Advertising Claims Board Determination

1. Matter Reference	LEH/3420533
2. Advertiser	Frucor Beverages (Australia) Pty Limited
3. Complainant	PepsiCo Australia Holdings Pty Limited
4. Type of Advertisement	Television and print advertisements
5. Nature of Complaint	Sections 1.1, 1.2 and 1.3 of the Australian Association of National Advertisers Code of Ethics.
6. Product	Mizone Rapid sports drink
7. Panel Members	Charles Alexander, Chair – Minter Ellison Eugenia Kolivos – Corrs Chambers Westgarth Catherine Logan – Hunt & Hunt
8. Determination	Advertising Substantiated
9. Date of Determination	6 June 2008

This is a determination of the Advertising Claims Board (**Board**) in relation to the Complaint made by PepsiCo Australia Holdings Pty Limited (**Complainant**) regarding a television commercial and print advertisements for Mizone Rapid sports drink manufactured by Frucor Beverages (Australia) Pty Limited (**Advertiser**). The Complainant is a competitor and markets the Gatorade sports drink.

DESCRIPTION OF THE ADVERTISEMENTS

The advertisements which are the subject of the Complaint are for the Mizone Rapid sports drink and include:

(a) a television commercial;

(b) advertisements which appeared as part of an outdoor advertising campaign and an indoor gym advertising campaign; and

(c) print advertisements that appeared in the following publications:

(i) Retail World – double page spread and front cover (6-17 August, 2007); and

(ii) Convenience World – single page and front cover (September 2007),

(together referred to as the **Advertisements**).

The Advertisements are not being published at present except for some possible member only advertising in Fitness First gyms. The Board has also been informed that no undertaking has been provided by the Advertiser that they will not use the representations in dispute in the future.

Television commercial

The television advertisement depicts a game of tennis where one player's performance is flagging and his ball hits the net. The player then drinks Mizone Rapid and hits the ball with such force that when the second player returns serve, he shatters into pieces. At the same time as this sequence, a male voiceover explains:

> *"With a third less sugar than the leading isotonic sports drink, Mizone Rapid's hypotonic formula is scientifically proven to re-hydrate you faster"*

The voiceover then concludes:

> *"Mizone Rapid…faster re-hydration…scientifically proven"*

At the same time as the voiceover, the screen shows the Mizone Rapid product and the words appear printed on the screen.

The Complainant informed the Board that since the original challenge by the Complainant the Advertiser has changed the above representation in their television advertisement to "Faster Rehydration. Scientifically Proven".

Outdoor and gym advertisements

The advertisements which appeared as part of an outdoor advertising campaign and an indoor gym advertising campaign show blown up pictures of the Mizone Rapid product with the headline:

> *"Faster Re-hydration No contest"*

A link to the Mizone website is also included.

Print advertisements

The print advertisements which appeared in Retail World and Convenience World show blown up pictures of the Mizone Rapid product with descriptive text on the left hand side with the headline:

> *"Faster Re-hydration No Contest"*

The descriptive text includes the following statements:

> *"Proven to re-hydrate faster than the leading isotonic sports drink with 1/3 less sugar (footnote: than leading isotonic sports drinks)"*

The print advertisement which appeared in Retail World additionally states:

> *"Hypotonic is a specific balance of carbohydrates & electrolytes proven to re-hydrate faster than the leading isotonic sports drink"*

It has been drawn to the attention of the Board by the Advertiser that the packaging of Mizone Rapid contains the statement "Faster Re-hydration" and the explanation that "Mizone Rapid is a

hypotonic sports drink which combines a specific balance of carbohydrates and electrolytes. Hypotonic drinks deliver faster re-hydration because they are absorbed by the body more readily than isotonic drinks".

THE COMPLAINT

1. The Complainant alleged that the representation made by the Advertiser, "with a third less sugar than the leading isotonic sports drink, Mizone Rapid's hypotonic formula is scientifically proven to re-hydrate you faster", contains false representations.

2. The Complainant specifically submitted that the Advertisements falsely represented that:

   (a) Mizone Rapid is scientifically proven to re-hydrate you faster; and

   (b) the faster re-hydration is due to Mizone Rapid's hypotonic formula.

   In addition, the Complainant submitted that the advertisements misleadingly imply a benefit of Mizone over the "leading isotonic sports drink", which the Complainant states is the Gatorade sports drink.

   The Complainant asserted that Gatorade is "the most researched sports drink in the world" and is supported by over twenty years of study into the science of hydration which has been conducted or commissioned by the Gatorade Sports Science Institute. In response the Advertiser asserted that Powerade (manufactured by Coca Cola) is the leading isotonic sports drink in New Zealand and Australia based on Nielsen Data MAT dated 9 March 2008.

3. The Advertiser denied the allegations and argued that the scientific evidence demonstrates that hypotonic drinks of the formulations used in Mizone Rapid re-hydrate faster than isotonic drinks such as Gatorade. The Advertiser has advised the Board that "Frucor's statements regarding the comparative speed of rehydration of hypotonic drinks apply to isotonic sports drinks in general".

4. The Board notes that neither the Advertiser nor the Complainant have submitted that other hypotonic sports drinks are currently available in Australia. The Board therefore assumes for the purposes of this dispute that Mizone Rapid is the only hypotonic sports drink currently available in Australia.

5. The Board is of the view that, in those circumstances, the Advertiser's representation that "with a third less sugar than the leading isotonic sports drink, Mizone Rapid's hypotonic formula is scientifically proven to re-hydrate you faster", is not a representation that the Mizone Rapid product itself has been scientifically proven to re-hydrate a person faster than isotonic sports drinks, as submitted by the Complainant in paragraph 2(a) above.

