



Arbitration CAS 2004/A/726 Maria Luisa Calle Williams v. International Olympic Committee (IOC), award of 19 October 2005

Panel: Mr Dirk-Reiner Martens (Germany), President; Mr Miguel Angel Fernandez Ballesteros (Spain); Mr Peter Leaver QC (England)

Track cycling

Doping (Isometheptene)

CAS jurisdiction

Substance with “a similar chemical structure or similar pharmacological effects” to the substances listed as prohibited
Criteria to be considered when deciding to treat a substance as similar to a listed substance

- 1. In contrast to a decision to include a particular substance on the Prohibited List, a WADA determination to treat a substance as “similar” to a listed substance can be challenged by athletes.**
- 2. The classification of a substance as having “a similar chemical structure or similar pharmacological effect(s)” requires a similarity to one or several of the particular substances on the list. It is not sufficient for WADA or the IOC, or any other anti-doping agency, simply to assert that a substance, such as Isometheptene, is “a stimulant” and thus a prohibited substance (when that assertion is disputed by an athlete) without specifying the particular substance on the List with which similarity is supposed to exist.**
- 3. Before treating a substance as similar, the three criteria mentioned in 4.3 of the WADA Code (potential performance enhancement, health risk, violation of the spirit of sport) must be considered. Only if two of these three are met can a substance be treated as similar and thus prohibited.**

On 25 August 2004, Maria Luisa Calle Williams, a Colombian national, competed in the women’s point race for track cycling at the Games of the XXVIII Olympiad in Athens (the “Athens Olympic Games”), and was placed third. Immediately following her participation she was requested to provide a urine sample. During laboratory analysis the sample showed the presence of Heptaminol. On the doping control form, the Appellant noted that she had taken the medication “Neo-Saldina” on the day of the competition.

On 27 August 2004, Dr Rabin of WADA wrote a letter to the IOC stating that Heptaminol was prohibited as a substance with “a similar chemical structure or similar pharmacological effects” to the substances listed as prohibited.

On 28 August 2004, the IOC was informed of an adverse finding on an “A” sample collected on 25 August. The finding was for Heptaminol. Pursuant to Article 7.2.2 of “[t]he International Olympic Committee Anti-Doping Rules applicable to the Games of the XXVII Olympiad in Athens in 2004” (the “IOC Rules”), Dr Schamasch of the IOC determined that the above referenced “A” sample belonged to Ms Maria Calle Williams, the Appellant.

On 28 August 2004, the Appellant and the Colombian delegation were informed of an adverse analytical finding for the Appellant’s “A” sample collected on 25 August 2004. The Appellant requested the analysis of the “B” sample.

A Disciplinary Commission heard the Appellant and five other members of the Colombian delegation on 29 August 2004. At this hearing, the Colombian delegation confirmed that the Appellant had been prescribed Neo-Saldina by a doctor attached to the Colombian National Olympic Committee delegation for a migraine headache. Neo-Saldina contains the substance Isometheptene.

On the same day, the IOC Executive Board, following a recommendation by the Disciplinary Commission, rendered the following decision (the “IOC Decision”):

- I. *The Athlete Mrs Maria Luisa Calle Williams, Colombia, Cycling Track is disqualified from the women’s point race event, in which she had placed third.*
- II. *The International Cycling Federation (UCI) is requested to modify the results of the above-mentioned event accordingly and to consider any further action within its own competence.*
- III. *The Colombian Olympic Committee is ordered to return to the IOC, as soon as possible, the bronze medal and diploma awarded to the athlete in relation to the above-noted event.*
- IV. *This decision shall enter into force immediately”.*

On 31 August 2004 the results of the analysis of the Appellant’s “B” sample were communicated to the IOC. The analytical finding confirmed the result of the “A” sample test.

The Appellant instituted CAS proceedings to appeal the IOC Decision on 21 September 2004 and filed her appeal brief on 21 October 2004. The Respondent’s answer was filed on 22 November 2004.

