**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

*Heard on September 26 and 27, 2016*

1. On September 26 and 27, 2016, a hearing was held in respect of the Notice of Application (the **"Notice of Application"** or the **"Application"**) by Board Staff dated January 19, 2016 alleging that Galderma Canada Inc. ("**Galderma**" or the "**Respondent**") failed to provide Board Staff with the pricing and sales information of medicines containing adapalene, sold under the brand names Differin, Differin XP, TactuPump and TactuPump Forte, as required under section 80 of the *Patent Act*[1] and sections 3 and 4 of the *Patented Medicines Regulations* (the "**Regulations**").[2]

2. Following the commencement of this Application, Galderma amended its Form 1 filings for TactuPump and TactuPump Forte to include, *inter alia*, the 451 patent. As a result of this amendment, Board Staff is no longer seeking relief in respect of these two medicines.

3. During the course of the Application, Board Staff and Galderma (together, the **"Parties"**) narrowed the issues for the consideration of the hearing panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**PMPRB**" or the **"Board"**). At the hearing, the only issues before the Panel were as follows:

[1] RSC, 1985, c. P-4.

[2] SOR/94-688.

i. Do any or all of the 237, 451 or 321 patents (as defined below) pertain to Differin?

ii. Do either or both of the 451 or 321 patents pertain to Differin XP?

4. For the reasons set out below, the Panel finds that (i) the 237 patent pertains to Differin and orders Galderma to file prescribed information on this basis for Differin for the period between January 1, 2010 and March 14, 2016; and (ii) the 321 and 451 patents do not pertain to Differin or Differin XP.

## Background

5. The original Notice of Application concerns the medicines sold in Canada under the brand names Differin, Differin XP, TactuPump and TactuPump Forte (collectively, the "**Medicines**"). Differin is available in cream and gel formats. Each of the Medicines, including each of Differin gel and cream, has been assigned a separate Drug Identification Number ("**DIN**") by Health Canada.

6. Differin and Differin XP are both topical monotherapy prescription acne medicines manufactured and marketed by Galderma in Canada. Differin and Differin XP contain only one active ingredient, adapalene, in concentrations of 0.1% and 0.3%, respectively.

7. Adapalene is a retinoid developed by Galderma. Retinoids belong to a class of medicines that exert their effects by modifying the mode and expression of specific genes involved in acne.

8. TactuPump and TactuPump Forte are both topical combination therapy prescription acne medicines manufactured and marketed by Galderma in Canada. TactuPump contains two active ingredients – adapalene (0.1%) and benzoyl peroxide ("**BPO**") (2.5%) – which are suspended in a gelling agent called Simulgel 600 PHA. TactuPump Forte contains the same ingredients as TactuPump except it contains a higher concentration of adapalene (0.3%).

9. During the period in which Galderma has been selling the Medicines in Canada, Galderma has obtained the following patents:

i. Canadian Patent No. 1,266,646 entitled "Benzonaphtalenic Derivatives, Process for their preparation and uses as Pharmaceutic and Cosmetic Agents", which was issued on March 13, 1990 and expired on March 13, 2007 (the "**646 patent**");

ii. Canadian Patent No. 1,312,075 entitled "Process for the Preparation of Adamant-1 Derivatives", which was issued on December 29, 1992 and expired on December 29, 2009 (the "**075 patent**");

iii. Canadian Patent No. 2,478,237 entitled "Use of Adapalene for the Treatment of Dermatological Disorders", issued on May 12, 2009 and lapsed on March 14, 2016 (the "**237 patent**")";

iv. Canadian Patent No. 2,466,321 entitled "Gel Comprising at Least a Retinoid and Benzoyl Peroxide", issued on November 8, 2011 and expiring on December 9, 2022 (the "**321 patent**"); and

v. Canadian Patent No. 2,656,451 entitled "Composition Comprising a Retinoid and Benzoyl Peroxide", issued on January 27, 2015 and expiring on July 11, 2027 (the "**451 patent**").

10. At the hearing, the Parties filed the following "Chart of Agreed Facts" with respect to the Medicines:

| Product | DIN | Notice of Compliance (NOC) | Date of First Sale in Canada | Patents that pertain or pertained to medicine (as agreed by the Parties)[3] | Patent Status | Filings for Reporting periods under ss. 3, 4 and 5 of the Regulations |
|---|---|---|---|---|---|---|
| Differin Gel | 2148749 | January 1995 | June 1996 | 1,266,646 | Expired | January 1996 to December 2009 |
| | | | | 1,312,075 | Expired | |
| Differin Cream | 2231592 | June 1997 | January 1998 | 1,266,646 | Expired | January 1998 to December 2009 |
| | | | | 1,312,075 | Expired | |
| Differin XP | 2274000 | December 2005 | July 2007 | 2,478,237 | Lapsed March 14, 2016 | January 2007 to March 14, 2016 |
| TactuPump (formerly Tactuo) | 2365871 | March 2011 | May 2011 | 2,466,321 | In force | January 2011 to June 2016 (current) |
| | | | | **2,656,451** | In force | |
| TactuPump Forte | 2446235 | September 2015 | January 2016 | 2,466,321 | In force | January 2016 to June 2016 (current) |
| | | | | **2,478,237** | Lapsed March 14, 2016 | |
| | | | | **2,656,451** | In force | |