6. Instead the Board prefers the Advertiser's approach to the representation and is of the view that the Advertiser's representation is that as Mizone Rapid is hypotonic, it re-hydrates a person faster, since it has been scientifically proven that hypotonic sports drinks re-hydrate a person faster than isotonic sports drinks (the **Representation**). This accords with the Complainant's submission in paragraph 2(b) above.

THE BOARD'S ROLE

7. The role of the Board is to determine whether the Representation contravenes sections 1.1, 1.2 and 1.3 of the Australian Association of National Advertisers Code of Ethics (**AANA Code**). The relevant sections of the AANA Code provide:

   1.1 Advertisements shall comply with Commonwealth law and the law of the relevant State or Territory.

   1.2 Advertisements shall not be misleading or deceptive or be likely to mislead or deceive.

   1.3 Advertisements shall not contain a misrepresentation, which is likely to cause damage to the business or goodwill of a competitor.

8. The members of the Board comprising Charles Alexander (Chair), Minter Ellison, Eugenia Kolivos, Corrs Chambers Westgarth, and Catherine Logan, Hunt & Hunt, have carefully considered:

   (a) the Advertisements;

   (b) the Complainant's submission dated 18 February 2008;

   (c) the Advertiser's preliminary response dated 27 March 2008 in which an extension was sought;

   (d) the Advertiser's further response dated 28 April 2008;

   (e) the Complainant's reply (undated); and

   (f) the Advertiser's further reply dated May 2008.

SUMMARY OF DETERMINATION

9. The Advertiser has provided a sufficient body of credible evidence (which is not directly contradicted by other credible scientific evidence presented to the Board) to substantiate the claim that hypotonic sports drinks rehydrate a person faster than isotonic sports drinks, which, while Mizone Rapid is the only hypotonic sports drink available in Australia, supports the Representation that the Advertiser has made in its advertising.

SHOULD THE BOARD HEAR THE COMPLAINT

10. The Advertiser submitted that it is inappropriate for the Board to hear the Complaint for a number of reasons. First, that the Complaint involves a highly technical matter and the Procedural Guidelines for Participants state that the Board does not consider matters involving highly technical matters. Despite the fact that the Complaint raises technical matters, the Board notes that this is not uncommon in relation to complaints to the Board and should not, of itself, prevent the Board from hearing the matter.

11. Second, the Advertiser submitted that "where there are scientific issues in dispute the Courts have recognised that disputes regarding such matters should be for scientists trained in the speciality area who are able to examine the weight of the evidence (as recognised by the Full Federal court in *re Tobacco Institute of Australia Limited v Australian Federation of Consumer Organisations Inc* [1992] FCA 630)" (**Tobacco Decision**). In that decision Hill J (who dissented but whose comments here remain relevant) at paragraph 49 states:

> *"the question of the relationship between environmental tobacco smoke and disease is a matter for scientists trained in the area, it is not a matter for a court of law which is ill-equipped to determine it and to make the skilled judgments upon which such a question depends. It should, accordingly, be borne in mind that the court, in the present proceeding, is not deciding whether environmental tobacco smoke does in fact cause disease. The issue before us is a more limited one, namely, whether, on the evidence adduced below, the applicant has established, on the balance of probabilities, that the material in paragraph three of the advertisement was misleading, or was likely to mislead, members of the public to whom the advertisement was addressed."*

The above extract makes it clear that the Board is not required to decide whether hypotonic sports drinks are scientifically proven to re-hydrate a person faster than the leading isotonic sports drink. Instead the issue before the Board is whether on the evidence adduced the Complainant has established, on the balance of probabilities, that Representation made by the Advertiser was false or misleading, or was likely to mislead, members of the public.

12. The Advertiser also submitted that the Board is not the appropriate forum for resolution of allegations of criminal conduct, namely, an infringement of section 75AZC of the *Trade Practices Act 1974* (Cth). The Board disagrees with this submission. It will not be making any determination as to whether any criminal conduct has occurred.

13. Finally, the Advertiser also submitted that the Complainant had delayed lodging the complaint, claiming that it was "not a bona fide attempt to obviate the need for court action but is the result of an inability…to obtain the necessary evidence". The Board does not accept this submission, which is mere assertion and does not appear to be supported by any evidence.

COMPARATIVE REPRESENTATIONS AND MEANING OF 'SCIENTIFICALLY PROVEN'

14. The Complainant asserted that "the claim that the Frucor product is 'scientifically proven' to re-hydrate you faster than an isotonic drink…attracts a very high requirement for substantiation: … in essence there must be no reasonable scientific doubt as to the accuracy of the statement".

15. The Complainant drew the Board's attention to the *ACCC Food and Beverage Industry Food descriptors guideline to the Trade Practices Act* (November 2006) which states:

> [In making comparative claims] *"with similar products of its competitor, businesses should keep in mind the underlying rule of ensuring that there is a reasonable basis for the comparison"*

16. In response, the Advertiser submitted that "the relevant burden of proof is on the balance of probabilities, not, as PepsiCo asserts, proof beyond reasonable doubt". The Advertiser referred to a decision of Conti J in *Reckitt Benckiser (Australia) Pty Limited v SC Johnson & Son Pty Ltd* [2004] FCA 1237 where he said at 55:

> *"The judicial tests for establishing contravention or otherwise of ss52 and 53(c) of the TP Act, which have earlier exemplified,* ***do not of course demand any requirement for the Court to be persuaded beyond reasonable doubt****, nor to assume the mantle of a scientific mediator, by itself entering upon any scientific resolution of conflicting scientific views of experts in a given field. The Court is dependent on the testimony of qualified experts to evaluate and report upon scientific issues, and* ***the only feasible course in the event of disagreement between those experts, is to determine whether on the balance of the probabilities, and in the light of the evidence placed before the Court, one conflicting scientific view, or more than one view, is or are (as the case may be) reasonably and authentically open to be drawn in preference to the other or others****."* (Advertiser's emphasis added).