Prof. Don H. Catlin submitted an expert report dated 22 November 2004 concerning Heptaminol, the substance found in the Appellant’s urine sample. During the hearing before this Panel on 11 March 2004 Luis Eduardo Contreras Vergara, the Appellant’s Medical Doctor fully agreed with Prof. Catlin’s report. The report states that Neo-Saldina, the medication which the Appellant admitted taking on the day of her competition, contains, inter alia, 30mg of Isometheptene. According to Prof. Catlin’s Report, “[i]f isometheptene is ingested it will be metabolised to N-desmethylisometheptene and this metabolite will be excreted in urine. However, during Procedure II it is converted chemically in the test tube to heptaminol. Therefore, isometheptene administration is expected to lead to the finding of heptaminol in urine and heptaminol is a marker for isometheptene use”.

During the oral hearing before this Panel on 11 March 2005 the parties took no issue with Prof. Catlin's conclusion

- that both Heptaminol and Isometheptene, even though not expressly listed in WADA's Prohibited List (see Article 4 IOC Rules), have a "*similar chemical structure or similar pharmacological effect(s)*" as those substances expressly named as "S.1-stimulants" in the WADA Prohibited List, and
- that both Heptaminol and Isometheptene are prohibited substances pursuant to the IOC Rules, and
- that Heptaminol is a marker for Isometheptene, i.e. "a compound, group of compounds or biological parameters that indicates the use of a prohibited substance or prohibited method" (Appendix 1 "Definitions" to the IOC Rules).

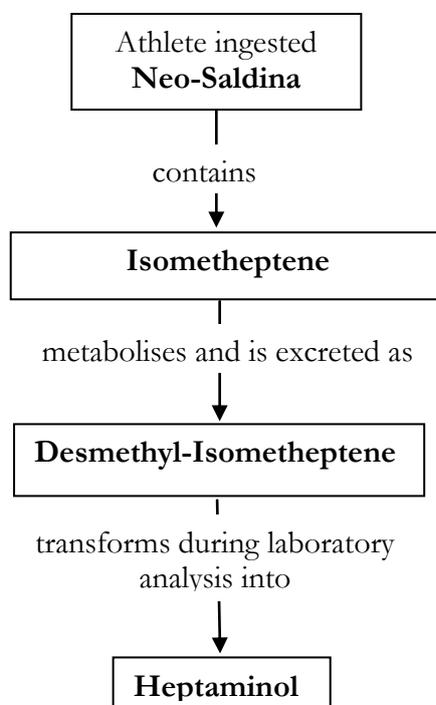
However, subsequent to the 11 March 2005 hearing, but before it had completed its Award, on 15 April 2005 CAS received a copy of a letter dated 14 April 2005 and sent to the Union Cycliste Internationale ("UCI") by UCI's lawyer Philippe Verbiest. According to this letter, Mr Verbiest "*came to the conclusion that Calle Williams did not commit a doping offence at the 2004 Athens Olympic Games*". Attached to the letter were "*Commentaires concernant le cas Williams et la prise d'isometheptène par cette cycliste lors des Jeux d'Athènes*" of 16 April 2005 by Dr Martial Saugy, head of the "Laboratoire Suisse d'Analyse du Dopage" in Lausanne. According to both documents the substance ingested by the Appellant ("Isometheptene") does not have "a similar chemical structure or similar pharmacological effect(s)" as the stimulants listed on the WADA's 2004 list and can thus not be considered to be "prohibited" under the IOC Rules.

Upon invitation by the Panel on 20 May 2005 WADA submitted a report from its Science Department dated 17 May 2005 which contends that Isometheptene is a prohibited substance.

The Appellant and her advisors were not aware until after the 11 March 2005 hearing that there was an expert in the area of doping analysis who disagreed with Prof. Catlin's view according to which Isometheptene was a prohibited substance. The Panel considered this to be an exceptional circumstance within the meaning of Art. R44.1 of the CAS Code and decided to re-open the proceedings.

A second hearing was held in this matter on 25 August 2005 during which expert testimony was heard from Dr Martial Saugy of the Lausanne Doping Laboratory and from Dr Oliver Rabin of WADA.

During the hearing on 11 March 2005 the Parties agreed that the presence of Heptaminol in the Appellant's sample was not due to the Appellant having ingested that very substance but was the result of the following process:



In her written pleadings the Appellant advanced three arguments against the IOC Decision, namely an alleged violation of due process, a lack of proper notification of the IOC Decision and a further theory explaining the presence of Heptaminol in her urine sample.