11. During the hearing, Board Staff noted that Differin XP only has the 237 patent listed, but there are two other patents (the 646 and 075 patents) for which filings were also made for Differin XP. Galderma believes that these two patents were never listed on Form 1. Ultimately, this was not relevant for Differin XP because the 237 patent expires later than both the 646 and 075 patents, and Galderma has filed the relevant required information for Differin XP under the 237 patent.

12. Board Staff alleges that the 237 and 451 patents pertain to Differin, and that the 451 patent pertains to Differin XP, and Galderma is, therefore, required to file prescribed information on this basis for Differin and Differin XP. As discussed in greater

[3] The patents in bold were added to the Form 1 after the application was brought by Board Staff.

detail below, Board Staff also brought a motion to amend its Notice of Application to allege that the 321 patent also pertains to Differin and Differin XP. This motion was not opposed by Galderma at the hearing.

13. In particular, Board Staff is seeking an order requiring Galderma to file the prescribed information for Differin for the period of January 1, 2010 to present and thereafter until the expiry of the 321 and 451 patents. Board Staff is also seeking an order requiring Galderma to file the prescribed information for Differin XP for the period of March 15, 2016 to present and thereafter until the expiry of the 321 and 451 patents.

**Pre-hearing Motion to Include 321 patent**

14. In its pre-hearing written argument, Board Staff raised for the first time that the 321 patent also pertains to Differin and Differin XP. Board Staff brought a motion to amend the Notice of Application and for the Panel to allow this allegation to be included and argued at the hearing.

15. The 321 patent was appended to the affidavit of Trent Mayers, and Board Staff submits that, although there are some differences (i.e., in gelling systems), both patents are for a retinoid plus BPO; both patents make references to adapalene; and the wording of the abstracts of both patents is the same. Board Staff submits that the 451 and 321 patents are very similar, and that Board Staff's arguments with respect to the 321 patent are essentially the same as its arguments for the 451 patent (which is already included in the Notice of Application).

16. At the hearing, Galderma submitted that there are differences between the patents but that it does not oppose the motion, and that it does not "think it is of any great consequence".[4]

17. The 321 patent expires in 2022 whereas the 451 patent expires in 2027. If the Panel reaches the conclusion that the 451 patent did pertain to Differin and Differin XP,

[4] Hearing Transcript, Volume I, pp. 13 - 14.

and thus created reporting obligations, the inclusion of the 321 patent would not create or extend Galderma's reporting obligations for Differin and Differin XP.

18. The Panel notes, however, that the allegations relating to the 321 patent should not have been raised for the first time at such a late stage of the proceeding, following the conclusion of the cross-examinations, and without providing Galderma an opportunity to respond to the allegations. Notwithstanding the foregoing, section 97(1) of the *Patent Act* provides: "[a]ll proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit." Furthermore, Rule 6 of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "**PMPRB Rules**")[5] grants the Panel broad discretion with respect to procedural issues, including deciding "any question of procedure." Given the Panel's mandate to conduct the hearings expeditiously, the lack of any prejudice to or objection from Galderma, the Panel allowed the inclusion of allegations related to the 321 patent with respect to Differin and Differin XP. This amendment related to the 321 patent did not, in any event, have any impact on the outcome of the hearing.

**Issues in the Main Proceeding**

19. As discussed in greater detail below, the Federal Court of Appeal (the **"FCA"**) in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*[6] ("**ICN**") sets out a three-part test to determine whether the PMPRB has jurisdiction over a company in respect of a drug being sold by that company in Canada:

i. Is the party a patentee of an invention?

ii. Does the invention pertain to a medicine?

iii. Is the medicine being sold in Canada?

20. Both Parties accepted this as the correct test. Furthermore, the Parties agreed that Galderma is a patentee of an invention and that Differin and Differin XP are being

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5 SOR/2012-247.

6 1 FCR 32, 1996 CanLII 4089.

sold in Canada. The only dispute between the Parties is in respect of the second part of the test, namely whether the patents pertain to the two medicines at issue.

