be rejected because it would unconstitutionally expand the Board's jurisdiction to off-patent medicines. In this respect, the Respondent submits that if, as in this case, a manufacturer innovates by patenting new inventions involving new dosage formats, new delivery mechanisms or new combination medicines creating new medicines based on the same active ingredient that was used in an older off-patent medicine, the Board cannot regain jurisdiction over the off-patent medicine.[19]

The Evidence

Introduction

27. There is no dispute that the 237 patent pertains to the medicine Differin XP, which uses a 0.3% concentration of adapalene to treat dermatological disorders. Accordingly, in determining what kinds of clinical similarities would support the conclusion that the invention of the 237 patent pertains to Differin, it is appropriate to assess the available evidence of the similarities and differences between Differin and Differin XP.

28. The active agent or molecule is the same for both Differin and Differin XP.[20] Specifically, adapalene is the only active ingredient in both and the main therapeutic effect of both products is through the action of adapalene.

29. Further, both Differin and Differin XP share the same basic indication, namely the topical treatment of dermatological conditions with an inflammatory or proliferative component, such as common acne.[21]

30. While Differin and Differin XP contain two different strengths or concentrations of the identical active agent (e.g. adapalene), this difference does not affect the chemical structure or physicochemical properties of adapalene, or the mechanism of action of

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19 Galderma Written Reply Submissions dated August 9, 2019 at para 3.

20 Affidavit of John Cook sworn on June 13, 2016 (Cook Affidavit) at Exhibit F – "Patent No. 2478237".

21 Cook Affidavit, Exhibit F; Affidavit of Vincent Ho sworn on June 13, 2016 (Ho Affidavit) at para 14 and Exhibit B – "Product Monograph for Differin and Differin XP".

adapalene.[22] In particular, in both Differin and Differin XP, adapalene selectively binds to certain retinoic acid receptors (e.g., certain beta and gamma receptors) to normalize the differentiation of follicular epithelial cells or to unblock the hair follicle, thereby reducing comedones and inflammation.[23]

Product Monograph and Evidence Concerning the Dose-Response Relationship

31. There is a single product monograph for both Differin and Differin XP, which confirms that Differin and Differin XP use the same medicinal ingredient, are indicated for the same dermatological disorder and work in the same way. The following sections of the Product Monograph speak to the similarities between Differin and Differin XP:[24]

(a) the "Indications and Clinical Use" section refers to both Differin and Differin XP together showing the same indications and clinical uses for both, namely the topical treatment of acne vulgaris in patients 12 years of age and older;

(b) the "Contraindications" section uses the singular word "drug" to refer to the contraindications relating to both Differin and Differin XP, e.g., the drug is contraindicated for "patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container" and "patients with eczema or seborrheic dermatitis";

(c) the "Warnings and Precautions" section identifies the same warnings and precautions for both products including, for general use and for use by special populations;

(d) the "Adverse Reactions" section, including the "Less Common Clinical Trial Adverse Drug Reactions (<1%)" section indicates the same potential adverse reactions for both;

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22 Ho Affidavit at para 18. See also Cook Affidavit, Exhibit F - the chemical structure of adapalene is identical to that referred to in the abstract of the 237 patent and in Claims 1, 2, 3, 6 and 7 of the patent.

23 Ho Affidavit at para 8.

24 Ho Affidavit, Exhibit B.

(e) the “Post-Market Adverse Drug Reactions” section does not distinguish between Differin and Differin XP at all, providing that certain adverse events are “probably/possibly related to treatment with an adapalene topical formulation”;

(f) Differin and Differin XP have the same administration and storage and stability guidelines;

(g) the non-medicinal ingredients used in both Differin and Differin XP (particularly the gel vehicle formulation) are nearly identical;

(h) at several points the two products are referred to as being the same medicine, in some cases they are referred to together in the singular, rather than in the plural; and

(i) the “Consumer Information” section refers to Differin and Differin XP as being different “dosage forms” of the same medicine and sets out the same consumer information for both products, including information about the medication, warning and precautions, proper use, side effects and what to do about them and storage guidelines.