During the first hearing on 11 March 2005 before this Panel the Appellant argued that while her disqualification by the IOC Executive Committee was based exclusively on the presence of Heptaminol as a *prohibited substance*, the IOC's answer to her appeal makes reference to Heptaminol as a *marker* for Isometheptene, another substance said to be prohibited. The Appellant submitted that this change of reasoning should not be accepted by the Panel, and requested the Panel to set aside the IOC's Decision. The Appellant repeated this argument in further submissions filed on her behalf after 11 March 2005.

At the 25 August 2005 hearing the Appellant further relied on the expert opinion of Dr Martial Saugy and submitted that Isometheptene was not a prohibited substance under the IOC Rules.

The Respondent submitted that "Neo-Saldina" contained the prohibited substance Isometheptene, which is a stimulant with a chemical structure very similar to Heptaminol.

The Respondent argued that the Appellant had admitted to a doping offence. According to the Respondent, the confirmation by the Appellant on the Doping Control Form and on 25 August 2004 at the Disciplinary Commission hearing, is evidence enough that the Appellant had ingested

Isometheptene, an active ingredient of “Neo-Saldina” and a prohibited substance under the IOC Rules. Isometheptene had been detected by the laboratory through its marker Heptaminol.

Finally, the Respondent argued that the rationale behind the “*related substances*” extension of the category entitled *S.1 Stimulants* in WADA’s Prohibited List is to have the capacity to identify and sanction the use of substances not expressly listed as prohibited substances but nonetheless related to a prohibited substance by its pharmacological actions or chemical structure. The Respondent submitted that this would be an imperative in the fight against doping at the Olympics and elsewhere. If that were not so, an athlete would be able, without risk, to use a drug that was only slightly different in make-up or formulation from the drug that appeared in the WADA Prohibited List, and so escape sanction.

After the proceedings were re-opened following the submissions made by UCI, the IOC relied on the statements made by Dr Rabin of WADA according to which Isometheptene was pharmacologically similar to the substances listed as Stimulants in the WADA Prohibited List.

LAW

Heptaminol as a prohibited substance?

1. Initially, the IOC Decision argued that as a result of the strict liability principle the mere finding of Heptaminol – which the IOC claims was a prohibited substance at the relevant point in time – in the Appellant’s sample must lead to her disqualification. However, during the proceedings before this Panel the IOC agreed that contrary to its original submissions the substance for which the Appellant tested positive was Isometheptene not Heptaminol. This was the result of the Appellant’s admission to having taken Neo-Saldina and the biological and chemical process described above. Therefore, the Panel does not have to determine whether Heptaminol is in fact a prohibited substance.

Isometheptene as a prohibited substance?

2. The outcome of this case depends entirely on the question whether Isometheptene is a prohibited substance under the IOC Rules.
3. The Anti-Doping Rules applicable to the 2004 Athens Olympic Games (the “IOC Rules”) are the relevant regulations in this case.

Article 2 of the IOC Rules provides:

“(T)he following constitute anti-doping rule violations:

2.1 The presence of a Prohibited Substance ... in an athlete’s bodily specimen”.

4. Prohibited Substances are defined as
“(A)ny substance so described on the Prohibited List” (Appendix 1 “Definitions” to the IOC Rules).
5. The 2004 Prohibited List applicable at the Athens Olympic Games inter alia provided the following:
“S1 Stimulants
The following stimulants are prohibited, including both their optical (D- and L-) isomers where relevant:
“Adrafinil, amfepramone, amiphenazole, amphetamine, amphetaminil, benzphetamine, bromantan, carphedon, cathine, clobenzorex, cocaine, dimethylamphetamine, ephedrine, etilamphetamine, etilefrine,, fencamfamin, fenetylline, fenfluramine, fenproporex, furfenorex, mefenorex, mephentermine, mesocarb, methamphetamine, methylamphetamine, methylenedioxyamphetamine, methylenedioxymethamphetamine, methylephedrine, methylphenidate, modafinil, nikethamide, norfenfluramine, parahydroxyamphetamine, pemoline, phendimetrazine, phenmetrazine, phentermine, prolintane, selegiline, strychnine, and other substances with similar chemical structure or similar pharmacological effect(s)”.
6. Isometheptene is not expressly listed as a Prohibited Substance on the 2004 Prohibited List.
7. However, the IOC argues that Isometheptene has a “similar chemical structure or similar pharmacological effect(s)” as the substances which are expressly listed, and in doing so relies on the confirmation by WADA in its 27 August 2004 letter to the IOC (see above) and WADA’s additional submissions in preparation for and during the second hearing of this case on 27 August 2005.
8. The IOC maintains in its 2 May 2005 submission that a determination by WADA that a particular substance not listed in the Prohibited List is “similar” to one (or several) of the substances expressly listed and is thus prohibited, is not subject to challenge in CAS proceedings according to Section 4.2 of the IOC Rules which provides the following:
“The Prohibited Substances ... included on the Prohibited List shall be final and shall not be subject to challenge by an Athlete ...”.
9. The Panel disagrees.
10. The inclusion of a substance on the List is made after a thorough evaluation by the so-called “List Committee”, a group of specialists in the field of doping substances representing all stakeholders in the fight against doping. It is thus justified to exempt a decision to put a substance on the List from challenge by the athlete.
11. On the other hand, the classification of a substance as “similar” to one of the listed substances is made by the WADA administration (at least in the case in hand) without the benefit of the input from experts from all interested groups. To exclude any challenge of such a decision would give too much responsibility to WADA alone. In addition, the wording of section 4.2 of the IOC Rules does not lend itself to an interpretation which exempts from challenge the

classification of a substance as “similar” to listed substances (“the Prohibited Substances ... included on the Prohibited List shall be final ...”).

12. The Panel is, thus, of the view that, in contrast to a decision to include a particular substance on the Prohibited List, a WADA determination to treat a substance as “similar” to a listed substance can be challenged by athletes. However, the Panel does not express a view, and does not have to express a view in this case, how far reaching this challenge may be.
13. The Appellant challenged the IOC’s (WADA’s) determination that Isometheptene is similar to substances expressly listed on the Prohibited List. In order for this determination to withstand the challenge, Isometheptene must:
 - be similar to one (or several) of the listed substances and, if it is,
 - must fulfil two of the three criteria mentioned in 4.3 of the WADA Code.

A. Is Isometheptene “similar” to substances on the Prohibited List?

14. The parties disagree on the interpretation of the term “similarity” of a non-listed substance with a substance specifically mentioned on the Prohibited List.
 - a) The Appellant’s Case
15. The Appellant adopts the arguments advanced by Mr Verbiest and Dr Saugy.
16. According to Mr Verbiest, for a non-listed substance to be treated as “similar” it is necessary that the similarity exists with respect to one (or several) of the particular substances on the List. In his view, it would not be sufficient to simply state that a substance is a “stimulant” and thus prohibited.
17. Dr Saugy’s 6 April 2005 report submits that Isometheptene is not a stimulant. The pharmacological similarities of Isometheptene to one or several of the substances on the list are limited to the classification of all of them as sympatomimetics and are not sufficiently close to justify a qualification of Isometheptene as “similar” within the meaning of IOC Rules.

“Commentaires concernant le cas Williams et la prise d’isometheptène par cette cycliste lors des Jeux d’Athènes.

Par la présente, je répons aux questions qui m’ont été posées par Maître Philippe Verbiest, au nom de l’UCI dans le cadre de cette affaire:

1. L’Isometheptène est-il un stimulant?

Selon la littérature que nous avons consultée et l’ouvrage de référence Martindale (The Extra Pharmacopeia (31st Edition), l’isometheptène n’est ni un stimulant cardiaque, ni un stimulant du système nerveux central.

L'action pharmacologique de l'isométhéptène est celle d'un sympathomimétique à action adrénergique indirecte ayant un effet vasoconstricteur pour le traitement des migraines. Il est une des alternatives à l'ergotamine.

Ce n'est donc pas ce que l'on appelle communément un stimulant.