21. Two main issues in this proceeding are, therefore, as follows:

i. Do any or all of the 237, 451 or 321 patents pertain to Differin?

ii. Do either or both of the 451 or 321 patents pertain to Differin XP?

**Submissions of the Parties**

22. The Panel has reviewed the extensive evidence and submissions filed by Galderma and Board Staff, and has summarized the Parties' positions below.

23. Differin and Differin XP both contain adapalene as the sole active ingredient and both have the same product monograph. Board Staff submits that, apart from the variations in the vehicle (i.e., the gel), the only difference between Differin and Differin XP is the concentration of adapalene. The vehicle carries the active ingredient but the therapeutic effect comes from the therapeutic agent which, in the case of both Differin and Differin XP, is adapalene.[7]

24. In ICN, the court held that for an invention to pertain to a medicine, there must be a rational connection between the invention and the pharmaceutical end product. The connection can be one of the merest slender thread and the word "pertain" shows clear legislative intent for a broad construction. Board Staff submits that the objective of the *Patent Act* and the PMPRB is to reward medical innovation while ensuring reasonable prices for patented medicines, and the merest slender thread is the necessary threshold to maintain this balance. Board Staff cited to ICN in this regard:

> There need only be a slender thread of a connection between a patented invention and the medicine sold in Canada in order to satisfy the test for a nexus. The legislative reason for this is simple. Requiring a stronger nexus would provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the

[7] Hearing Transcript, Volume I, p. 34.

> Board, and would limit the ability of the Board to protect Canadian consumers from excessive pricing.[8] [emphasis added]

25. Board Staff submits that the 237 patent is listed only for Differin XP but it also pertains to Differin and should be listed because there is a rational connection between the 237 patent and Differin. The abstract of the 237 patent states:

> [t]he present invention relates to the use of 6-[3-(1-adamantyl)-4-methoxypheny]-2-naphthanoic acid (adapalene), or its salts, for producing a pharmaceutical product composition intended for the treatment of dermatological elements with an inflammatory or proliferative component, comprising 0.3% by weight of adapalene relative to the total weight of the composition.[9]

26. Board Staff submits that, although the 237 patent refers to 0.3% adapalene (as opposed to 0.1%), there is a slender thread connecting the patent to Differin. The chemical structures and mechanisms of action of both 0.1% and 0.3% adapalene are identical, and the name of the patent alone suggests that there is a slender thread connecting the 237 patent and Differin; the 237 patent is entitled "Use of Adapalene for the Treatment of Dermatological Disorders".

27. Differin and Differin XP have the same product monograph, and the main submission of Board Staff is that "adapalene is adapalene", whether at 0.1% concentration or 0.3% concentration, and because the 237 patent applies to 0.3% adapalene, it also applies to 0.1% adapalene.

28. With respect to the 451 and 321 patents, Board Staff submits that the titles of both patents refer to a composition or gel comprising a "retinoid" and adapalene is a retinoid. The abstract of the 451 patent states, "[t]he invention relates to a composition comprising, in a physiologically acceptable medium, at least one retinoid, dispersed benzoyl peroxide and a gelling system comprising at least two categories of

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8 Hearing Transcript, Volume I, pp. 57 - 58.

9 Exhibit D, Trent Mayers Affidavit.

compounds".[10] Board Staff submits that there are repeated references to adapalene in the patents, creating, at the very least, a slender thread which is all that is required for a patent to pertain to a medicine.

29. Board Staff also directed the Panel to the Anatomical Therapeutic Classification ("**ATC**") system, noting that the narrowest classification for Tactupump and Tactupump Forte, for which the 321 and 451 patents are listed, focuses on adapalene. In Board Staff's submission, this shows that adapalene products are closely interconnected and that adapalene is the defining medicine in respect of the combination of adapalene and BPO.

30. Although the combination products Tactupump and Tactupump Forte utilize a different vehicle, Board Staff submits that "adapalene is adapalene", and is unchanged by the different vehicle. In Board Staff's submission, given that adapalene is the defining medicine, the addition of BPO (or the different vehicle) does not break the merest slender thread connection between the 451 and 321 patents, and Differin and Differin XP.

31. Board Staff submits that it is not important that the Medicines have distinct DINs and Notices of Compliance ("**NOCs**"). Restricting the analysis in this way, in Board Staff's submission, is directly contrary to ICN. Furthermore, the fact that Board Staff acknowledged in its communication with Galderma in the past, that Differin XP is a different product than Differin, does not lead to the conclusion that the same patent cannot pertain to both Differin and Differin XP. Board Staff submits that the hearing is a *de novo* process and this case is about whether Galderma has met its requisite reporting obligations. Any previous communication between Board Staff and Galderma is thus of very limited to no relevance.

