CAS 2002/A/374 Muehlegg v/IOC

ARBITRAL AWARD

delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President: Prof. Richard H. **McLaren,** Barrister-at-law, London, Canada
Arbitrators: Dirk-Reiner **Martens**, Attorney-at-law, Munich, Germany
Jean-Pierre **Morand**, Attorney-at-law, Geneva, Switzerland
Ad-hoc Clerk: James **Bunting**, Articling Student -at-law, Toronto, Canada

in the arbitration between

Mr. Johann **MUEHLEGG,** Spain
- Appellant -
Represented by Marcos de Robles and Elisabeth de Nadal, Attorneys-at-law, Barcelona, Spain

and

INTERNATIONAL OLYMPIC COMMITTEE (IOC), Lausanne, Switzerland
- Respondent -
Represented by Jan Paulsson and Zachary Douglas, Attorneys-at-law, Paris, France

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I. PARTIES CONCERNED

1.1 The Appellant, Johann Muehlegg (“Muehlegg”) was selected by the Spanish Olympic Committee to compete for Spain at the Winter Olympic Games in Salt Lake City (“Games”) as a cross-country skier.

1.2 The Respondent, the International Olympic Committee ("IOC"), is the Supreme Authority of the Olympic Movement and was the organiser of the Winter Olympic Games held in Salt Lake City, USA and has its seat in Lausanne, Switzerland.

II. FACTS

2.1 Muehlegg competed in the Men's 30 km Free Mass Start (February 9, 2002), the Men's 10 km Free Pursuit (February 14, 2002) and the Men's 50 km Classical (February 23, 2002). Muehlegg placed first in all three events acquiring Spain's only medals of the Games.

2.2 On 21 February 2002, the Appellant was requested to, and did provide, an out-of-competition urine and blood sample. The samples were tested by the on-site laboratory (hereinafter referred to as "SLC Lab”).

2.3 The analysis of the blood sample by the SLC Lab produced an “on score” coefficient of 2.9. In accordance with the parameters applied at the Sydney Summer Olympic Games, the threshold for proceeding to a urine EPO test is a coefficient of 2.55.

2.4 On the morning of 23 February 2002, Muehlegg competed in the men’s 50 km Classical cross-country skiing event and placed first. At approximately 19:00 hours the same day the acting Chair of the IOC Medical Commission decoded the analytical positive finding on the “A” urine sample, collected on 21 February 2002, and identified Muehlegg as the athlete concerned. The analytical finding was for Darbepoetin (a substance also referred to by its registered trade mark Aranesp or NESP and hereinafter referred to as "Aranesp").

2.5 An Inquiry Commission was appointed pursuant to the Olympic Movement Anti-Doping Code ("OMAC") Bye-Laws[1]. The Inquiry Commission informed the Spanish delegation in writing of the positive findings and indicated that a hearing would take place that evening, the 23 February 2002. Five members of the Spanish delegation, including Muehlegg, attended the hearing. Following the hearing, the Inquiry Commission prepared the Report for the IOC Medical Commission and concluded that Muehlegg had committed the doping offence of using a substance prohibited by Chapter II, Articles 2.1 and 2.2 of the OMAC. The Report was delivered to the acting Chair of the IOC Medical Commission.

2.6 The President of the IOC designated five members of the IOC Executive Board to act as a Disciplinary Commission. The Disciplinary Commission reached the same conclusion as the Inquiry Commission. It recommended and forwarded to the Chairman of the IOC Executive Board, the following sanctions:

- disqualification from the men's 50 km classical cross-country skiing event;
- withdrawal of the medal and diploma obtained in the event; and
- exclusion from the XIX Olympic Winter Games at Salt Lake.

2.7 On 24 February 2002, the IOC Executive Board accepted the facts as stated and reported by the Inquiry Commission and adopted the sanctions proposed by the Disciplinary Commission.

2.8 The Appellant filed an appeal with the Court of Arbitration for Sport (hereinafter referred to as "the CAS") by letter of 16 March 2002. A series of procedural issues arose thereafter. The first was a procedural challenge to the jurisdiction of the CAS, which was abandoned on 8 May, 2002. The Appellant raised further procedural issues insisting that the proceeding be conducted in the French language; and requesting extensive documentary disclosure. The continued requests for disclosure resulted in a written ruling of the Panel on 5 July 2002 requiring the parties to proceed with the case and file their written submissions. This accounts for the lengthy delay between the filing of the appeal and the receipt of the Appeal brief by

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[1] Bye-Laws to the "Olympic Movement Anti-Doping Code" as adopted by the IOC Executive Board and distributed by letter of the President of the IOC dated 13 December2001. Exhibit IOC-22

CAS on the 6 August 2002. Thus, the appeal process was not completed until the filing of the Reply brief of the Appellant on 27 September, 2002. As a consequence, the Respondent has requested that the costs of the IOC for the period up to the filing of the Appeal brief be borne by the Appellant in accordance with the discretion conferred upon the Panel pursuant to R65.3 of The Code of Sports-Related Arbitration {"the Code"}.