2. *Est-il similaire à l'adrénaline (qui ne figure pas sur la liste)?*

Même si en chimie et en pharmacologie, les limites du terme «similaire» sont difficiles à définir, on peut dire par analogie avec ce qu'on utilise dans les analyses de dopage:

a) ***Il n'y a pas une structure chimique suffisamment proche pour que l'on puisse parler de similitude.***

b) ***L'action pharmacologique de l'adrénaline est celle d'un sympathomimétique à action directe très importante sur les adrénorécepteurs bêta et dans une moindre mesure sur les récepteurs alpha. Ceci lui donne des propriétés évidentes de stimulation adrénergique que en font un produit de base en cas d'urgence pour traiter un choc anaphylactique afin de maintenir le rythme cardiaque.***

Il n'y a donc pas un effet pharmacologique similaire à l'adrénaline.

3. *Est-ce un sympathomimétique?*

Oui, l'isométhéptène est un sympathomimétique.

4. *S'il est un sympathomimétique, est-il pour autant un stimulant ou similaire à l'adrénaline?*

Les sympathomimétiques ont selon les cas un spectre d'actions très diverses et très large. Cela va du traitement du choc anaphylactique à celui de l'asthme, en passant par le traitement des migraines, des congestions nasales, de l'hypotension à la maladie chronique d'obstruction pulmonaire. On ne peut donc pas tous les mettre dans une seule catégorie du point de vue des effets pharmacologiques recherchés.

Ainsi, on l'a vu, on ne peut pas considérer l'isométhéptène comme un stimulant, ni comme ayant une action similaire à l'adrénaline, parce qu'il est un sympathomimétique.

Nous en voulons pour preuve d'autres exemples de la grande famille des sympathomimétiques appartenant ou n'appartenant pas à la liste des produits interdits de l'AMA.

Le plus flagrant est celui de l'éphédrine (faisant partie de la liste) et de la pseudo-éphédrine ayant été sortie de la liste par l'AMA.

La similitude chimique entre ces deux produits est évidente puisque que ce sont deux isomères. Leur action pharmacologique est cependant légèrement différente en terme d'intensité d'effet. Comme l'avaient en son temps expliqué les experts ayant retiré la pseudo-éphédrine de la liste, toutes deux sont des sympathomimétiques à action adrénergique à la fois directe (stimulantes) et indirectes (vasoconstrictrice), mais comme indiqué dans la littérature, l'effet direct chez la pseudo-éphédrine est moindre que chez l'éphédrine. On voit donc que l'intensité de l'effet direct peut être à l'origine du retrait d'une substance de la liste.

Dans le cas de l'isométhéptène, aucun effet direct (stimulant) n'est reconnu. Il y aurait dès lors, par analogie à la problématique des éphédrines, d'autant moins de raisons de le considérer comme substance similaire à celle de la catégorie des stimulants.

(...)

Encore une fois, la similitude chimique avec l'heptaminol est discutable. L'effet biologique est clairement différent également puisque l'heptaminol est un stimulant cardiaque alors que l'isométhéptène est un vasoconstricteur”.

18. In “supplementary comments” of 6 June 2005 Dr Saugy confirms his earlier opinion:

“Supplementary comments on Isomethoptene

Concerning Isomethoptene and its pharmacological effects, I read carefully several correspondence between WDA and UCI concerning the Case Williams, including the opinion of WADA on May, 20th 2005.

First of all, I need to state two points which were certainly wrongly interpreted by WADA in my statement of April 6th, 2005.