32. Board Staff submits that a distinction should not be made based on the concentration of the ingredient. The inquiry should focus on the active ingredient itself, which in the case of both Differin and Differin XP, is adapalene. Board Staff notes that it

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[10] Exhibit C, Trent Mayers Affidavit.

is not suggesting that the different adapalene medicines are identical or that they don't exhibit any clinical differences. Board Staff acknowledges that there are many reasons why one formulation may be preferred over another. However, Board Staff submits that the evidence of Galderma (in particular of Charles Lynde, Leithe Holowaty and Jerry Tan) exaggerates the differences between the two medicines at issue. Board Staff argues that the clinical differences are "fundamentally irrelevant" because the issue is whether the slender thread test is met, and Board Staff submits that the slender thread is established between the patents in issue and between Differin and Differin XP.[11]

33. Galderma submits that Differin XP is a specific innovation. The PMPRB treated Differin XP as a "new medicine" when it was introduced in Canada in 2007, referring to it as a category 1 new medicine.[12] Further, Differin and Differin XP are treated as different medicines for the purposes of provincial reimbursement programs.[13] Galderma submits that the 237 patent is for 0.3% adapalene, and is not intended or capable of being used for producing 0.1% adapalene.[14]

34. The onus is on Board Staff to demonstrate that the patent pertains to the medicine (i.e., that the 237, 451 and 321 patents pertain to Differin, and the 451 and 321 patents pertain to Differin XP). Galderma submits that Board Staff attempts to reverse the logic and, instead of demonstrating that the patent pertains to the medicine, Board Staff is trying to argue that the medicine pertains to the patent which is not the correct test.[15] In ICN, the FCA confirmed that there must be a rational connection between the invention (i.e., patent) and the pharmaceutical end product (i.e., medicine), and the PMPRB has acknowledged this in its 2006 Newsletter, "The Scope of the PMPRB's Jurisdiction".[16]

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11 Hearing Transcript, Volume I, pp. 99 - 100.

12 Hearing Transcript, Volume I, pp. 135 – 136.

13 Galderma's Written Submissions, para. 4.

14 Galderma's Written Submissions, para. 64.

15 Galderma's Written Submissions, paras. 60 - 61.

16 Hearing Transcript, Volume I, pp. 137 – 148.

35. Galderma submits that the Board does not have jurisdiction over a medicine unless the patent in question is capable of creating the medicine (i.e., the patent must be capable of being used for the medicine or its preparation), and the 237 patent is not capable of producing 0.1% adapalene:

> [Adapalene is] an ingredient, it's mentioned, but that doesn't mean… that a bare mention of an ingredient that is off-patent means that the invention pertains to the medicine.
>
> That involves an analysis, as we know, of whether the patent is intended or capable of being used for the medicine… And the [237, 321 and 451] patents… the abstracts, are not intended or capable of being used to make adapalene. There is no 0.1, Differin 0.1. There is no protection there to the company from those patents. They protect other ideas. They protect the novel combination and they protect the higher dosage strength, which is treated as a new and different medicine by the Board, or it was when it arrived on the Canadian market.[17]

36. Galderma submits that the 237 patent pertains to Differin XP, a new and stronger strength medicine. Similarly, Galderma submits that the 451 patent is not intended to, nor is it capable of, producing 0.1% or 0.3% adapalene. The 451 patent pertains to the combination medicines, not the entry level 0.1% adapalene. Like BPO, adapalene is a component of a combined medicine created by the 451 patent. Neither adapalene (0.1%) or BPO, individually, are subject to patents, and their pricing is beyond the jurisdiction of the Board.[18]

37. With respect to the 451 patent, Galderma submits that the gel used in the patent is not the same vehicle but is an entirely new gel which stabilizes the two chemicals (adapalene and BPO).[19] Furthermore, the 321 and 451 patents are not capable of providing any protection to Galderma in respect of either 0.1% or 0.3% adapalene (or Differin and Differin XP, respectively).[20]

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17 Hearing Transcript, Volume I, pp. 40 - 141.