32. The product monograph describes a “slightly greater incidence” of adverse reactions from the use of Differin XP as compared to Differin, and explains that this is expected with the higher concentration of adapalene.[25] The Board received additional evidence about this effect, commonly referred to as the “dose-response relationship”, from Dr. Vincent Ho. Dr. Ho explained that the clinical effect of a medication is tied to the concentration of the active ingredient up to a maximum level, and a higher concentration of the active ingredient will provide a greater incidence of adverse reaction as well as a greater clinical effect, generally. In other words, it is expected that the pharmacologic effect of the higher concentration of adapalene in Differin XP will provide greater efficacy

[25] Ho Affidavit, Exhibit B at 5. See also Ho Affidavit at para 17.

and greater adverse reactions as compared to the lower concentration of adapalene in Differin.[26]

33. While there is a slightly higher incidence of adverse reactions with Differin XP as compared to Differin, the same types of adverse reactions (mild to moderate cutaneous irritation such as erythema, scaling, dryness, and/or burning/stinging) occurred with the use of both Differin and Differin XP. These adverse reactions were of average intensity and occurred typically in the first two to four weeks of treatment with Differin and the first week of treatment with Differin XP. With the continued use of Differin and Differin XP these adverse reactions generally subsided, thus indicating that both Differin and Differin XP are tolerated well by patients.[27]

34. With respect to efficacy, the product monograph includes results of certain studies which provide clinical evidence that topical adapalene is effective in reducing the inflammatory component of acne. Again, as is expected based on the dose-response relationship, certain of these studies identify higher efficacy (e.g., decrease in the inflammatory component) with the use of 0.3% adapalene compared to 0.1% adapalene.[28]

35. The Board pauses here in its summary of the evidence to address one argument raised by the Respondent. The Respondent submits that the fact that Differin and Differin XP share the same product monograph is of little importance, because shared product monographs are a relatively common feature of medicines marketed in Canada by the same manufacturer. The Board does not accept this argument for two reasons. First, no evidence was provided to support it. Second, it incorrectly downplays the status of a product monograph. A product monograph is an official document with prescribed requirements that is required by the *Patented Medicines Regulations*[29] to be provided to the Board. It is a factual, scientific document that, devoid of promotional material,

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26 Ho Affidavit at paras 17-18.

27 Ho Affidavit, Exhibit B at 4.

28 Ho Affidavit, Exhibit B at 15-17 .

29 SOR/94-688 at s 3(1).

describes the essential characteristics of the medicine, including the properties, claims, indications, proper dosages, method of administration and side effects and contains any other information that may be required for the optimal, safe and effective use of the drug.[30] While not determinative, the fact that the Respondent chose to include Differin and Differin XP in the same product monograph supports Board Staff's position that Differin and Differin XP are simply different strengths or dosage forms of the same medicine.

The 237 Patent

36. The 237 patent is titled "Use of Adapalene for the Treatment of Dermatological Disorders."[31]

37. The 237 patent states that the Respondent "has developed a new pharmaceutical composition containing adapalene at a weight concentration of 0.3%, intended for the treatment of dermatological ailments with an inflammatory or proliferative component. Specifically, the [Respondent] has noted, surprisingly, that, in addition to exhibiting better therapeutic efficacy compared to known compositions, the composition according to the invention exhibits good tolerance, comparable to those of the known compositions with a lower concentration of the active principle."[32]

38. The 237 patent further provides: "Thus, an object of the present invention is the use of [adapalene] for producing a pharmaceutical composition intended for the treatment of dermatological ailments with an inflammatory or proliferative component, characterized in that the pharmaceutical composition comprises 0.3% by weight of adapalene relative to the total weight of the composition and the composition is a gel or a cream."[33] The 237 patent then goes on to list various formulations of compositions comprising 0.3% adapalene and asserts seven different claims.

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30 *ICN Pharmaceuticals, Inc v Canada (Staff of the Patented Medicine Prices Review Board)* (1996), [1997] 1 FC 32 [*ICN Pharmaceuticals*] at para 23; *Duchesnay Inc v Canada (Attorney-General)*, 2012 FC 976 at para 4; *Patented Medicines Regulations* at s 3(1).

31 Cook Affidavit, Exhibit F at 1.

32 Cook Affidavit, Exhibit F at 2.

33 Cook Affidavit, Exhibit F at 3.

39. The 237 patent also discusses the effectiveness of 0.3% adapalene gel compared to that of 0.1% adapalene gel, including comparative clinical tests showing the two gels provide similar therapeutic effects but that (i) 0.3% adapalene gel acts more rapidly than 0.1% adapalene gel; specifically from the fourth week of treatment, a difference is noted between the effectiveness of the 0.3% adapalene gel and the 0.1% adapalene gel, and (ii) the 0.3% adapalene gel produces a clearly greater therapeutic effect after 8 weeks of treatment.[34]

