ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held August 13, 2013

GlaxoSmithKline Australia Pty Limited ("GSK") v. Reckitt Benckiser Australia Pty Limited ("RB")

Nurofen for Children advertisements.

1 GSK complains that a television advertisement and a print advertisement for Nurofen for Children ("NfC") breached section 5.1.3 of the ASMI Code of Practice ("the Code") and that the television advertisement also breached sections 4(1), 4(2)(c) and 4(5) of the Therapeutic Goods Advertising Code ("TGAC"), with which members are required to comply pursuant to the Code, section 4.3.1.

2 RB denies breach of the Code and submits that the Complaint has been used simply as a competitive tool, in breach of the Code, section 9.4.2.1.

Procedural matters

3 Contrary to section 9.4.2.7 of the Code, informal correspondence was submitted to ASMI as part of both the Complaint and Response. This was removed before the material was placed before the Panel.

4 Pursuant to section 9.4.2.10 of the Code, the Panel invited GSK to provide a Reply to RB's submission that the Complaint was being used simply as a competitive tool and the parties attended the Panel meeting by telephone to address questions from the Panel on that issue.

5 RB requested the Panel to ignore section 4 of GSK's Reply, since it was directed to the issue whether the RB advertisements breached the Code. The Panel has not taken that section of the Reply into account in its determination.

Use of the complaint as a competitive tool

6 RB says this complaint is being used by GSK simply as a competitive tool because:

(a) the complaint is weak and involves a top parity claim of a kind the same as used by GSK;

(b) GSK appears to have disregarded RB's response to GSK's concerns raised in a letter of May 16, 2013; and

(c) the GSK letter of May 16, 2013 and the response it sought by 20 May, 2013, came at a time when RB was engaged in intensive preparation for the hearing, scheduled for May 27, 2013, of its application for an urgent interlocutory injunction against GSK for alleged patent infringement over a dosing system for Children's Panadol 1-5 years. Although RB responded to the May 16 letter within time, its response appears to have been ignored.

7 For these reasons RB says the complaint appears to have been a tactic designed to secure a collateral advantage rather than a genuine complaint which GSK sought to have resolved with the assistance of the ASMI complaints system.

8 In response, GSK provided a chronology, amended on the day of the Panel hearing, showing that:

(a) the patent proceedings commenced on May 2, 2013;

(b) RB began distributing the print advertisement on or about May 6, 2013 and began broadcasting the television advertisement on May 13, 2013;

(c) the parties held "without prejudice" discussions about the advertisements on or about May 14, 2013;

(d) subsequently there was informal correspondence prior to the formal complaint being made on May 27, 2013;

(e) On May 27 and 28, the Federal Court heard RB's application for an interlocutory injunction in the patent proceedings.

Panel consideration

9 As appears below, the Panel upholds the Complaint in relation to both advertisements, so the Complaint cannot be properly described as weak. The chronology is consistent with an attempt to address genuine concerns informally and subsequently formally, at the earliest possible opportunity once GSK became aware of the advertisements. The fact that the timing coincided with preparations on both sides for an interlocutory hearing in the patent litigation commenced by RB appears co-incidental. Accordingly the Panel is not satisfied that the Complaint has been used simply as a competitive tool and finds no breach of section 9.4.2.1 of the Code.

The television advertisement

10 This advertisement contains the voiceover:

"*Luckily, you can rely on Nurofen for Children, because nothing works faster or lasts longer on fever – including Children's Panadol*".

11 During the voiceover the words "faster" and "longer" appear prominently on the screen.

12 GSK submits that the overall impression conveyed to a reasonable person to whom the advertisement is directed is that NfC (an ibuprofen product), works faster and longer than anything else, including Children's Panadol (a paracetamol product). In claiming breach of section 5.1.3 of the Code, GSK implies that such an impression is misleading, citing the Explanatory Notes to that section, which give as an example of information that may be considered false and misleading "*claims that are more favourable than has been demonstrated by the body of clinical evidence or experience*".