18 Hearing Transcript, Volume I, pp. 114 - 115.

19 Hearing Transcript, Volume I, pp. 127 - 128.

20 Hearing Transcript, Volume I, p. 153.

38. Galderma submits that there is no evidence that the 237 patent is intended or capable of being used to produce 0.1% adapalene, and there is no evidence that the 321 or 451 patents are intended or capable of being used to produce either 0.1% or 0.3% adapalene:

> [W]e will take the position here on the evidence, including by reference to the Board's documents and the ICN case, that based on looking at the face of the patents and the facts as you know them, including Ms. Segura's affidavit and Mr. Mayers affidavit and the affidavits of our experts, we don't think there is -- there is no evidence before you, and it would be my friends' burden, the Board staff's burden, to show that the '237 patent, the '451 patent or the '321 patent are intended or capable of being used to produce the entry level product. There is no evidence of that and in fact it defies reason and it defies the evidence before you.
>
> The patent for that chemical has expired, so it's not -- those patents aren't used, they are not intended to be used, they are not capable of being used to make adapalene, the simple 0.1 version of the chemical.[21] [emphasis added]

39. Galderma further submits that there is nothing in the PMPRB's *Compendium of Policies, Guidelines and Procedures* (the **"Guidelines"**) or the PMPRB's jurisprudence that indicates that off-patent medicines have to be reported after the product has gone off-patent, simply because the old medicine is used as an ingredient in a new medicine.[22] Galderma submits that the reporting obligation in such a situation should only apply to the new medicine, which is under patent, and not the original medicine (which is just an ingredient in the new medicine and is now off-patent).

40. The Parties also made submissions with respect to synergies between adapalene and BPO in the combination medicines. Synergy describes a situation where the combination medicine exhibits greater therapeutic effect than each medicine administered or applied separately but at the same time. Both Parties agreed, however, that the issue of synergy is not material to the outcome of the case.[23] The Panel agrees

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21 Hearing Transcript, Volume I, pp. 129 - 130.

22 Hearing Transcript, Volume I, p. 126.

23 Hearing Transcript, Volume I, p. 171.

with the Parties that this issue was not material in the outcome of this case. Any alleged synergistic benefits (or lack thereof) between combining adapalene and BPO were irrelevant in the Panel's determination of whether the 451 and 321 patents pertain to adapalene (i.e., Differin and Differin XP).

41. The Parties also made submissions with respect to procedural fairness and legitimate expectations. Galderma submits that the "Board failed to inform the industry in any document that an off-patent medicine that became an ingredient in a new medicine would create new reporting requirements for the old medicine".[24] Galderma argues that the PMPRB is trying to acquire jurisdiction over an old off-patent medicine that, on the basis of existing law and administrative practice, has not required any reporting for almost 7 years.[25]

42. Board Staff submits that this case is based on the *Patent Act* and the Regulations, and is not derived from the Guidelines or any other publication. Given that the PMPRB relies on self-reporting by patentees, if Board Staff identifies a breach of the *Patent Act* in evaluating a complaint, bringing an application for an order to provide information for the past does not create issues of procedural fairness. Board Staff submits:

> The difficulty with bringing legitimate expectations into this discussion is that it has nothing to do with this case. What Board Staff is doing in this case is saying that there's been a breach of statutory requirements, and what Galderma is saying is the Board has no jurisdiction.
>
> So the question at issue is one of substantive rights, does the PMPRB have jurisdiction or does it not.
>
> The aspect of legitimate expectations doesn't come to play because the doctrine of legitimate expectations cannot create substantive rights. It has nothing to do with substantive rights.
>
> […]

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[24] Galderma Written Submissions, paras. 84 – 86.

[25] Galderma Written Submissions, para. 54.

> We accept, and I fully accept, that Galderma is entitled to procedural fairness, and in fact, that's exactly why we're here. There's been an allegation of a failure to file. We're here in front of you to make our arguments. Galderma has a chance to make its arguments. Evidence has been submitted, et cetera.[26]

## Analysis

43. As noted above, the only issue in dispute between the Parties was whether the patents pertain to the two medicines at issue. For the reasons that follow, the Panel finds that (a) the 237 patent pertains to Differin, and orders Galderma to file prescribed information on this basis for Differin for the period between January 1, 2010 and March 14, 2016; and (b) the 321 and 451 patents do not pertain to Differin or Differin XP.

### (a) *237 patent pertains to Differin.*

44. Section 79(2) of the *Patent Act* outlines two general ways in which a patent may pertain to a medicine. Either it is (i) intended or capable of being used for medicine; or (ii) intended or capable of being used for the preparation or production of medicine. These two types of uses are confirmed by subsection 79(2) of the French version of the *Patent Act* which provides that a patent is linked to a medicine if it can be used for medicine or for the preparation of medicine:

> 79(2) Pour l'application du paragraphe (1) et des articles 80 à 101, une invention est **liée** à un médicament si elle est destinée à des médicaments ou à la préparation ou la production de médicaments, **ou susceptible d'être utilisée à de telles fins**. [emphasis added]

45. Section 79(2) of the *Patent Act* and the concept of "pertains to" have been considered previously on a number of occasions, both by the Federal Court of Appeal as well as by the hearing panels in other PMPRB proceedings. The following is a summary of the key principles from prior jurisprudence (and as summarized in

[26] Hearing Transcript, Volume I, pp. 95 - 98.