17. His Honour held at paragraph 82 that "In my opinion, the evidentiary opinions and findings of a scientific nature, adduced in evidence by SC Johnson, are more significantly persuasive in their reasoning and conclusions to those presented to the Court on behalf of Reckitt".

18. The above quotations provide useful guidance to the Board in determining the issue before it.

19. The next issue is how the words "proves scientifically" should be considered. In the Tobacco Decision, the representation was as follows:

> *"And yet there is little evidence and none which proves scientifically that cigarette smoke causes disease in non-smokers"*

In that case each of the judges analysed the meaning behind 'proves scientifically'. Hill J (dissenting) provided the following useful comments (emphasis added):

(a) *"the statement in the advertisement can only reasonably be understood as a representation that given that there will be some who hold diverse views, the* ***general body of science*** *regards the causal connection between environmental tobacco smoke and disease as not having been proved"* (paragraph 77);

(b) *"The question before his Honour was… whether there was a* ***generally accepted view in the scientific world*** *as to whether there was* ***proof*** *that environmental tobacco smoke caused disease"* (paragraph 126);

(c) *"If the evidence is such that* ***scientists are so evenly divided*** *on the issue that the court is unable to determine the truth or falsity of the issue on the balance of probabilities, then the applicant will fail"* (paragraph 48);

The other two judges, Sheppard and Foster JJ, in the majority, took a different approach and applied a less demanding test. They held that since there was a large body of epidemiological material and opinion which reported a connection between environmental tobacco smoke and lung cancer, then the representation was misleading. This approach is particular to the representation made since it concerned a negative statement that *"there is little evidence and none which proves scientifically that cigarette smoke causes disease in non-smokers"*. We set out below some relevant passages from their judgments:

- "Prove" may mean to make a trial of or to test. It may also mean to establish something as true, to make certain, to demonstrate the truth of by evidence or argument. Another meaning is to show the existence or reality of. "Proof" is that which makes good or proves a statement such as evidence sufficient or contributing to establish a fact or produce a belief in the certainty of something. [Sheppard J at paragraph 15]

- "Scientifically" is a reference to something being done in a scientific manner i.e. according to the laws of science or by means of scientific or demonstrative reasoning. It is also a reference to something being done systematically, methodically or thoroughly. "Scientific" may mean the producing of knowledge or something which is demonstrative. [Sheppard J at paragraph 15]

- The various meanings of "proves", "proof", "scientifically" and "scientific" to which I have referred show that the ordinary meaning of the expression "proves scientifically" is, generally speaking, the **demonstration or establishment of something in a scientific manner i.e. according to the ways or methods of scientists**. **But it needs to be understood that no field of scientific research is ever still.** It continues to develop and, although scientists may speak of something being proved beyond reasonable doubt, they are speaking in terms of the state of scientific knowledge of the day. No doubt all scientists are searching for the ultimate truth but in no field is that found. Sometimes truths thought to have been established by earlier research are falsified by later investigations. [Sheppard J at paragraph 20 with his emphasis added]

- The epidemiological studies which there are, and which existed prior to the publication of the advertisement, cannot be dismissed as "nothing". If the issue were what ultimate conclusion should be drawn, there might be something to be said for both sides simply because research in the matter was continuing in 1986 and continued on thereafter. But one cannot justify the making of a statement in 1986, a statement which many people would have read as a statement of fact, that there was nothing which proved the matter scientifically. On the contrary there was a large body of epidemiological material and opinion, of a circumstantial kind though it may have been, which suggested strongly that there was in fact a causal link between environmental tobacco smoke and lung cancer. It is for that reason

that I consider that the statement that there was nothing that proved the matter scientifically was misleading or deceptive. [Sheppard J at paragraph 35]

- I consequently do not accept the need for the investigation of the extensive scientific evidence undertaken by his Honour nor for the resolution of the scientific controversies emerging from the evidence. The matter, in my opinion, falls for determination not on the basis of the accuracy, validity or acceptability of the scientific evidence or aspects of it, but simply upon its existence. [Foster J at paragraph 29]

- Scientifically – It is a word that has an authoritative ring. It suggests that wise men of science have formed a view favourable to the proposition being advanced. [Foster J at paragraph 45]

20. The facts in the Tobacco Decision can be distinguished from the present facts. In that case the issue was whether something has **not** been scientifically proven. The fact that there was evidence to support the proposition that there may be a causal link between environmental tobacco smoke and lung cancer was enough for the Court to determine that the statement "And yet there is little evidence and none which proves scientifically that cigarette smoke causes disease in non-smokers" was misleading.

21. The difficulty the Board has with the Hill J approach is that it would require the Board to determine what constituted a "generally accepted view in the scientific world", or what the "general body of science" considers to be correct. We do not consider that the Board is qualified to answer this question and there is no evidence before the Board which gives answers either in favour of the proposition or against it.

22. The Board also notes that the Tobacco Decision did not involve the consideration of a claim that was comparative in nature, that is, where a product is claimed as being superior to a competitive product, which is the case here.

23. The Board therefore has adopted its own test to meet these circumstances. It believes that the test of "scientifically proven" should be:

> "*Is there a sufficient body of credible scientific evidence to establish the truth of the claim which is not directly contradicted by other credible scientific evidence?*"

It will be seen that this is a somewhat less stringent test than that adopted by Hill J but a more rigorous test than that offered by Sheppard and Foster JJ, and which draws on all the judgments.