40. In addition, the 237 patent discusses side effects, including comparing the side effects from the use of 0.1% adapalene gel to those experienced from the use of 0.3% adapalene gel. Overall, the same types of side effects were observed in both populations, with the occurrence of undesirable side effects being "statistically the same for the two gels with different concentrations of the active agent".[35] The 237 patent concludes that the "intensity of undesirable side effects is average, which leads to the conclusion that the two gels are well-tolerated by the patients".[36]

Evidence of Clinicians

41. Board Staff's witness, Dr. Ho, gave evidence about the clinical similarities and differences between Differin and Differin XP and concluded that the only difference is the concentration of adapalene. Dr. Ho explained that the chemical structure of adapalene in these products and the single mechanism of action for adapalene remains the same despite the different concentrations in Differin and Differin XP.[37] As noted previously, Dr. Ho testified that the higher concentration of adapalene in Differin XP simply provides a greater clinical effect until a maximum is reached and that the different concentrations of adapalene in Differin and Differin XP gives clinicians the flexibility to tailor the medication to an individual's skin colour and type, which can influence the chosen formulation of a

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34 Cook Affidavit, Exhibit F at 9.

35 Cook Affidavit, Exhibit F at 10-12.

36 Cook Affidavit, Exhibit F at 12-13.

37 Ho Affidavit at para 18.

topical medication generally.[38] Further, Dr. Ho opined that "there is no topical acne product that would be considered irreplaceable, or that cannot be substituted".[39]

42. While each of the Respondent's clinician witnesses testified that Differin and Differin XP are different products, mainly because of the higher concentration of adapalene in Differin XP and the resultant higher efficacy and incidence of adverse reactions, both Dr. Charles Lynde and Dr. Jerry Tan testified that Differin and Differin XP work in the same way, using the same mechanism of action to treat the same disorder with 0.3% adapalene providing slightly "higher efficacy" than 0.1% adapalene in patients "able to tolerate" the "slightly more irritating properties associated with a higher adapalene concentration".[40] While Dr. Tan testified that he would use Differin in milder cases of acne and Differin XP for patients with mild to moderate acne, he agreed that "milder to moderate acne localized to the face is treated with topical medications including retinoids,"[41] such as adapalene and, he further testified that "[f]or comedonal acne, I typically recommend…the use of retinoids and/or derivatives thereof. I would use Differin or Differin XP for this type/stage of acne".[42] Similarly, Dr. Lynde testified that "adapalene both 0.1% and 0.3% concentrations, can be used alone if the predominant feature presented by a patient is comedonal acne and there is only mild inflammation".[43]

43. The Respondent also relied on the evidence of Leithe Holowaty, a pharmacist with prescribing authority. While Ms. Holowaty testified that Differin and Differin XP are different medicines in part because of differences in efficacy and adverse events, she also described both as "medium strength recommendations" for treating certain types of acne.[44]

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38 Ho Affidavit at paras 17-18. See also, Affidavit of Charles Lynde sworn August 10, 2016 (Lynde Affidavit) at para 15.

39 Affidavit of Vincent Ho sworn August 22, 2016 at para 23.

40 Lynde Affidavit at para 28; Executed Report of Dr. Jerry Tan dated August 5, 2016 (Tan Report) at 7,9-12.

41 Tan Report at 9 and 21.

42 Tan Report at 9-10.

43 Lynde Affidavit at para 26.

44 Affidavit of Leithe Holowaty sworn August 12, 2016 (Holowaty Affidavit) at 2-3.

44. In support of her position that Differin and Differin XP are different medicines, Ms. Holowaty stated that there is no instance she is aware of in which any adapalene containing prescription (e.g., including Differin and Differin XP) could be automatically substituted with any other product or with each other. In support of this statement, Ms. Holowaty testified that no provincial formulary or private insurer considers Differin and Differin XP as substitutable with one another let alone any other type of retinoid.[45]

45. The Board is not convinced that decisions by provincial formularies or private insurers about the substitutability of different drug products for reimbursement purposes is in any way relevant to the question it must answer on this redetermination. In any event, in cross-examination, Ms. Holowaty conceded that many of the provincial formularies do not include adapalene-containing drug products, including British Columbia, Alberta and Ontario and, only Nova Scotia lists Differin. This may explain why automatic substitution of Differin and Differin XP is not possible under provincial reimbursement programs since, in order for automatic substitution to occur, both the prescribed product and the product being substituted would need to be on the public formulary.[46] To the same point, in British Columbia and Nova Scotia where substitution by pharmacists is permitted for certain classes of medications, none of those classes include any retinoids at all.[47] For these reasons, the Board placed little weight on Ms. Holowaty's opinions about substitution.