paragraph 72 of the Sandoz[27] case) in determining whether the invention described in a patent pertains to a medicine:

i. There must be a "rational connection or nexus" between the invention and the medicine;

ii. There is no requirement that the invention actually has been used or be in use (in relation to the medicine or otherwise) for there to be a connection between the invention and the medicine;

iii. The connection between the invention and the medicine can be one of the "merest slender thread";

iv. The rational connection between a patent and a medicine can be the medicine itself;

v. In ascertaining whether there is a connection between the invention and the medicine, the Panel should not go beyond the face of the patent (such as by engaging in patent or claims construction, or infringement analysis); and

vi. There is no requirement that the patent provide any market power or monopoly to the patentee – the existence of the patent creates a presumption of market power, which is all that the statute requires.

46. The FCA noted in ICN that the use of the word "pertain" invites a broad construction, and that jurisdiction of the PMPRB extends also to patents containing "process" and "use" claims:

> [T]he Board's jurisdiction extends not only to patents which contain product claims (a claim for the medicine itself), but also patents which contain 'process' and 'use' claims. The law might be otherwise if subsection 83(1) had been drafted

[27] August 1, 2012 Decision: PMPRB-10-D2-SANDOZ – Merits ("**Sandoz**"). The Panel notes that this decision was appealed. The issue of 'pertains to' was not litigated and this case was settled at the SCC, which is why it will not go back down to the trial judge on the "pertains to" issue.

> to read, for example, 'an invention <u>for</u> a medicine'. That the word <u>pertaining</u> invites a broad construction is reinforced by subsection 79(2) which expands upon the notion of when a patent pertains to a medicine. [emphasis in original]

47. While the legal question in ICN is the same as the question faced by the Panel in this case (i.e., whether a patent pertains to a particular medicine), the circumstances in ICN were different. It is useful, therefore, to start by reviewing the specific circumstances of ICN.

48. In that case, ICN Pharmaceuticals, Inc. (**"ICN Pharma"**) argued that one of the patents at issue, the 264 patent, was not used for making the medicine Virazole, and that its invention could not be used to make even enough Virazole for a single dose. The 264 patent was for a method of making microscopic quantities of ribavirin (the active ingredient in Virazole) in a laboratory setting for experimental purposes. ICN Pharma asserted, therefore, that it did not monopolize an important aspect of making and using Virazole. ICN Pharma also argued that the patents in issue did not preclude competitors from entering the market in which Virazole was being sold in Canada, nor did they vest an "exclusionary right" in ICN so as to enable it to exercise market power for the purpose of extracting non-competitive or excessive prices. For these reasons, ICN Pharma asserted that there was no connection between the invention in the 264 patent and Virazole.

49. The Federal Court of Appeal disagreed with ICN Pharma and, consistent with the summary of the law outlined above, held that the invention pertained to the medicine. The court used the "slender thread" analysis, indicating that determining whether there is a thread connecting an invention and a medicine is a contextual exercise that involves, in each case, considering the intended uses and potential uses of the invention.

50. In ICN, the invention was used to prepare or produce the active ingredient in the medicine Vizarole. The Federal Court of Appeal noted that the patent conferred an exclusive right to ICN in respect of that medicine and whether that right offered any actual market share or market power advantage was not determinative. Rather, the

potential for the rights granted under the patent to be used in connection with the medicine was sufficient to establish jurisdiction.

51. The question for this Panel to decide is whether, looking only at the face of the 237 patent, this patent pertains to the medicine Differin. In contrast to ICN, the 237 patent is not, on its face, intended to or capable of being used to prepare or produce the molecule adapalene. Rather, the 237 patent is entitled "Use of Adapalene for the Treatment of Dermatological Disorders" and the abstract states,

> [t]he present invention relates to the use of 6-[3-(1-adamantyl)-4-methoxypheny]-2-naphthanoic acid (adapalene), or its salts, for producing a pharmaceutical product composition intended for the treatment of dermatological elements with an inflammatory or proliferative component, comprising 0.3% by weight of adapalene relative to the total weight of the composition.

52. Galderma (drawing on ICN) focused on the second category of use in section 79(2) of the *Patent Act* and argued that the 237 patent is not intended or capable of producing 0.1% adapalene, and, consequently, the 237 patent cannot pertain to Differin. While the Panel agrees that the 237 patent is not, on its face, intended for, or capable of, being used to produce adapalene, as illustrated above, the necessary connection or link between the patent and the medicine under section 79(2) of the *Patent Act* is not limited to circumstances where the patent is intended or capable of being used for the production of the medicine.

