April 9, 2010 **Decision: PMPRB-99-D10-NICODERM - Merits**

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Hoechst Marion Roussel Canada Inc. (the "Respondent") and the medicine "Nicoderm"

DECISION

I. *Introduction*

1. This case first came before the Board by way of a Notice of Hearing dated April 20, 1999. This was followed by several interlocutory motions, applications for judicial review, appeals and attempts by Board Staff and the Respondent to resolve the matter. The case ultimately came before a panel of the Board (the "Panel") for resolution on the merits in hearings that commenced on July 3, 2008.

II. *Background*

2. Nicoderm is a nicotine patch applied to the skin in order to introduce nicotine to the bloodstream. The therapeutic objective is to have nicotine from the patch substitute for nicotine from tobacco, and thus assist people who are attempting to quit smoking.

3. In the case of Adderall XR (*PMPRB-06-D3-ADDERALL XR*, April 10, 2008) a panel of the Board set out the legal framework for the Board's consideration of excessive pricing in accordance with the provisions of the *Patent Act* (the "Act") and the role of the Board's Compendium of Guidelines, Policies and Procedures (the "Guidelines") in that analysis. Without repeating the observations and conclusions of the Adderall XR panel here, this Panel endorses those conclusions.

4. The Guidelines suggested a price at which Nicoderm could be presumed to be introduced to the Canadian market at a non-excessive level (the "maximum non-excessive price" or "MNE") by comparison to the prices of other comparable medicines (medicines in the same "therapeutic class") being sold in Canada at the time that Nicoderm was first sold in Canada.

The Guidelines, implementing the provisions of the Act, require the Panel to consider other factors, such as the international price of Nicoderm, the international prices of other comparable medicines and changes in the consumer price index. However, where (as in this case) there are appropriate domestic comparators (and the domestic price of the medicine is not higher than its international price, and where price changes relative to changes in the CPI are not in issue) the Board places the greatest weight on the prices of domestic comparator medicines.

5. Accordingly, in this case, given that Nicoderm was not priced higher in Canada than internationally, and given that price changes relative to CPI were not in issue, the Panel's focus in establishing the MNE of Nicoderm was the therapeutic class comparison; that is, the MNE of Nicoderm is to be established by reference to the highest non-excessive price of another medicine in the same therapeutic class sold in Canada.

6. At the time of its first sale in Canada, Nicoderm was priced above the price of the only other patented nicotine patch available in Canada, Habitrol. The price of Habitrol was subject to the jurisdiction of the Board, and the maximum price of Habitrol had been established by way of a Voluntary Compliance Undertaking ("VCU") between the manufacturer of Habitrol and the Board.

7. As a result of Nicoderm being priced above the price of Habitrol, the staff of the Board ("Board Staff") considered Nicoderm to be excessively priced and brought the matter before the Panel for a hearing and the determination of that issue.

8. In the course of the hearing, a number of issues were raised by the parties and were the subject of evidence called by both the Respondent and Board Staff. Each of these issues pertained to the comparable smoking cessation medicines (the therapeutic class) and the appropriate way in which to compare the price of Nicoderm to the prices of the other medicines said to be in the same therapeutic class as Nicoderm, all in order to determine the MNE of Nicoderm. Board Staff argued that Habitrol was the appropriate comparator and that the basis of comparison should be the price of one Habitrol nicotine patch to the price of one Nicoderm patch (a "patch to patch" comparison).

9. The Respondent argued that there were other comparator medicines to be considered (such as Nicorette gum and other nicotine patches) and that the appropriate comparison was not "patch to patch" but (since a course of treatment with Nicoderm was different than a course of treatment with Habitrol) on the basis of the relative costs of a course of treatment with each medicine.

Also, the Respondent argued that, even if Habitrol were a potentially appropriate comparator, the fact that the MNE of Habitrol was established by a VCU made that MNE an artificial or otherwise inappropriate benchmark for the MNE of Nicoderm.

10. In addition to disputing the appropriate comparators and methods of comparison for Nicoderm, the Respondent argued that, because there was a period after the period of alleged excessive pricing during which the Respondent had sold Nicoderm below the MNE advocated by Board Staff, there should be a corresponding "credit" or "off-set" against the allegedly excessive revenues. The result of this credit would have been to completely offset the excessive revenues alleged by Board Staff.

11. Finally, the Respondent raised an argument that the Respondent characterized as its most persuasive argument against a finding that Nicoderm had been sold at an excessive price. This argument was that Board Staff's case (of excessive pricing) was premised on the exclusion of the nicotine patch "Nicotrol" from the therapeutic class price comparison. An important premise of the Respondent's argument is that when (as is the normal course in these matters) Board Staff asked the Human Drug Advisory Panel (HDAP) to establish the therapeutic class for Nicoderm, the HDAP proposed that the therapeutic class include Nicotrol. This was also the opinion of Dr. Levine, an expert witness called by Board Staff.