24. We now turn to an examination of the products and the scientific material.

THE MIZONE RAPID AND GATORADE PRODUCTS

25. The Mizone Rapid product is a hypotonic carbohydrate-electrolyte beverage which is specifically formulated to a tonicity of 230 milliOsmol/L. It contains 3.9g of sugars per 100mls and the electrolyte is sodium.

26. Gatorade is also a carbohydrate-electrolyte beverage with differing concentrations than Mizone Rapid and is isotonic.

27. Both beverages are known as sports drinks and are considered to be a subset of preparations known as oral rehydration solutions.

28. The sports drinks in question differ, amongst other things, according to:

    (a) the type and quantity of carbohydrates used in the formulation;

    (b) the type and quantity of the electrolyte used in the formulation; and

    (c) the osmolality of the formulation.

29. The Advertiser stated that "as the hypotonic formulation is inherently comprised of a combination of carbohydrates which determines the osmolality of the solution, one cannot be separated from the other, just as the carbohydrate content determines the osmolality of isotonic drinks. If the carbohydrate composition is changed you can change the tonicity of a drink with the same concentration of carbohydrates".

REHYDRATION AND TONICITY

30. Before the Board considers the scientific studies on rehydration and tonicity, it must first consider the various terms that are relevant to this discussion.

31. The Complainant stated that a person's hydration and the speed at which that is restored following exercise (rehydration) is determined by three main factors:

    (a) fluid intake (how much fluid the person has consumed);

    (b) fluid absorption (how much and how rapidly that consumed fluid is absorbed from the intestine into the blood); and

    (c) fluid retention (how much fluid is then retained in the body, as opposed to being excreted as urine).

    The Advertiser agreed that these three factors affect hydration.

32. The Advertiser provided the following definitions and explanations for tonicity:

    Tonicity is a measure of effective osmolarity or effective osmolality in cell biology.

    Osmolality is a measure of the osmoles of solute per kilogram of solvent.

    An osmole is a unit of measurement that defines the number of moles of a chemical compound that contribute to a solution's osmotic pressure.

    Tonicity is classified in three ranges:

- *Hypertonicity (which is where the cell is surrounded by a higher concentration of impermeable solute than exists in the cell itself and results in a net movement of water out of the cell).* The Board understands that 'Hyper-' means high.

- *Hypotonicity (which is where the cell contains a higher concentration of solute than exists outside it and results in the net movement of water into the cell).* The Board understands that 'Hypo-' means low.

- *Isotonicity (which is where the cell and the surrounding solute are in a state of equilibrium and there is no net movement of water).* The Board understands that 'Iso-' means "the same".

33. The Advertiser also provided the following figures for solutions with varying tonicity:

- water is markedly hypotonic at 5-15mosmol/L;

- moderately hypotonic solutions are approximately 229mosmol/L;

- isotonic solutions are approximately 277mosmol/L; and

- mildly hypertonic solutions are approximately 352 mosmol/L.

THE SCIENTIFIC EVIDENCE

34. The Board will now consider whether there is a sufficient body of credible scientific evidence to establish the Advertiser's Representation that a hypotonic sports drink rehydrates a person faster than an isotonic sports drink, and that the Advertiser's Representation is not directly contradicted by other credible scientific evidence.

35. The Board first notes the Complainant's submission that "*of the list of references set out in…the Defence…just 1…deals in any way with comparative hydration between isotonic drinks that are comparable in formulation to sports drinks available in Australia and hypotonic drinks such as Mizone Rapid*". The Board notes that the studies discussed below might not involve solutions that are the same as the formulations of Mizone Rapid and Gatorade or Powerade, but as far as the studies concern hypotonic and isotonic solutions with similar formulations, they will be considered.

Mizone Rapid Study

36. The main supporting evidence is the study commissioned by the Advertiser to test its Mizone Rapid product (**Mizone Rapid study**). This study, the abstract of is entitled "The Effect of Consumption of Four Drinks on Endurance Performance and Physiology" which details the study that was conducted by the Institute of Sports and Recreation Research New Zealand, Division of Sport and Recreation, at the Auckland University of Technology by Darrell Bonetti, Matthew Wood, Jennifer Doyle, Elizabeth Fox and Professor Will Hopkins. The study tested how cyclists responded after exercise when they consumed Mizone Rapid, water and two unnamed sports drinks, one of which is an isotonic sports drink. The results showed that when the cyclists consumed Mizone Rapid, peak power improved by 4.3%, 3.2% and 0.4% with similar outcomes for differences in

peak heart rate and peak lactate. Further, Mizone Rapid consumption produced the most diluted urine and in the largest volume of urine, "which represents good evidence that the hypotonic drink was excreted and therefore absorbed more rapidly than the other drinks". The study concluded:

> *"The new hypotonic sports drink aimed at optimizing fluid absorption, gave slightly better peak performance than the isotonic sports drink…the new drink was absorbed more rapidly than all three other drinks"*

This study forms part of the basis upon which the Advertiser makes the Representation that a hypotonic sports drink rehydrates faster than an isotonic sports drink. An abstract of the study appears on the Mizone website in support of the Representation. Only this abstract has been provided to the Board so the Board has not had the benefit of reading the full paper, which we assume exists.

37. The Complainant disputed the integrity of the Mizone Rapid Study and the scientific reasoning behind its conclusions and therefore submitted that the study does not provide adequate substantiation to the Advertiser's Representation. The Complainant discussed a number of flaws in the Mizone Rapid Study.