53. The 237 patent is a "use" patent and falls into the first category of use specified in section 79(2) of the *Patent Act*. In particular, the 237 patent pertains to the use of adapalene to treat dermatological disorders. The question before this Panel, therefore, is whether the 237 patent is or can be used for the medicine Differin, which is a medicine containing 0.1% adapalene that is used to treat dermatological disorders.

54. Galderma asserts that the 237 patent relates to Differin XP, which has a 0.3% concentration of adapalene but that the 237 patent does not relate to Differin which has a 0.1% concentration of adapalene. The Panel notes that, while the abstract of the 237 patent refers to 0.3% adapalene, it is not clear from the face of the 237 patent that the

patent pertains exclusively to 0.3% adapalene. In particular, the introductory paragraph of the 237 patent states: "[t]he invention relates to the use of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid… in pharmaceutical compositions, in particular dermatological compositions, for the treatment of dermatological ailments with an inflammatory or proliferative component." The 237 patent further states that:

> Thus, an object of the present invention is the use of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) or of one of its pharmaceutically acceptable salts, 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.[28] [emphasis added]

55. As such, although 0.3% is mentioned in the abstract, it is not mentioned in the introductory paragraph or the title of the 237 patent and the patent does not, on its face, relate exclusively to a 0.3% concentration of adapalene.

56. Patent laws relating to pharmaceutical products are complex – there can exist patents for the ingredient, the process, the use – and a medicine with an off-patent ingredient may nonetheless be under patent protection if it is covered by a new patent. The PMPRB was not established to decide patent infringement cases, and it is for this reason that the Panel is not to look beyond the face of the patent. At least on its face, it appears that the use of 0.3% adapalene may be one (and not the only one) of the objectives of the 237 patent, and the Panel cannot conclude that the 237 patent pertains exclusively to 0.3% adapalene.

57. The decision of whether a patent pertains to a medicine is a discretionary one. This is not to say that the discretion of this Panel is unfettered but the analysis of "pertains to" requires a holistic evaluation of various factors outlined above. Of particular significance to the issues in this case, the Panel notes that:

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[28] Application Record, p. 541.

i. In ascertaining whether there is a connection between the invention and the medicine, the Panel should not go beyond the face of the patent (such as by engaging in patent or claims construction, or infringement analysis). The 237 patent is entitled "Use of Adapalene for the Treatment of Dermatological Disorders" and it is not clear from the face of the patent that it applies exclusively to 0.3% adapalene;

ii. Adapalene is the only active ingredient in Differin and Differin XP;

iii. The 237 patent provides for the use of adapalene to treat dermatological disorders and Differin is a medicine that uses adapalene to treat dermatological disorders; and

iv. The 237 patent pertains to Differin XP which is a medicine that uses adapalene to treat dermatological disorders.

58. Board Staff bears the onus of establishing, on a balance of probabilities, the requisite connection between the invention and the medicine. Based on the observations above, in particular that it is the same molecule used for the same purpose, and that the face of the patent suggests that the invention is the use of adapalene for the treatment of dermatological disorders, the Panel is satisfied that there is a rational connection, at least of the merest slender thread, which connects the 237 patent and Differin. Put differently, the Panel concludes that, on the face of the 237 patent, the patent pertains to Differin because the patent is capable of being used for Differin.

59. For these reasons, the Panel finds that the 237 patent "pertains to" Differin under section 79(2) of the *Patent Act*, and, on this basis, orders Galderma to file the prescribed information for Differin for the period between January 1, 2010 and March 14, 2016.

**(b) *321 and 451 patents do not pertain to Differin or Differin XP.***

60. As noted above, Board Staff bears the onus of establishing, on a balance of probabilities, the requisite connection between the invention and the medicine (i.e., between the relevant patents and Differin and Differin XP). In this case, Board Staff relies extensively on the "slender thread" analysis in ICN in an effort to establish that the inventions in the 451 and 321 patents pertain to Differin and Differin XP.

61. Board Staff argues that the 451 and 321 patents pertain to Differin and Differin XP because these two medicines contain adapalene as an active ingredient and both patents refer to adapalene as one of two possible ingredients in the manufacture of a combination product.

62. The Panel agrees with Board Staff that the merest slender thread analysis sets a very low threshold for establishing a connection and jurisdiction over a medicine. However, in order for this very low threshold to be met, the thread, no matter how slender, must be grounded in a patent that actually connects to or is linked to the medicine in question. This requires, in the Panel's view and as the Court held in ICN, that there be a rational connection between the patent and the medicine.

63. On their face, the 451 and 321 patents provide for the use of a combination of medicines, which can include adapalene as one of the two active ingredients. The invention is that a combination of two types of medicines can be used as a medicine. The 451 and 321 patents are not intended or capable of being used for Differin or Differin XP, nor for the preparation or production of Differin or Differin XP. Differin and Differin XP are medicines that contain a single active ingredient and neither is a combination medicine.