2.9 It should also be noted that the Appellant was tested on 6 February, 2002 in Salt Lake City prior to the commencement of the Games. That anti-doping test was negative. Once the Games began, the athlete was subject to the regular anti-doping tests within the competition. In all of the cases, including the final 50 km Classical cross-country race from which he has been disqualified and which is the subject of this appeal, the results of the tests did not result in any further action by the Respondent.

III. PROCEEDINGS

3.1 By letter of 16 March 2002 the Appellant filed a Statement of Appeal with the CAS against the decision of the IOC of 24 February 2002.

3.2 By letter of 18 April 2002 the parties were informed that the arbitration court would comprise the following persons: Professor Richard H. Mclaren as President, Dirk-Reiner Martens and Jean-Pierre Morand as co-arbitrators (hereinafter referred to as "the Panel")

3.3 An issue arose as to the language in which this arbitration was to proceed. By letter of 22 April 2002 the President of the Panel ruled that all communications between the parties and CAS from that date forward were to be in English. The pleadings to that date remained in French.

3.4 By letters on 22 March and 25 April 2002 the Appellant raised a variety of document production issues as well as an issue regarding the jurisdiction of the CAS. The President of the Panel by letter 26 April 2002 advised of rulings on production and the jurisdiction issue. In response on 8 May 2002 the legal representative of Mr. Muehlegg advised the Panel that he no longer intended to challenge the jurisdiction of the CAS to hear the appeal. There remained on-going correspondence on the

production issues throughout the months of May and June. A letter finally closed the production issues on 5 July 2002 advising that all productions that can be made had been made and requiring the Appellant to file his appeal brief by 6 August 2002.

3.5 By letter dated 22 March 2002 an application was made, on behalf of the Norwegian Olympic Committee and identified Norwegian athletes[2] who participated in the Games, to intervene in the proceedings on the basis that the identified Norwegian athletes were "immediately affected by these proceedings". In response to the Panel's inquiries Mr. Muehlegg's legal representative indicated he objected to the proposed intervention. On 6 May 2002 the President of the Panel ruled that the application for intervention was dismissed. There was no agreement by the parties as to intervention and the Panel had no independent jurisdiction to otherwise permit it.

3.6 On 12 July 2002 Johann Muehlegg filed a statement of appeal against the decision of 3 June 2002, made by the Council of the International Ski Federation {FIS}. That decision was based upon the out-of-competition doping control test at the Games arising from the urine sample given on 21 February 2002 which is the subject matter of this proceeding. FIS imposed a two-year suspension effective from the 21 February 2002 based upon the FIS Doping Rules. The Appellant filed a request for joinder with the current proceedings. As a result the hearings in the FIS matter took place in conjunction with those of the IOC.

3.7 By letter dated 15 November 2002 the Appellant sought to introduce new documentary evidence from the IOC Lab in Lausanne. The IOC by letter of 22 November 2002 sought to have the request dismissed. The President of the Panel by letter from the Secretary General dated 29 November 2002 dismissed the Appellant's request for production of additional evidence on the grounds set out in the correspondence.

3.8 The hearing was held on December 9 and 10 at the Royal Savoy Hotel in Lausanne, Switzerland. The Panel, Mr. Matthieu Reeb (Secretary General of CAS) and Mr. James Bunting (CAS *ad hoc clerk*) were in attendance.

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[2] Thomas Alsgaard, Ole Einer Bjorndalen, Frode Estil, Fristen Skjeldal, Bente Skari, Anita Moen, Hilde Gjermundshaug Pedersen

3.9 Mr. Marcos de Robles, Ms. Elizabeth de Nadal, Ms. Tatiana Gari and Ms. Maria Estefuleas represented the Appellant. Mr. Johann Muehlegg was not in attendance but filed a letter of explanation.

3.10 Mr. Jan Paulsson and Mr. Zachary Douglas represented the Respondent. Also present were the (FIS) representatives for the CAS case of Muehleg v. FIS (CAS 2002/A/400) which was heard jointly with this case. The FIS were represented by Ms. Sarah Lewis (Secretary General of FIS) and Dr. Hans-Kaspar Stiffler, Attorney-at-Law, Zurich, Switzerland

3.11 The following witnesses were heard:

For the Appellant:

- Dr. Jordi Mallol Morin, full professor of Pharmacology, Head of the Unit of Pharmacology, Faculty of Medicine and Health Sciences, Universidad Rovira y Virgili;
- Dr. Jorge Martin Pérez, Doctor in Chemical Sciences (Bio-Chemistry); Madrid, Spain; and,
- Dr. Joan D. Fernandez Ballarty Department of Preventive Medicine and Public Health of the Rovira y Virgili University, Faculty of Medicine & Health Sciences (Reus, Spain).