(a) The Complainant asserted that "the results of urine concentration and volume reported in the Mizone Rapid Study were indicators of fluid retention, not fluid absorption, and as both fluid absorption and fluid retention in the body are critical determinants of re-hydration, the conclusion drawn from the Mizone Rapid Study…is invalid". The Complainant stated that "in fact, the greater urine production on the Mizone Rapid treatment is direct evidence of poorer re-hydration."

(b) The Complainant explained that "an effective rehydration solution that is quickly and easily absorbed in the small intestine will be readily retained by the body, thereby, contributing to the rapid restoration of fluid balance. A solution that is unable to be retained by the body will be excreted in larger volumes in the urine, as occurs when plain water is ingested post-exercise (referenced in the Gonzalez-Alonso et al (1992) study originally submitted). A high urine output (or greatest urine volume) suggests that the fluid has not been easily absorbed by the body and, therefore, is not an effective rehydration solution".

(c) The Complainant included comments by Mark Hargreaves, a professor in the Department of Physiology at the University of Melbourne, which provide that "in the absence of any direct measure of fluid absorption from the gut…I do not believe one can derive an absorption estimate from an indirect measure such as urine volume". Professor Hargreaves further points out that "it is known that drinks containing lower amounts of sodium are more readily excreted than those with a higher amount of sodium. Thus, an alternate explanation is that this drink impaired rehydration because it promoted a greater loss of the ingested fluid as urine due to its relatively lower sodium content"

Finally, the Complainant submitted that since the study has not been published and therefore has not been peer reviewed and accepted by the scientific community, it cannot be used as substantiation for "scientifically proven" representations.

38. In reply, the Advertiser disputed the Complainant's assertions about the integrity and scientific reliability of the Mizone Rapid Study and argued that the study does provide substantiation to the Representation.

    (a) The Advertiser stated that "there are a number of scientifically valid methods of assessing re-hydration. They…include measurement of urinary output. Earlier urine production, as evidenced in the Mizone Rapid Study does not evidence poorer rehydration as PepsiCo claims but means that the subjects absorbed the drink faster"

    (b) Further, "the Mizone Rapid Study also found that analysis of urine composition and volume after the performance test provided evidence that Mizone Rapid was excreted and therefore absorbed more rapidly than the other drinks: It produced the lowest urine osmolality and the greatest urine volume".

    The Advertiser added that the paper was presented at the 12th Annual Congress of the European College of Sports Science in Finland held on 11 to 14 July 2007 and the manuscript is currently being presented for peer review and acceptance by a key journal.

39. The Board has considered the Complainant's and the Advertiser's submissions in relation to the Mizone Rapid Study. The Board notes the conclusions drawn by the study but cannot give it the credibility that would be required if it were to rely on the study alone because:

    (a) only an abstract of the study has been provided to the Board so the Board has not been able to adequately consider how the study was conducted and upon what results and scientific reasoning the conclusions of the study were made;

    (b) it does not appear that the study has been published so it has not been possible for other scientists to examine and test its results by way of peer review, and although the paper is currently being presented for peer review, the Board must consider the time at which the Advertisements were made; and

    (c) the study was commissioned by the Advertiser, rather than a study that was conducted completely independently of the comparative absorption qualities of hypotonic and isotonic sports drinks.

Eleven scientific papers submitted by the Advertiser

40. The Board now turns to the numerous scientific papers included in the Advertiser's response to the Complaint. Each of the papers will be considered in turn and following an analysis of each paper's conclusions the Board will determine whether each study may support the Advertiser's Representation.

41. The first study is by RJ Maughan, LR Bethell and JB Leiper and is entitled "Effects of ingested fluids on exercise capacity and on cardiovascular and metabolic responses to

prolonged exercise in man" (*Exp Physiol* (1996), 81, 847-859) (the **Maughan Study**). The Advertiser provided the following excerpt in its submissions:

> *"It is well established that dilute glucose-sodium solutions will stimulate water absorption in the small intestine without significantly delaying gastric emptying. Hypotonic solutions appear to promote greater net absorption of water than do isotonic solution."* (Advertiser's emphasis added; citing the Leiper and Maughan Study below)

In response, the Complainant submitted:

> *"This study was designed to measure performance, not rehydration. The paper includes just one sentence in the discussion about hypotonic beverages and provides no evidence that hypotonic beverages conclusively rehydrate faster than isotonic beverages.*

The Board has considered the paper and agrees that the study was designed to measure performance, not rehydration. The paper does not enter into a discussion on the differences between hypotonic and isotonic sports drinks and the above excerpt from the study is the only mention of it. Since the Board has not been provided with the cited study, the conclusion drawn cannot properly be assessed. Therefore the Board can only note that the cited study could support the Advertiser's Representation but it does not provide definitive evidence.

42. The second study is by GE Vist and RJ Maughan and is entitled "The effect of osmolality and carbohydrate content on the rate of gastric emptying of liquids in man" (*Journal of Physiology* (1995), 486.2, 523-531) (the **Vist Study**). The Advertiser extracted the statement "both osmolality and carbohydrate content influence gastric emptying of liquids in man" and submitted that "this supports…that hypotonicity and solute flux related primarily to carbohydrate absorption are the primary factors determining net fluid absorption". The Complainant stated that "This paper concludes 'carbohydrate content appears to have a greater influence than osmolality' on gastric emptying, and the paper references that 'the data in the published literature are inconclusive' on the effects of osmolality on gastric emptying" (Complainant's emphasis added).