64. The relevant question is whether there is a patent that pertains to a medicine, not whether there is a medicine that pertains to a patent. Board Staff has framed the issue as the latter, i.e., whether the medicine pertains to the patent, and in particular, argues that because Differin and Differin XP both contain the active ingredient adapalene, they pertain to the patents in issue because those patents refer to adapalene.

65. The position of Board Staff is incorrect. 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*. In the Panel's view, Board Staff has not discharged its onus of satisfying this Panel that the patents in question pertain to adapalene under the merest slender thread analysis. The 451 patent is entitled "Composition Comprising a Retinoid and Benzoyl Peroxide" and the 321 patent is entitled "Gel Comprising at Least a Retinoid and Benzoyl Peroxide". These patents, on their face, are for a combination. There is no rational connection to adapalene as a single agent, even on a merest slender thread analysis.

66. Based on the foregoing, the Panel dismisses Board Staff's application in respect of the 321 and 451 patents.

**(c) *Alleged Breach of Procedural Fairness***

67. Galderma argues that, even if the 237, 321 or 451 patents pertain to Differin, "the Board has failed to follow the principles of procedural fairness and legitimate expectations" in bringing this application. The Panel is of the view that Galderma's position in this regard is flawed and does not prevent or otherwise preclude the PMPRB from having jurisdiction over Differin for the period of time when the 237 patent was in force.

68. There has been no breach of procedural fairness. The issue before the Panel is whether the 237 patent pertains to Differin. The hearing before this Panel is *de novo* and Galderma was given a full and fair opportunity to present its case. No objections were raised in regard to the composition of the Panel or the right of Galderma to present its case.

69. Similarly, the doctrine of legitimate expectations has no application to this case. Galderma referred the Panel to *Canada (Attorney General) v. Mavi* in support of its submission that the doctrine of legitimate expectations applies. That decisions states, in relevant part:

> Where a government official makes representations within the scope of his or her authority to an individual about an administrative process that the government will follow, and the representations said to give rise to the legitimate expectations are clear, unambiguous and unqualified, the government may be held to its word, provided the representations are procedural in nature and do not conflict with the decision maker's statutory duty [emphasis added].[29]

70. It is important to note the statements emphasized above in which the Supreme Court held that the representations must be procedural in nature, and clear, unambiguous and unqualified. Furthermore, subsequent jurisprudence of the Supreme Court has confirmed that an "important limit on the doctrine of legitimate expectations is that it cannot give rise to substantive rights".[30] These points are significant to this case and dispositive of Galderma's submissions.

71. The question of jurisdiction over Differin is a substantive one. Even if this Panel were to conclude (which it does not) that Board Staff made a clear, unambiguous and unqualified representation to Galderma that the 237 patent did not pertain to Differin, such a representation is not procedural in nature because the issue of "pertains to" is a substantive issue, and the doctrine of legitimate expectations is not engaged.

72. Furthermore, the Panel does not agree with Galderma's position that Board Staff is not following its published Guidelines or policies by asking Galderma to report on Differin based on the 237 patent. The PMPRB relies on self-reporting by patentees and it is not unreasonable or contrary to the expectations of a patentee for Board Staff to commence an application against a patentee if Board Staff finds after an investigation (whether due to a complaint or otherwise) that a patentee is not in compliance with its self-reporting obligations. In fact, a hearing panel is entitled to make an order against a former patentee up to three years after the expiry of a patent under section 81(3) of the *Patent Act*. In the current case, the Notice of Application is dated January 19, 2016, before the lapsing of the 237 patent.

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29 2011 SCC 30 (CanLII), para. 68.

30 *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, para. 97.

73. For the reasons noted above, the doctrine of legitimate expectations cannot be applied to preclude the PMPRB from having jurisdiction over Differin during the period when the 237 patent was in force.

**Conclusion and Order**

74. Based on the foregoing reasons, the Panel finds that:

i. the 237 patent pertains to Differin and orders Galderma to file the prescribed information for Differin for the period between January 1, 2010 and March 14, 2016; and

ii. the 321 and 451 patents do not pertain to Differin or Differin XP and the Panel dismisses Board Staff's application in respect of these patents.

Dated at Ottawa, this 19th day of December, 2016.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

**Panel Members**

Dr. Mitchell Levine
Carolyn Kobernick

**Counsel for Galderma Canada Inc.**

Malcolm Ruby
David Woodfield
Alan West

**Counsel for Board Staff**

David Wilson

Calina Ritchie
Julie Mouris

**Counsel for Panel**

Jim Bunting
Badar Yasin