12. Throughout the period that Board Staff alleges that Nicoderm was sold at excessive prices, it was sold below the price of Nicotrol. Accordingly, by application of the Guidelines, if Nicotrol were included in the same therapeutic class as Nicoderm for price comparison purposes, Nicoderm was never sold at an excessive price. Put another way, Board Staff's case that Nicoderm was sold at excessive prices was premised on the exclusion of Nicotrol from the class of medicines for comparison with the price of Nicoderm.

13. Board Staff argued for the exclusion of Nicotrol from the price comparison because Board Staff believed that Nicotrol was itself excessively priced. This Panel (as with the *Adderall XR* panel, when the same issue was before it), agrees with Board Staff that it is neither logical nor consistent with the objectives of the Guidelines and the Act to establish the MNE of a medicine by reference to the price of a medicine that is itself excessively priced.

14. However, it remains to be determined whether it is appropriate to characterize the price of Nicotrol as excessive. Board Staff argued that the price of Nicotrol was excessive for the same reason that the price of Nicoderm was excessive: it exceeded the price of Habitrol.

15. If Nicotrol had been a patented medicine, the Panel would have accepted that, *prima facie* and subject to evidence to the contrary*,* its pricing at a level above the price of Habitrol would allow the Panel to presume that it was excessively priced, so as to justify excluding Nicotrol from the therapeutic class of Nicoderm for price comparison purposes.

16. However – and the identical issue arose in the *Adderall XR* case – the point is subject to debate, because Nicotrol was not a patented medicine during the period in question. In the *Adderall XR* case, the Board concluded that the excessive price tests in the Guidelines are premised on the patented status of medicines, including comparator medicines, and that the price of an unpatented medicine could not be presumed to be excessive by reference to the Guidelines. Rather, it would be open to Board Staff to convince the Board that the price of the unpatented medicine was excessive by establishing that there was an absence of competition or other market conditions that allowed the unpatented medicine to be priced at an excessive level.

17. In the *Adderall XR* case the Board stated as follows:[1]

> The Panel accepts that it is appropriate for Board Staff, in the course of its investigations, to exclude, from a Domestic Therapeutic Class Comparison ("DTCC"), those patented medicines sold in Canada that would be presumed by the Guidelines to be excessively priced. In a regime where the Board is setting the MNE price of a medicine by reference to the prices of comparable medicines, it would not be logical to include, among those comparators, patented medicines that are themselves excessively priced.
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> However, the Panel believes that, in the *Patent Act* (the "Act") and the Excessive Price Guidelines, the concept of an excessive price is based on the premise that a medicine to which a patent pertains could be priced at excessive levels, given the potential market power associated with a patent. While the Board does not inquire into whether a pertaining patent actually confers market power on the patentee, this does not change the premise on which the concept is based.
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> Needless to say, that premise does not apply to a medicine to which no patent pertains. The Panel does not purport to preclude the possibility that an unpatented medicine could be excluded from a DTCC based on its price. However, for such a finding to be made, there would have to be evidence of an absence of competition or other market conditions on which the Board could conclude that the medicine should be thus excluded. In this case, the evidence is to the contrary.

[1] Decision: PMPRB-06-D4-ADDERALL XR (Admissibility of Evidence), July 16, 2008, paragraphs 6, 7 and 8

18. The Panel understands the reasoning of the Adderall XR panel to be as follows. Patents are statutory monopolies. A patented medicine could be marketed at a higher price than an unpatented medicine because of its statutory monopoly. Therefore, the Board should not establish the MNE for a new medicine by reference to the price of an existing patented medicine that itself might be excessively priced through the use of the market power of its statutory monopoly. Allowing a new medicine to be priced on the basis of the price of an existing medicine that might have used its monopoly to achieve an excessive price defeats the objective of controlling the prices of drugs that have statutory monopolies.

19. Put another way, if the MNE of a new medicine were to be priced on the basis of the price of an existing medicine that the Guidelines would characterize as excessively priced, and whose manufacturer might have used its monopoly to achieve that excessive price, the patentee of the new medicine would get the benefit of the actions of a patentee who had breached the Guidelines (and potentially the Act). This would not allow the Board to apply the Act in the consistent manner that the Guidelines were designed to permit.

20. For unpatented medicines, there is no statutory monopoly and thus the price of an unpatented medicine cannot have been based on such a monopoly. Accordingly, if an unpatented medicine is in the therapeutic class of a medicine under review for price comparison purposes, the new medicine is not getting the benefit of a manufacturer who has breached the Guidelines or the Act. Rather, some other aspect of the market has allowed the unpatented medicine to be priced at a relatively high level. This relatively high level might be the result of early entry, marketing, a desire for a higher profit at lower volumes, or any number of factors. The Board cannot characterize such a price as excessive in the sense used by the Act and in the context of the mandate of the Board.