The Complainant also submitted that in this study:

> *"a 40gm CHO/L (4% carbohydrate) hypotonic solution rehydrated faster than a 188gm CHO/L isotonic solution (19% carbohydrate). By comparison, Gatorade has a 56gm CHO/L (6%), Powerade a 76gm CHO/L solution (7.6%) and Mizone 39gm CHO/L solution (4%). The results of these studies are no surprise, it is well known that at carbohydrate levels greater than 8%, absorption rates significantly decrease (Ryan et al, 1998)."*

The Board understands from the paper and accepts that both osmolality and carbohydrate content influence gastric emptying (the emptying of the fluid from the stomach) but the carbohydrate content appears to have a greater influence than osmolality. However the Board does not accept the conclusion drawn by the Advertiser that this study

"supports…that hypotonicity and solute flux related primarily to carbohydrate absorption are the primary factors determining net fluid absorption".

In contrast, the Board also understands from the paper that:

> *"It might be proposed that, because a glucose polymer solution has a lower osmolality than an isoenergetic glucose solution, the glucose polymer solution will empty more quickly than the monomeric glucose solution.* ***There is some experimental evidence to support this hypothesis, but the data in the published literature are inconclusive"*** (at page 523 and with emphasis added)

The Board notes that osmolality is a measure of the osmoles of solute per kilogram of solvent and that the solutes used in sports drinks are carbohydrates and electrolytes. Mizone Rapid has an osmolality of 230 mosmol/L (average value) and the isotonic sports drinks have an osmolality close to that of blood which is approximately 277 mosmol/L. The Board notes that a solution with a similar osmolality to Mizone Rapid (but not the same carbohydrate composition) was tested in this study but a solution with a similar osmolality to blood was not tested. Further, as the Complainant observes, of all the solutions tested in the study none had the same percentage of carbohydrates as isotonic sports drinks.

Since the paper does not compare isotonic solutions with hypotonic solutions, and since the paper expresses doubt as to whether hypotonic sports drinks are absorbed faster than isotonic sports drinks, the Board is of the view that this paper does not directly support the Advertiser's Representation.

43. The third study is by H Takii, Y Takii, T Kometani, T Nishimura, T Nakae, T Kuriki and T Fushiki and is entitled "Fluids containing a highly branched cyclic dextrin influence the gastric emptying rate" (*Int J Sports Med* (2005), 26, 314-319) (the **Takii Study**). The Advertiser submitted in relation to this study that "the efficiency of rehydration after ingestion of a sports drink depends on the rates of gastric emptying and intestinal absorption". The Complainant stated that this study cannot conclusively support the argument that hypotonic drinks rehydrate faster than isotonic sports drinks.

The Board has reviewed the paper and considers the following excerpts relevant:

> *"A high concentration of CHO in a drink delays gastric emptying, and thus decreases the amount of fluid that is available for absorption…a low CHO concentration accelerates the rate of gastric emptying and thus increases the amount of fluid available".* (at page 315)
>
> *"[gastric emptying time] increased with an increase in osmotic pressure".* (at page 316)

These statements appear to support the Advertiser's Representation. However the Board notes that the study does not directly compare hypotonic and isotonic sports drinks of a similar osmolality to the sports drinks relevant to this dispute. In light of this, the Board cannot afford the paper its full weight.

44. The fourth study is by JB Leiper, J Davidson and RJ Maughan and is entitled "Gastric emptying and absorption of three oral rehydration solutions in man" (*Clinical Science* (1991), 81, supplement 25, 27P (the **Leiper and Davidson Study**). The Advertiser stated that this study concluded that "net water absorption was fastest for hypotonic solutions compared to isotonic solutions" and "hypotonic oral rehydration solutions 'can promote greater water and electrolyte absorption'".

The Board believes that this paper may support the Advertiser's Representation but notes that only the Abstract has been provided. Further, the osmolality and carbohydrate concentrations of the solutions tested were similar but not the same as the hypotonic and isotonic sports drinks currently in dispute, and therefore this study does not provide definitive supporting evidence.

45. The fifth study is by JB Leiper and RJ Maughan (the **Leiper and Maughan Study**) and is entitled "Net and uni-directional water flux from four oral rehydration solutions perfused into the intact human jejunum" (*Proc Nutr Soc* (1998), 57, 31A). The Board firstly notes that the jejunum is the central of the three divisions of the small intestine and lies between the duodenum and the ileum. The Advertiser submitted that this study concludes "there are faster rates of water absorption which occur from moderately hypotonic drinks compared with isotonic drinks".

The Board has reviewed the Abstract of the paper, which was all that was provided, and notes the concluding sentence:

> *"These data suggest that the faster rates of water absorption which occur from moderately hypotonic (≈250 mosmol/kg) compared with isotonic oral rehydration solutions, are due to an increased rate of luminal-to-mucosal water flux rather than a change in mucosal-to-luminal water flux".*

The Board is of the view that this paper directly supports the Advertiser's Representation since the sports drinks tested were of a similar osmolality to the sports drinks currently in dispute.

Although only the Abstract was provided, it does relate to an independent published study and therefore the Board is inclined to give it greater weight than was the case with the Mizone Rapid Study.

46. The sixth study (which is a peer review paper) is by JB Leiper and is entitled "Intestinal water absorption – implications for the formulation of rehydration solutions" (*Int J Sports Med 19* (1998), S129-132) (the **Leiper Paper**). The Advertiser noted that the paper concludes "dilute hypotonic glucose-sodium solutions are highly effective oral rehydration solutions".

The Board understands from the paper that hypotonic solutions do lead to effective water absorption but notes that the paper does not directly compare and contrast hypotonic solutions to isotonic sports drinks, which is the nature of the Complaint before the Board. The Board also notes that this paper is a peer review of other papers rather than reporting a trial that was conducted. For these reasons, the Advertiser cannot rely on this paper as supporting evidence to its Representation.