13 RB does not contend that the evidence supports any such impression. Indeed the material before the Panel includes a study, sponsored by RB, which concluded that in children 3 months to 12 years, 10mg/kg ibuprofen and 15mg/kg paracetamol "*have equivalent efficacy and tolerability*"[1]. Rather, RB denies that the advertisement conveys the impression put forward by GSK and submits that the voiceover amounts to a top parity claim of the kind made by GSK itself, as in a GSK television advertisement for Children's Panadol:

"*...it is my little one's first fever. It is my pain too. That's why I trust Children's Panadol. Nothing works faster or is more effective...*"

14 RB also refers to the top parity claim "*...no other tablet works faster"* made by GSK in an advertisement for an ibuprofen product considered by the Federal Court of Australia in *Boots Company (Australia) Pty Limited v SmithKline Beecham Healthcare Pty Limited 33 IPR 266*. The court found the relevant advertisement not misleading and said (at page 278) that the claims about speed in the detailer under consideration were:

"*merely top parity claims of a by no means unprecedented kind and are not misleading or deceptive...I think a statement that nothing works faster than a particular product fairly clearly leaves open the possibility...that other products work equally fast*".

15 RB adopts those remarks, contending that GSK's objection to the top parity claim is weak and suggesting that it is entirely without foundation.

[1] Autret-Leca E *et al. Curr Med Res Opin 2007; 23(9): 2205-11.*

Panel consideration

16 In considering television advertisements, the Full Federal Court noted in *Global One Mobile Entertainment Pty Ltd v Australian Competition and Consumer Commission* [2012] FCAFC 134 :

> "83. Having had the benefit of looking repeatedly at each of the advertisements we make these observations about them.
>
> 84.First, repeated viewing of the advertisements for the purpose of seeing the images, hearing the voiceover and examining each of the component parts of each advertisement, pausing each advertisement to be better able to read and absorb the text, and making a deconstructed assessment of the relationship between those component parts is an entirely artificial analytical exercise. The primary judge rightly described the broadcast of the advertisements by television as an ephemeral communication to a consumer. The advertisements are transient communications that leave a dominant impression in the mind of a consumer. A consumer cannot turn to a fixed reference point to check or re-check messages conveyed by the advertisement. The consumer must deal with the cognitive cues triggered by the dominant impression the advertisement makes in the space of time the advertisement is screened.
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> 85. Second, the consumer is drawn to the medium of television to watch the *program* not the advertisement. The advertisement in one sense is a distraction from the primary focus of the consumer in choosing to watch a particular program. Of course, advertisements are designed to capture the attention of the viewer in the periods when the program is broken by the period of the advertisements. In the appellants' submissions reference is made in respect of each of the advertisements to the "featured" component of the advertisement. That there is a featured component is immediately obvious upon viewing each advertisement. No doubt, the featured component of the advertisement is designed to attract the attention of the viewer to the subject matter of each advertisement. The viewer is drawn to the featured component and engages with it. Obviously enough, during the course of engaging the viewer through the featured component of the advertisement, the advertiser seeks to convey a range of information. The method by which that might be done, the content of the information and the extent to which that information is actually brought to the attention of the viewer in the context of the attention the featured part of the advertisement commands, determines the dominant impression left upon the mind of the consumer."

17 The top parity claims considered by the court in *Boots Company (Australia) Pty Limited v SmithKline Beecham Healthcare Pty Limited 33 IPR 266* appeared in print: a cardboard detailer, a leaflet and promotional articles and advertisements,

all published to pharmacists. It is in that context, in which the audience comprised healthcare professionals and the medium comprised a fixed reference point enabling the messages conveyed by the advertisement to be checked and re-checked, that the top parity claim was considered by the judge. Further, in noting that "*a statement that nothing works faster than a particular product fairly clearly leaves open the possibility...that other products work equally fast*", the Court exposed the potential for ambiguity inherent in such a claim.

18 Here it is necessary for the Panel to consider RB's top parity claim in the very different context of a 30 second television advertisement broadcast to consumers.

19 As to whether the television advertisement makes the representation for which GSK contends, the following passage from the Full Federal Court judgement in *Global One* (omitting case references) is instructive:

> "108.Whether impugned conduct conveys the making of the representation is always a question of fact to be determined having regard to all of the contextual circumstances within which something was said or done. The question is, "whether the misconceptions, or deceptions, alleged to arise or to be likely to arise are properly to be attributed to the ordinary and reasonable members of the classes of prospective purchasers".... [T]he focus of the inquiry is whether a not insignificant number within the class or cohort have been misled or deceived or are likely to be misled or deceived by the conduct, whether in fact or as a matter of inference."

20 Applying this approach, the Panel considers that the dominant impression likely to be left upon the minds of a not insignificant number of ordinary and reasonable viewers by the television advertisement is that NfC works faster and longer on fever than Children's Panadol. In coming to this conclusion, the Panel takes into account the advertisement as a whole, noting the emphasis, both visually and audibly, on the words "faster" and "longer" and the express reference to Children's Panadol.