- 1. I was speaking of adrenaline because in a letter of Oliver Niggli to UCI concerning this matter, the reference to the effect of adrenaline was made. I was then simply answering to the question relatively to that product.*
- 2. I was effectively proposing to introduce Isomethoptene in the new list for technical reasons due to any analytical artefact occurring during the management of the sample, and **not** because of its supposed stimulant action on the performance. This was already done for the same reason with Selegiline.*
- 3. Regarding the potential stimulant effect of Isomethoptene: I can only confirm what I said in my first statement. Isomethoptene is not described as a cardiac stimulant nor as a CNS stimulant. Isomethoptene is one of the major products used to treat migraine. Several papers describe these effects widely used in healthcare (see for example Gibbs et al, Headache 2003, 330-35). It is recognized to be a sympathomimetic with adrenergic indirect action with vasoconstrictor effect. It is one of the alternative to ergotamine which seems to have more adverse effects (and which is not in the list of forbidden compounds). Isomethoptene is used to act as a anti-spasmodic agent on the smooth muscle. As an antagonist of the parasympathic system, Isomethoptene to my point of view does not correspond to what is stated in the S1 list for stimulants. I can not see in the literature any proof that it is an ergogenic substance for the athletes as it is commonly understood.*
- 4. I do not understand how WADA is defining the classification of all substances to be considered as stimulants outside the monitoring list. The opinion of WADA that S1 is an open list is giving too much space to interpretation. Phenylpropanolamine, synephrine, phenylephrine are not forbidden, but belong the monitoring list. They are sympathomimetics and their findings in urine do not allow the labs to declare them as adverse findings. From the laboratory point of view, it is very difficult to consider that all the other substances, with chemical or pharmacological similarities, with those from the S1 list, and not present in monitoring list, have to be declared as adverse finding. If difficult for the lab, it should be even more difficult for the athlete treated for headache or migraine to just think about it. For a compound like Isomethoptene, if one takes into account the sympathomimetics from the monitoring list, it would be rather understandable to put it on the monitoring list (this argumentation differs of course from the proposal to put it on the list only for technical reasons, see point 2 above)”.*

b) The IOC's Case

19. At the 11 March 2005 hearing the IOC based its case on Prof. Catlin's 22 November 2004 expert report which inter alia states the following:

"Isometheptene is an indirect acting sympathomimetic amine that has been in the medical armamentarium for many years. Like other drugs classified by WADA as S.1 Stimulants it stimulates adrenergic receptors. In conventional medicine it is used primarily to treat migraine and other types of headaches. It is also used for the treatment of spasm involving the biliary tract or the urinary tract.

Chemically, it is an unsaturated aliphatic amine, which means that its molecular structure has a double bond, no ring, and a nitrogen atom as shown in the figure below. In the figure, isometheptene is shown juxtaposed to heptaminol in order to emphasize the similarity in chemical structure.

(...)

Pharmacologically, it acts by constricting dilated cranial and cerebral arterioles, thus reducing the stimuli that lead to vascular headaches. It has an antispasmodic effect on the gastrointestinal and urinary tract".

20. In essence, it is Prof. Catlin's opinion that Isometheptene
- is a stimulant,
 - which is chemically related to Heptaminol, and
 - which has a similar chemical structure or pharmacological effect(s) as the stimulants expressly listed.
21. However, Prof. Catlin did not specify the particular substance on the List with which, in his opinion, Isometheptene had a similar chemical structure or pharmacological effect. When Prof. Catlin gave evidence the identification of a particular substance to which Isometheptene was similar was not a live issue, as it was accepted on behalf of the Appellant that it was in fact similar.
22. When WADA was asked its opinion it did not immediately identify the prohibited substance to which Isometheptene was similar. Again, that was not a surprising omission because it was not until the 25 August 2005 hearing that the Appellant's case that the particular substance had to be identified became clear. WADA became involved after the submission by the Appellant of Dr Saugy's report. The Panel was provided under cover of a 20 May 2005 letter from WADA with an additional expert report dated 15 May 2005 by Dr Rabin of WADA. The following are quotes from this expert report and the 20 May 2005 accompanying letter from WADA:
- (...)*
Dear Colleague,
(...)
You will find attached to this letter a report from our Science Department, which confirms WADA's position, that isometheptene is a prohibited substance.

This report has been prepared by our Science Director, Dr Olivier Rabin, and two experts of our List Committee, Prof. Hidenori Suzuki and Prof. Joseph Hanig. All three are experts in pharmacology and are therefore particularly specialized in this field. Their conclusion is clear, that isomethoptene has similar biological or pharmacological effects to a number of prohibited stimulants on the List. There is therefore no doubt that isomethoptene falls under the stimulant category as a substance with similar pharmacological effects”.

23. In summary, and most importantly, according to WADA, the Prohibited List is an “open list” and “all substances pharmacologically classified as a stimulant and not identified under the Monitoring Programme are by definition prohibited”.

c) The Panel’s Conclusion

24. The Panel is unanimously of the view that the classification of a substance as having “a similar chemical structure or similar pharmacological effect(s)” requires a similarity to one or several of the particular substances on the list. It is not sufficient for WADA or the IOC, or any other anti-doping agency, simply to assert that a substance, such as Isomethoptene, is “a stimulant” and thus a prohibited substance (when that assertion is disputed by an athlete) without specifying the particular substance on the List with which similarity is supposed to exist.