47. The seventh study is by JB Leiper and RJ Maughan and is entitled "Accumulation in the circulation of a tracer (deuterium) for water from three oral rehydration solutions in man" (not published) (the **Second Leiper and Maughan Study**). Since the study is unpublished, not discussed by the parties and the Board has only been provided with the Abstract, the Board will note its conclusion that "deuterium accumulation rate…was faster from [the hypotonic solution] than from [the isotonic solution]", but not consider it further.

48. The eighth study (which is a peer review paper) is by S Mettler, C Rusch and PC Colombani and is entitled "Osmolality and pH of sport and other drinks available in Switzerland" (*Schweizerische Zeitschrift für Sportmedizin und Sporttraumatologie* (2006), 54(3), 92-95) (the **Mettler Paper**). This paper is not discussed by the parties.

The Board believes the following extract from the paper to be relevant:

> *"Second and contrary to widespread belief, even the really isotonic beverages (around 280 and 290 mmol/kg) are not the ones that are absorbed the fastest. This fact should already become evident when considering that per definition there is a water flux from hypotonic solutions in direction to the hypertonic counterpart and along the osmotic gradient. In the case of beverages, this means that water from hypotonic beverages is pulled into the circulation, which represents the hypertonic compartment. This pulling force is, by definition, not present when two solutions are isotonic to each other. Indeed, it is suggested that intestinal water absorption rates are higher with hypotonic solutions compared with isotonic solutions [10,13]. The optimal osmolality for a sports drink has, therefore, been defined to be in the slightly hypotonic range between 200 and 250 mmol/L [13].* (at page 94)

This extract directly supports the Advertiser's Representation. However the Board notes that this reference was not the result of clinical testing of sports drinks but instead the paper is a peer review of other studies and trials conducted by scientists in the rehydration field. The extract above is actually a commentary on the conclusions drawn from the Leiper study discussed above. Therefore this paper only indicates to the Board that other countries and other scientists have considered the findings of JB Leiper and appear to agree.

49. The ninth study is by JB Hunt, EJ Elliott, PD Fairclough, ML Clark and MJG Farthing and is entitled "Water and solute absorption from hypotonic glucose-electrolyte solutions in human jejunum" (*Gut* (1992), 33, 479-483) (the **Hunt Study**). The Complainant submitted that "in other studies, such as the Hunt studies referenced, the form and combination of carbohydrate used is not comparable to the Gatorade formula. The Board notes that this is a correct statement but the paper relevantly provides that:

> *"Hypotonic solutions may promote increased water and solute absorption in the jejunum when compared with their isotonic or hypertonic counterparts".*
>
> *"One advantage of hypotonic solutions is that they offer 'free' water absorption in the jejunum and allow solute stimulated absorption in the ileum."* (at page 483)

The Board also notes that two of the solutions tested had osmolalities similar to those of Mizone Rapid and isotonic sports drinks, and out of the two, the sports drink with an osmolality similar to Mizone Rapid (being 240 mmol/L and the osmolality of Mizone Rapid is 230 mmol/L) was found to have an increased rate of water absorption in the jejunum. The authors concluded that:

> *"We are encouraged by these findings and propose to test the merits of a hypotonic solution such as oral rehydration solutions 60:240 in a double blind controlled clinical trial.* (at page 483)

Although the solutions tested are not exactly the same as the products currently being discussed, the solutions are very similar.

The Board notes the following statements which question how generally accepted the Advertiser's Representation is by the scientific world:

> *"the optimal composition of oral rehydration solutions for the developed world, particularly with regard to sodium and glucose concentrations and osmolality, has not been clearly established."* (at page 479)

> *"It is also known that in man water absorption and osmolality are inversely related in solutions with osmolalities of 250 mOsm/kg or greater but below this osmolality the relation has been found to break down".* (at page 482)

In light of the above observations, the Board does not believe that this study can be relied upon by the Advertiser to support the Representation that it makes.

50. The tenth study is by JB Hunt, AV Thillainayagam, AF Salim, S Carnaby, EJ Elliott and MJ Farthing and is entitled "Water and solute absorption from a new hypotonic oral rehydration solution: evaluation in human and animal perfusion models" (*Gut* (1992), 33, 1652-1659) (the **Second Hunt Study**). The Board considers the following extracts relevant to the present discussion:

> *"Hypotonic oral rehydration solution promoted significantly greater water absorption than other oral rehydration solutions in all rat models ($p<0.001$) but apparently increased water absorption failed to achieve significance in human jejunum".* (at page 1652)

> *"These findings show that there is agreement in the apparent efficacy of oral rehydration solutions in these animal and human perfusion models, and that improved water absorption with adequate sodium absorption may be achieved by reducing oral rehydration solution osmolality".* (at page 1652)

In light of the above apparently contradictory statements, the Board is unable to determine whether this study can be relied upon by the Advertiser to support its Representation.

51. The eleventh study is by AV Thillainayagam, JB Hunt and MJ Farthing and is entitled "Enhancing clinical efficacy of oral rehydration therapy: is low osmolality the key?" (*Gastroenterology* (1998) Jan, 114(1), 197-210) (the **Thillainayagam Study**). The parties

have not discussed this study. This study is only provided to the Board as an Abstract and no conclusions are drawn. It therefore provides no assistance to this discussion.

52. The Advertiser submitted two additional studies (in Abstract form only) in their May 2008 submissions. Since both studies are by JB Leiper and RJ Maughan whose other papers have been considered at length above and since the Abstracts do not add any further light to comments already made, the Board does not set out further details.

53. The above eleven studies and the two additional studies were all the studies that were submitted by the Advertiser. Although the Advertiser submitted to the Board that there are other, much older, studies which support their Representation, since they were not provided to us, we do not need to consider them. The Board will now consider the scientific evidence submitted by the Complainant.