Notices of Compliance/Drug Identification Numbers

46. In support of its position that Differin and Differin XP are separate medicines and not interchangeable, the Respondent pointed to the fact that it received separate Notices of Compliance (NOCs) from Health Canada and was assigned different Drug Identification Numbers (DINs) for its various adapalene products, including Differin and Differin XP.[48] The Board does not consider the different DINs or NOCs to be relevant to the question it must answer on this redetermination. They are administrative matters imposed under a separate regulatory regime that has a different focus. Whether different

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45 Holowaty Affidavit at 2-3.

46 Transcript of Cross-Examination of Leithe Holowaty dated September 2, 2016 (Holowaty Transcript) at 12.

47 Holowaty Transcript at 15.

48 Galderma Written Submission dated September 19, 2016 at paras 4 and 17.

DINs or NOCs were received for Differin and Differin XP does not assist the Board in determining, for purposes of section 79(2) of the *Patent Act*, whether the invention of the 237 patent pertains to Differin.[49]

Analysis

47. The question the Board must answer is whether the invention of the 237 patent pertains to Differin, taking into account the directions provided by the Federal Court of Appeal, the totality of the evidence before the Board and the Board's consumer protection mandate.

48. It is important to situate this question in the context of the Board's mandate under the Act. The Board's mandate is to ensure that the statutory monopoly granted to patentees of medicines is not abused by excessive pricing of those medicines. The Act gives the Board two powers to fulfill this mandate: (i) the power to compel disclosure of certain kinds of information from patentees pursuant to sections 80 and 81 of the Act, and (ii) the power to make a remedial order if it concludes that a patentee is selling a patented medicine at an excessive price pursuant to section 83 of the Act. The issue in this redetermination relates solely to (i).[50]

49. The Board may only exercise its powers against patentees, former patentees or persons entitled to the benefit of a patent "of an invention pertaining to a medicine." Section 79(2) of the Act provides that "an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine. In this case, the question is whether the invention of the 237 patent pertains to Differin. If it does, the Respondent is required to file the prescribed sales and financial information with the Board and this Panel has the power to enforce that obligation.

50. Before proceeding to answer the question whether the invention of the 237 patent pertains to Differin, the Board will address the Respondent's submission that for an

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49 *ICN Pharmaceuticals* para 53.

50 [cite to FCA decision at para 10 and 11.]

invention to pertain to a medicine within the meaning of section 79(2) of the *Patent Act*, the invention must "encompass" the medicine that a patentee is selling in Canada.

51. The Board rejects the Respondent's interpretation of section 79(2). It is inconsistent with both the wording of section 79(2) and the decisions of the Federal Court of Appeal in both *ICN Pharmaceuticals* and in this proceeding. In both cases, the Federal Court of Appeal confirmed that section 79(2) is to be given a broad interpretation consistent with the ordinary meaning of the words used and with the Board's mandate to protect Canadian consumers from excessive prices.

52. In *ICN Pharmaceuticals*, the Court concluded that "subsection 83(1) of the Act is concerned only with the existence of a related patent and not its potential or actual effect on the ability of potential competitors to enter a market, or for that matter the ability of patent holders to exercise market power. In my view, the phrase, "…an invention pertaining to a medicine…", and in particular the word *pertaining,* evinces a clear intention that the nexus between the patent and the medicine is of broad import." The Court went on to say "[t]hat the word *pertaining* invites a broad construction is reinforced by subsection 79(2) which expands upon the notion of when a patent pertains to a medicine."[51]

53. Further, in this proceeding, the Federal Court of Appeal noted that the use of the words "pertains to" in section 79(2) shows an intention to express a "looser association than conveyed by other more restrictive expressions (such as an invention "comprising a medicine)".[52] The Board includes "encompassing a medicine" in that list of "other more restrictive expressions."

54. The test the Board is compelled to apply, as directed by the Federal Court of Appeal, is as set out in section 79(2) and not as reformulated by the Respondent. Indeed, if the appropriate test was that the invention must encompass the medicine at issue, the Federal Court of Appeal would not have directed the Board to consider what "kind of

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51 *ICN Pharmaceuticals* at para 57.