25. This conclusion follows from the wording of the IOC Rules alone. Section S1 of the Prohibited List specifies a number of precise substances and adds that “other substances with similar chemical structure or a similar pharmacological effect(s)” also have to be treated as prohibited. The semantics alone lead to the conclusion that the similarity must be present with respect to (a) substance(s) expressly listed. The Panel rejects WADA’s argument according to which “every stimulant” is prohibited no matter whether it is expressly listed, because even if not listed it is by definition “similar” to the substances listed. First of all, if the draftsmen of the IOC and WADA Rules had had in mind such an interpretation, they would have simply stated that “stimulants are prohibited” (a rule which would most likely not pass the test of clarity and predictability). In addition, the term “stimulant” does not seem to be scientifically defined and simply indicates that a substance which stimulates a certain effect. Finally, it appears that even WADA’s List Committee did not abide by its own alleged rule: nicotine and caffeine are stimulants and are not on the Prohibited List (and also not on the monitoring list); the same applies to pseudoephedrine which, even though a stimulant, has recently been taken of the list.

26. As a consequence, it is not conclusive for the outcome of this case to state that Isomethoptene is a stimulant. Even if it is, this is not sufficient to classify it as a Prohibited Substance. What is required is a similarity with one or several of the listed substances.

B. *Similar Chemical Structure or Similar Pharmacological Effect(s) with one of the Listed Substances?*

27. In the light of its finding that a similarity must be established between one (or several) of the substances specified on the Prohibited List and the substance said to be “similar”, in the

present case the Panel finds itself with the task of having to determine whether a similar chemical structure or similar pharmacological effect(s) exists between Isometheptene and a listed substance. This task is made more difficult by the fact that two highly respected experts in the field of doping analysis have given dissenting opinions:

28. Dr Saugy in his 6 April and 6 June 2005 reports and again during the hearing on 25 August 2005 expressed the view that no similar chemical structure exists between the listed substances and Isometheptene. With respect to a pharmacological similarity Dr Saugy believes that even though many of the listed substances on the one hand and Isometheptene on the other hand are sympathomimetics, they cannot be put into one group of sympathomimetics which would trigger similarity because their sphere of action is much too wide (see Dr Saugy's 6 April 2005 report: *"Les sympathomimétiques ont selon les cas un spectre d'actions très diverses et très large. ... On ne peut donc pas tous les mettre dans une seule catégorie du point de vue des effets pharmacologiques recherchés"*).
29. WADA on the other hand relies on the classification of Isometheptene as a sympathomimetic and relates it to amphetamine, ephedrine, amiphenazole/amphetaminil/niketamide and cocaine. When asked by the Panel during the 28 August 2005 hearing whether a pharmacological similarity within the meaning of the IOC Rules exists between these substances and Isometheptene, the two experts disagreed: Dr Rabin affirmed while Dr Saugy denied.
30. The Panel wishes to repeat and emphasise that Prof. Catlin's expert report and his testimony before the Panel on 11 March 2005 do not assist the Panel in resolving the "similarity question" because at the time of the first hearing of this case both parties agreed with Prof. Catlin that Isometheptene was a prohibited substance, so that no question of similarity was in dispute. Prof. Catlin simply had no reason to elaborate on similarity and to specify substances with which in his view similarity exists. He was unavailable at the time of the second hearing and the IOC did not insist that he be heard a second time.
31. Under these circumstances the Panel has no option but to rely on the rules of burden of proof. According to Section 3.1 of the IOC Rules the IOC (WADA)
"... shall have the burden of establishing that an anti-doping violation has occurred. The standard of proof shall be whether the [IOC] has established an anti-doping rule violation to the comfortable satisfaction of [the Panel] bearing in mind the seriousness of the allegation made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt".
32. While the Panel's findings up to this point are unanimous, only a majority of the arbitrators is not "comfortably satisfied" that Isometheptene is a prohibited substance under the applicable rules. The majority reaches this conclusion, inter alia, on the basis of the following considerations:
 - The two experts dissented on the crucial question of pharmacological similarity between the listed substances and Isometheptene. While Dr Rabin believes that the classification of Isometheptene as a sympathomimetic provides a sufficient basis to treat it as pharmacologically similar to other sympathomimetics on the list, Dr Saugy disagrees with that analysis and is of the view that the sphere of action of sympathomimetics is

too broad to justify grouping all of them in one class which is similar to sympathomimetics on the list. In addition, the experts disagree as to whether Isometheptene can be characterized as a “stimulant” at all.