The scientific evidence submitted by the Complainant

54. The Complainant has referenced two scientific studies to support its argument that the hypotonic sports drink Mizone Rapid does not rehydrate faster than isotonic sports drinks.

55. The first study submitted by the Complainant in support of its argument is by CV Gisolfi, KJ Spranger, RW Summers, HP Schedl and TL Bleiler and is entitled "Effects of cycle exercise on intestinal absorption in humans" (*J Appl Physiol* (1991), 71(6), 2518-2527) (the **Spranger Study**). The Complainant included this study as authority for their submission that "fluid absorption is the main determinant of the speed of rehydration, and no fluid has a higher fluid absorption rate than water". In response the Advertiser submitted:

> *"Water generally has a tonicity of 2-5 milliOsmol/L and although it is markedly hypotonic, when comparing osmolality values, water is not the same and cannot be compared to a hypotonic carbohydrate-electrolyte beverage such as Mizone Rapid which is specifically formulated to a tonicity of 230 milliOsmol/L (average value);*
>
> The Gisolfi et al study *"negates PepsiCo's argument as 'the results show significantly greater fluid absorption rates from the carbohydrate-electrolyte solution than from water'".*

The Complainant agreed that this is true but submitted that other studies referenced by it conclude that "in other parts of the small intestine, greater absorption occurs with ingestion of water compared with carbohydrate-electrolyte solutions so the overall result is that the carbohydrate-electrolyte solutions are absorbed at similar rates as plain water".

The Board notes that the Complainant in making the above statement relies on the first and second studies it has submitted and two other studies which the Board has not received.

The Board has considered the first study and believes that the concluding statement is relevant. It is stated that "from a practical viewpoint, these data indicate that drinking water alone is better than drinking water with only added electrolytes; however, if electrolytes are added to a fluid replacement beverage, carbohydrate should also be added to enhance fluid absorption" (at page 2526). The paper also states that "fluid absorption

from a 6% carbohydrate solution without electrolytes was the same as from a 6% [carbohydrate-electrolyte] solution. Moreover, fluid absorption from either of these solutions was greater than from water" (at page 2526).

Therefore the Board does not agree with the Complainant that the paper establishes that carbohydrate-electrolyte solutions are absorbed at similar rates as plain water and is instead of the view that there is evidence to establish that carbohydrate-electrolyte solutions do have higher rates of absorption than water. The Representation made by the Advertiser that Mizone Rapid rehydrates faster is therefore not refuted by this study.

56. The second study submitted by the Complainant is by AJ Ryan, GP Lambert, X Shi, RT Chang, RW Summers and CV Gisolfi and is entitled "Effect of hypohydration on gastric emptying and intestinal absorption during exercise" (*J Appl Physiol* (1998), 84, 1581-1588) (the **Ryan Study**). This study does not compare hypotonic and isotonic sports drinks directly but instead analyses one carbohydrate-electrolyte solution with a similar osmolality to blood and two carbohydrate-electrolyte solutions with higher osmolalities (i.e., hypertonic solutions). The Board therefore does not believe that this paper is very helpful to the present discussion.

THE BOARD'S DECISION

57. The Board has considered the above studies and now turns to the decision as to whether there is a sufficient body of credible scientific evidence to establish the truth of the Advertiser's Representation which is not directly contradicted by other credible scientific evidence. In coming to its conclusions the Board notes that it labours under the distinct disadvantage of not being able to assess expert evidence which would undoubtedly be available to a Court which heard the Complaint. In these circumstances it must adopt a conservative approach in making a finding which may have the effect of substituting its own views on technical scientific matters for those of experts who are far more qualified to make such assessments.

58. The Board notes that it is not required to make a determination as to whether hypotonic sports drinks do in fact rehydrate a person faster than isotonic sports drinks.

59. The Board understands that the Advertiser relies principally on the Mizone Rapid Study as the basis for which it makes its Representation that hypotonic sports drinks rehydrate faster than isotonic sports drinks. Although the Mizone Rapid Study appears to support the Advertiser's Representation, the Board has a number of reservations about the Mizone Rapid Study for the reasons stated above at paragraph 39, which prevents the Board from giving it the credibility that would be required if it were to rely on the study alone.

60. However, that study is not an isolated study and the Advertiser has additionally provided to the Board a number of other scientific studies which appear to support the Advertiser's Representation that hypotonic solutions are absorbed faster and therefore rehydrate faster than isotonic solutions. Although various deficiencies of the studies have been identified and discussed, the Board is of the view that taken collectively they do meet the test that there is a sufficient body of credible scientific evidence to establish the truth of the Representation.

61. The Board must now consider whether any credible scientific evidence which has been referenced by the Complainant directly contradicts the Advertiser's Representation. The first scientific study submitted by the Complainant does not appear to sufficiently refute the Advertiser's Representation and the second scientific study that was submitted does not compare hypotonic and isotonic solutions.

62. The Board is also aware that the Complainant relied on supporting evidence from Professor Mark Hargreaves in relation to the weight that should be afforded to the Mizone Rapid Study (as extracted at paragraph 37(c)). The Board has noted these remarks in relation to the Mizone Rapid Study, and if taken alone would be very compelling, but as discussed above, there does appear to be a number of other scientific studies which support the Representation and which do not suffer from the defects that Professor Mark Hargreaves alleges. The Board is therefore of the view that the Complainant has failed to provide credible supporting evidence that directly contracts the Advertiser's Representation.

63. In these circumstances, and on the basis of the evidence before the Board, the Board has formed the view that it has not been established by the Complainant on the balance of probabilities that the Representation made by the Advertiser was false or misleading or likely to mislead or deceive members of the public, and makes a finding that the advertising is substantiated.