21 Since this representation is incorrect, the Panel finds the television advertisement to be misleading, in breach of section 5.1.3 of the Code and, since the audience was consumers, the Panel also finds the advertisement to have breached sections 4(1)(b), 4(2)(a) and (c) and 4(5) of the TGAC.

22 The Panel makes no finding in relation to the GSK television advertisement for Children's Panadol to which RB refers, since that is not before the Panel as a formal complaint under the Code. The Panel notes, however, that there is no express reference in that advertisement to the product of a competitor, as there is in the advertisement presently under consideration.

The Print advertisement

23 This advertisement, entitled "*Bring down a child's fever fast"* and depicting three packages of NfC, for baby 3+ months and children 1-5 and 5-12 years, includes the statement about NfC:

> *"...it's also the relief more parents would use again"*.

24 This statement is referenced in a footnote to the Autret-Leca paper already mentioned.

25 GSK says the overall impression conveyed by the statement is that more parents would use NfC again than would use Children's Panadol again (the Use Again Representation). GSK says efficacy is not the sole determinant of parental choice, since parental perception of the product and of its trustworthiness plays a part. The Autret-Leca study was conducted in France, where Children's Panadol is not sold, so the study did not measure what effect the strong positive perception of Children's Panadol has on a parent's decision as to which product to use again. The study acknowledged parental perception of the product as a possible explanation for more parents of children in the paracetamol treatment group reporting that they would use paracetamol again after the open label phase than after the double-blind phase, albeit that the difference was not statistically significant. Accordingly GSK says the Use Again Representation is misleading because it is an unqualified statement unsupported by the referenced study.

26 RB says GSK's stated concerns appear to overstate the matter, having regard to comments by Yates J. in *SC Johnson & Son Pty Limited v Reckitt Benckiser (Australia) Pty Limited* [2012] FCA 1266, including:

> "*Thus I do not accept that consumers who are purchasers of relatively inexpensive items approach the purchase of those items in a mechanistic or uncritical way"*.

27 RB says the statement in the advertisement is clearly footnoted and, consistent with the observations of Yates J., there is no reason to think that consumers will not note the footnote. The message conveyed is therefore not a generalised one but a message about the parents in the study.

28 RB says the study was properly conducted and the advertisement correctly reports that a majority of the parents in the study in the ibuprofen treatment group reported that they would use the treatment medication again and that this exceeded those in the paracetamol treatment group. As to GSK's reference to different results in the open label phase, RB says results from a blinded phase, where the identity of the medication is not known, are of significantly superior relevance.

Panel consideration

29 GSK does not identify the publication(s) in which this advertisement appeared. In light of the statement: "*When children have discomfort from fever, recommend Nurofen for Children"* and the mandatory consumer statements contained in the advertisement, the Panel considers that it was published to pharmacy assistants (who are considered consumers) and possibly to other consumers.

30 The context in which the Panel considers it appropriate to determine the meaning likely to be conveyed by the Use Again Representation is that the advertisement was published to an audience of pharmacy assistants (and possibly to other consumers) in Australia, where Children's Panadol and NfC are both very well-known brands and where parental decisions as to which product to use again for fever in children are influenced by past experience with products, especially branded products, that they have previously purchased.

31 The ibuprofen and paracetamol products used in the Autret-Leca study were given rather than sold to parents. There is nothing in the Autret-Leca paper to indicate that any brand names were used. Accordingly, the parental decisions made in the Autret-Leca study, conducted in France, where Children's Panadol is not sold, were not subject to the same influences as those made by parents in Australia because the parents participating in the study did not take into account parental perception of the Children's Panadol brand and of its trustworthiness.

32 The Panel accepts that, although NfC and Children's Panadol may be inexpensive, the nature of those products and their purpose mean that parents, including pharmacy assistants, do not approach those tasks in a mechanistic way and would take some care in reading the advertisement. They would see the reference to the footnote citing the Autret-Leca study but would not, in the opinion of the Panel, be likely to consult that paper. Instead they would understand the advertisement to represent that the Autret-Leca paper shows that more parents in Australia would use NfC again than other products suitable for fever in children, including Children's Panadol. Since the Autret-Leca paper does not support this representation, the Panel finds the advertisement to be misleading, in breach of the Code, section 5.1.3.