- Based on the experts’ testimony and the documentation provided by the parties, the majority does not feel “comfortably satisfied” that Isometheptene – in contrast to Heptaminol – can be classified as a stimulant, at least if narrowly construed as a substance which stimulates performance.
- On the basis of the evidence submitted to the Panel, it seems that no performance-enhancing effect was caused by the Appellant’s ingestion of Isometheptene. In fact, it appears that very large quantities of Isometheptene need to be administered in order to generate even a theoretical performance-enhancing effect. The Panel notes with interest that in a like scenario substances have been taken off the list (Pseudoephedrine, see Dr Saugy’s expert report).

During the 25 August 2005 hearing both experts accepted that there was no scientific literature supporting the view that Isometheptene enhances performance, a characteristic to be considered when treating a substances as similar to a substance on the list.

Heptaminol, which both experts seem to agree has a similar chemical structure as Isometheptene, has been on the 2003 WADA Prohibited List but has been removed from the 2004 list. As of 1 January 2006 Heptaminol will again be expressly listed as a Prohibited Substance as will be Isometheptene for the first time.

33. These considerations lead the majority to the following conclusion:

If an athlete’s sample is positive for Heptaminol and if Heptaminol is treated as a prohibited substance (either because it is expressly listed or related), the athlete may try to explain that finding by stating the he ingested Isometheptene which transformed into Heptaminol during laboratory analysis. This is what caused Dr Saugy to suggest that Isometheptene be included in the List “for technical reasons”, i.e. in order to avoid the uncertainties in connection with a positive finding for Heptaminol. If this is so, Isometheptene can only be treated as a prohibited substance if it is expressly listed.

The reverse scenario seems to have caused WADA to remove Pseudoephedrine (which appears to have a very low performance-enhancing effect, if any) from the list because it is no longer difficult to differentiate Ephedrine (which continues to be a prohibited substance) from Pseudoephedrine during laboratory analysis.

C. Criteria to be Considered when Deciding to Treat a Substance as Similar to a Listed Substance

34. Having found that similarity between Isometheptene and one of the listed substances has not been proven to the comfortable satisfaction of the majority of the arbitrators, the Panel must allow the Appeal.
35. However, for the sake of completeness the Panel wishes to add that even if “similarity”

existed, the IOC and WADA would still have to “consider” the criteria listed in 4.3 of the WADA Code before deciding to treat a substance as similar and thus prohibited. The three criteria are:

- potential performance enhancement,
- health risk, and
- violation of the spirit of sport.

36. Only if two of these three are met, a substance can be treated as similar and thus prohibited.

37. The Panel reaches this conclusion on the basis of the following consideration:

38. The WADA Code provides that the above criteria need to be considered before putting a substance on the list. It would be absurd to put less stringent requirements on the determination of a “similar substance” than are necessary for the decision to put a substance on the list. This may be a theoretical consideration if the term “similar” is narrowly construed: in these instances a substance which passes the test of similarity will almost definitely meet at least two of the above criteria.

Summary

39. In summary, the Panel is unanimous in finding

- that a decision by WADA to treat a substance as “similar” is subject to challenge,
- that the S1-Stimulants category of the 2004 Prohibited List is not an “open list” and that similarity must exist with a particular substance before a non-listed substance can be treated as similar, and
- that before treating a substance as similar the three criteria mentioned in 4.3 of the WADA Code must be considered.

40. Further, the majority of the Panel finds that the IOC failed to discharge the burden of proving that Isometheptene is a prohibited substance under the applicable rules.

The Appeal is allowed and the Panel decides as follows:

1. The decision of the IOC of 29 August 2004 is set aside.
2. The award to Maria Luisa Calle Williams of the bronze medal for the women’s Point race at the 2004 Olympic Games is confirmed.

(...)