21. The relatively high price of the unpatented medicine could have resulted from the absence of competition or other market conditions that gave the manufacturer market power. However, absent the existence of a patent, the Board cannot presume that this is the case. Rather, evidence on the point would be required.

22. The Panel agrees with the Board's decision on this issue in the *Adderall XR* case. It is fully open to Board Staff to convince a panel of the Board that an unpatented medicine should be excluded from a therapeutic class for price comparison purposes. Board Staff would do so by leading evidence that satisfies the panel that the price of the medicine is excessive. However, unless the panel is convinced by Board Staff on this point, the unpatented medicine should be included in the therapeutic class for price comparison purposes.

23. In this case Board Staff did not lead any evidence on this point. The issue was not addressed by Board Staff during the evidentiary portion of the hearing. When the issue was raised by the Respondent in oral argument, Board Staff responded, in argument, by asserting that, at the relevant time, Nicotrol was a prescription medicine, and thus not subject to market competition. The relatively high price of Nicotrol, Board Staff argued, could thus be presumed by the Panel to be excessive, with the result that Nicotrol could be excluded from the therapeutic class of Nicoderm for price comparison purposes.

24. However, these submissions by Board Staff were made only in argument. As noted, there was no evidence on the record on this issue. The proposition that the prescription status of Nicotrol created market conditions that gave its manufacturer the ability to sell Nicotrol at excessive levels is not, to say the least, a self-evident one, nor one that the Panel considers to fall within its inherent expertise. The Panel would have required convincing evidence to accept this proposition.

25. As no evidence was presented on this point, the Panel concludes that Nicotrol, having been properly included by the HDAP in Nicoderm's therapeutic class, should not be excluded from that therapeutic class for price comparison purposes as argued by Board Staff. Given that Nicotrol was priced above the price of Nicoderm throughout the relevant periods, Nicoderm's MNE ought to have been set by reference to the price of Nicotrol. The result of this conclusion is that Nicoderm was not sold at excessive prices in any market in Canada at any time.

III. *Other issues*

26. Having reached the conclusion noted above, it is not necessary for the Panel to come to several conclusions on the other matters that were the subject of evidence and argument before the Panel. However, given that at least two of these matters could be relevant in other proceedings, the Panel considers it appropriate to express its views in the following section of this decision.

Off-setting excessive revenues

27. During the interlocutory proceedings prior to the hearing of this matter and during the hearing itself, the issue arose as to whether or not sales of Nicoderm below its MNE during periods subsequent to the periods during which it was alleged to have been sold above its MNE could "off-set" the allegedly excessive revenues from the former period.

28. This issue has been considered by the Board on several occasions and the Panel believes that it is important to reiterate the Board's earlier views on this point. A patentee cannot decide to sell a medicine at an excessive price and then decide of its own volition when and how to remedy that situation by altering the price of the medicine. A patentee may not, for example, sell its patented medicine at 150% of the medicine's MNE for five years and then at 50% of the MNE for the following five years and claim to be in compliance with the Guidelines or the Act. Such an approach would completely defeat the Board's ability to fulfill its mandate. The Guidelines, which were established after extensive consultation with industry and all stakeholders, require a patentee to maintain the price of a patented medicine at non-excessive levels on an annually averaged basis. The Panel finds this to be a reasonable implementation of the provisions of the Act.

29. Accordingly, if the Panel had found that Nicoderm had been sold at an excessive price, it would not have allowed any "off-set" of the resulting excessive revenues by virtue of sales of Nicoderm below its MNE the years after the periods of excessive pricing.

The prices of medicines established by Voluntary Compliance Undertakings

30. As noted above, it was argued by the Respondent that the MNE of Nicoderm should not be established by reference to the price of Habitrol because the MNE of Habitrol was governed by a VCU between the manufacturer of Habitrol and the Board. This was characterized by the Respondent as a "negotiated" or otherwise artificial pricing reference.

31. The Panel disagrees. A VCU is not negotiated. In accepting a VCU, the Chairperson of the Board (or, where a hearing has commenced, the hearing panel) must be satisfied that the MNE proposed in the VCU is in compliance with the Act. Absent submissions to the contrary, this conclusion will be based on the application of the Guidelines, but in all events the decision of the Chairperson or the panel in approving the VCU is based on a conclusion that the MNE proposed in the VCU is fully in compliance with the Act.

Accordingly, it is reasonable for Board Staff to have reference to the reported prices of medicines that are subject to VCUs when conducting therapeutic class price comparisons.

IV. *Dissent of member Sureau*

32. I agree with the submissions of Board Staff that Nicotrol should be excluded from the therapeutic class of Nicoderm for price comparison purposes. I conclude that the Board's Excessive Price Guidelines can be applicable to non-patented medicines for the purposes of concluding that a non-patented medicine is excessively priced and thus should be excluded from a therapeutic class comparison, without evidence that the non-patented medicine was sold in circumstances that permitted excessive pricing.

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Appearances

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Original signed by

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