52 *Galderma FCA* at paras 63-64.

clinical similarities would support a finding that the invention of a patent was intended or capable of being used for that medicine".[53]

55. Further, adopting the restrictive interpretation of section 79(2) advanced by the Respondent would, as noted by the Federal Court of Appeal in *ICN Pharmaceuticals,* "provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the Board, and would limit the ability of the Board to protect Canadian consumers from excessive pricing".[54]

56. Turning now to the issue that the Board must decide, the question of whether the invention of a patent pertains to a medicine is fact-specific, and the Board's decision in this case is based on the particular factual circumstances presented in the evidence submitted by the parties.

57. The Board has carefully considered all of the relevant evidence and submissions in determining what kinds of clinical similarities support a finding that the invention of the 237 patent pertains to Differin. The Board concludes that, based on the entirety of the evidence, Board Staff has met its onus of showing, on a balance of probabilities, that the invention of the 237 patent (being a pharmaceutical composition having a concentration of 0.3% adapalene to be used in the treatment of dermatological conditions with an inflammatory or proliferative component, such as common acne) pertains to (e.g., is intended or capable of being used for) Differin. The result of the Board's conclusion is that the Respondent must file the prescribed sales and financial information for Differin for the period until the 237 patent was allowed to lapse.

58. The collective effect of these clinical similarities between Differin and the invention of the 237 patent as reflected in Differin XP establish that the invention of the 237 patent is intended or capable of being used for Differin.

(a) Differin and Differin XP are two different strengths or concentrations of the same single active therapeutic ingredient (i.e., adapalene); have the same

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53 *Galderma FCA* at 73.

54 *ICN Pharmaceuticals* at para 60.

indication (namely, the treatment of common acne), and employ an identical mechanism of action. The difference in strength or concentration does not affect either the chemical structure or mechanism of action of the active therapeutic ingredient;

(b) Differin and Differin XP are the subjects of a single product monograph which identifies, in addition to the facts outlined in (a) above, contraindications; warnings and precautions; types of potential adverse reactions; and dosage, administration, storage and stability guidelines, common to both;

(c) The adverse reactions for both Differin and Differin XP are of the same type and of average intensity and typically occur in the first two to four weeks of treatment with Differin and the first week of treatment with Differin XP. With the continued use of both Differin and Differin XP, the adverse reactions generally subside, indicating that both products are well tolerated. Further, the occurrence of undesirable side effects is statistically the same for the 0.1% adapalene and 0.3% adapalene gels; and

(d) The different concentrations of adapalene in Differin and Differin XP allows the clinician to tailor the medication to individual skin type to obtain optimal combination of efficacy and tolerance, but no topical acne product, including Differin and Differin XP, is considered unsubstitutable, and clinicians view both Differin and Differin XP as appropriate treatment for certain forms of acne.

59. The Board accepts that there is a slightly greater incidence of adverse reactions as well as higher efficacy from the use of Differin XP as compared to Differin, but the evidence also reveals that these differences are the normal consequences of the dose-response relationship and are not, in the Board’s view, significant enough to outweigh the significant clinical similarities taken as a whole.

60. The Board's consideration of the 237 patent is limited to answering the question posed by the Federal Court of Appeal, in the context of its mandate to protect Canadian consumers from excessive pricing of patented medicines. The answer to that question determines whether the Respondent is required to file with the Board the prescribed sales and financial information for Differin. Differin went off patent on December 29, 2009. Differin XP went off patent on March 14, 2016, the date the 237 patent lapsed. Considering that Differin and Differin XP are the same medicine, albeit in different concentrations, requiring the Respondent to file the prescribed sales and financial information for Differin during the approximately 6 years between the date when Differin went off patent and the date when Differin XP went off patent, is consistent with the Board's mandate.

61. Finally, we agree with the Respondent's objection to Board Staff's request that the Respondent provide information in respect of Differin for the period from January 1, 2010 to the "present and thereafter". The Initial Decision was limited to the period between January 1, 2010 and March 14, 2016, the date the 237 patent lapsed. No basis or justification was provided by Board Staff for extending the time period indefinitely, and this request is denied.

Conclusion and Order

62. The Board finds that the invention of the 237 patent pertains to Differin. Since the Respondent is a person who was entitled to the benefit of the 237 patent for the period between January 1, 2010 and March 14, 2016, the Board orders the Respondent to file the prescribed sales and financial information for Differin for that period.

Dated at Ottawa, this 7th day of May, 2020.

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members

Dr. Mitchell Levine
Carolyn Kobernick

Counsel for Galderma Canada Inc.

Malcolm Ruby
R. Scott Joliffe
Alan West
Charlotte McDonald

Counsel for Board Staff

David Wilson
Calina Ritchie
Julie Mouris

Counsel for Panel

Sandra Forbes
Alysha Manji-Knight