Categories of breach

33 GSK says the breaches are Severe. RB says it is not for GSK to purport to classify a breach not yet established in a complaint not yet accepted for processing by the Panel and that GSK's introduction of a suggestion of severe breach appears to be a tactical matter inconsistent with the spirit of the Code. In any event, RB denies any basis on which a question of severe breach would fairly arise.

34 The Panel notes that the Code, section 9.4.2.4, requires the formal complaint to identify the category of breach.

35 The Panel finds the breaches to be Moderate since they are likely to impact on the perceptions of the consumer regarding the efficacy of NfC and Children's Panadol. However, the Panel also finds the breaches to be Repeat Breaches, as discussed below.

Section 10.1.3 factors

36 On the material before the Panel, the Panel has considered these factors as follows:

- *Whether publication has ceased*
  The Panel does not know whether publication has ceased.

- *Whether steps have been taken to withdraw the material published.*
  There is nothing before the Panel to indicate that any such steps have been taken.

- *Whether corrective statements have been made.*
  No corrective statements appear to have been made.

- *Whether the breach was deliberate or inadvertent.*
  It is clear the wording and presentation of the advertisements was deliberately chosen. There is no evidence that the breaches were deliberate. The breaches were nevertheless similar to several of those mentioned below. In this regard the Panel notes that in his decision of October 29, 2012 on appeal from the Panel's decision of May 27, 2012 mentioned below, the Arbiter said:

  > "*RB should in the future take greater care to ensure that claims which it makes in advertisements of the nature which are the subject of this complaint are properly substantiated in accordance with the requirements of the Code"*.

- *Whether the Member that is the subject of the complaint has previously breached the Code.*

  On July 17, 2008, RB was found by this Panel to have breached the Code in claiming that NfC and Nurofen for Children Infant Drops reduce fever for up to 2 hours longer than children's paracetamol.

  On 3 August, 2009, RB was found by this Panel to have breached the Code in claiming that Nurofen Zavance works twice as fast as other painkillers.

  On August 26, 2010, RB was found by this Panel to have breached the Code in claiming that NfC offers more time without fever in the first four hours than paracetamol.

On May 27, 2012, RB was found by this Panel to have breached the Code in claiming that Mums prefer NfC, that NfC works better and that more Mums are switching to NfC.

The Panel takes only the last of these into account in considering the Issues of Repeat Breach and Sanctions.

- *Whether there were or are safety implications.*
  There are no safety implications.

- *Whether the perceptions of healthcare professionals or consumers have been or will be affected.*
  The perceptions of consumers are likely to have been and will be affected.

Repeat breaches

37 The Panel considers the breaches to be Repeat Breaches, as defined in section 10.1.1 of the Code, since they are similar to breaches by RB in the promotion of NfC within the preceding 24 months, as follows:

(a) the breach in the television advertisement is similar to that in the television commercial found to be in breach on May 27, 2012 in that both convey a representation of superior efficacy for NfC, without substantiation; and

(b) the breach in the print advertisement is similar to that in the point of sale material and in the television advertisement found to be in breach on May 27, 2012 in that both advertisements represent, without substantiation, that consumers prefer NfC to Children's Panadol.

Sanctions

38 The Panel requires RB:

(a) to give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that Nurofen for Children works faster and/or longer in fever than Children's Panadol;

(b) to ensure that any print material the subject of this complaint that is in circulation be removed from exposure to consumers within 30 days and to notify the Executive Director of ASMI that this has been done; and

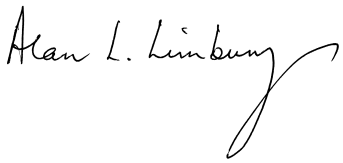
(c) to pay fines of $25,000 for the Repeat Breach found by the Panel in relation to the print advertisement and $50,000 for the Repeat Breach found by the Panel in relation to the television advertisement.

39 The Panel makes no determination to alter the usual operation of section 9.4.2.2 of the Code.

40 Attention is drawn to sections 10.2.6 and 11.1 of the Code.

Dated: August 28, 2013

For the ASMI Complaints Panel



Chairman

Note: although this is called a Final Determination, each party has a right of appeal to the Arbiter. If no appeal is lodged this determination will be published on the ASMI website once the time for lodging an appeal has expired. If there is an appeal, the Arbiter's determination will be published on the ASMI website together with this determination. Until publication on the website, parties and their representatives should maintain the privacy of these proceedings.