For the Respondent:

- Professor Don Catlin, Head of the SLC Lab and Head of the UCLA IOC-Accredited laboratory; and
- Dr. Steve Elliott, Amgen Inc.

3.12 Prior to giving their testimony, the witnesses were cautioned about their duty to tell the truth in accordance with R44.2 of the Code. Each witness was first examined by the parties' representatives and then by the Panel.

3.13 An issue arose with respect to the Appellant's witness Dr. Fernandez who was to have an interpreter. However, the interpreter was not scheduled to arrive until the morning of December 10 and the Panel was ready to proceed with the witness's testimony on the afternoon of December 9. To deal with the situation three options were put before the Appellant by the President. They could proceed and provide their

own translation for Dr. Fernandez; the proceedings could be adjourned until the following morning and commence with Dr. Fernandez's testimony; or, the Respondent could present its witnesses and Dr. Fernandez could testify the following morning after the Respondents' witnesses. The Appellants selected the first option with the witness speaking in English and being assisted in Spanish and sometimes in French where required.

3.14 Both parties took the opportunity to submit opening and closing arguments.

3.15 None of the parties raised any objections to the way in which the arbitration proceedings were carried out, nor to the composition of the Panel. After each party had made its closing arguments the Panel closed the hearing and informed the parties that an award would be issued by 31 January 2003.

3.16 Finally, it is to be noted that, on the application of the IOC and with the approval of the Appellant, the Panel agreed to hear this appeal at the same time as Muehlegg's appeal from the decision of the FIS Council (respectively CAS 2002/A/400).

3.17 The IOC decision and the FIS decision arose out of the same test, and the medical and scientific evidence was the same in both appeals. This appeal addresses whether Muehlegg committed a doping offence that could result in the loss of his medal. The FIS case reviews the decision of the FIS to impose the two-year sanction upon Muehlegg and also determines the degree to which, if any, that sanction might be mitigated.

IV. PARTIES' SUBMISSIONS

IV.1 Facts pleaded by the Appellant

4.1.1 The Appellant is appealing the decision of the IOC Executive Board.

4.1.2 The Appellant alleges that Aranesp is a new substance that is not included in the list of Prohibited Substances in the OMAC.

4.1.3 The Appellant alleges there is no specific test to detect the use or presence of Aranesp. The test used was the EPO test, which is alleged to be neither suitable nor validated to detect Aranesp. It is further alleged that the test used to detect r-EPO itself is not fully validated.

4.1.4 The Appellant alleges that r-EPO and Aranesp are different substances. The test used by the SLC Lab to detect Aranesp gave a false positive because a positive Aranesp can be, as it clearly was in this case, from endogenous EPO.

4.1.5 The Appellant asserts that the IOC has not proved the doping infraction because the test used did not fulfil the requirements of the European Standard ISO 17025 as required by Annex 1 of the OMAC and related documents. Furthermore, the scientific and other procedures were not observed for the adoption and validation of a new method.

4.1.6 The Appellant alleges that the SLC Lab lacked accreditation to do the r-EPO test. The Appellant argues that the presumption that the testing and custodial procedures were properly performed as contained in Chapter III Article 2 of the OMAC is inoperative as a consequence. The Respondent must prove that the testing procedures employed were in accordance with the prevailing standards of the scientific community.

4.1.7 The Appellant argues that the Respondent fails to prove that the test results prove a doping infraction occurred because:

a) the r-EPO test is not valid and reliable to discover the presence of Aranesp;

b) even if the test were reliable for discovering r-EPO some of the steps required for carrying out the r-EPO test were not followed in the processing of Muehlegg's sample.

Finally the Appellant alleges that the blood test has no bearing on any results obtained from the urine test and does not add additional certainty.

4.1.8 The Appellant moves the court:

- To reverse the disqualification from the 50km. race;
- To reverse the exclusion from the SLC Winter Olympic Games; and
- To return the gold medal won in the 50 km Classical race.

IV.2. Facts pleaded by the Respondent

4.2.1 Aranesp was recently invented and developed as a pharmaceutical product. Therefore, the IOC Medical Commission did not have the opportunity to expressly include the substance on the list of Prohibited Substances in the OMAC before the commencement of the Games. The Respondent alleges that Aranesp is, by its pharmacological actions and chemical structures, an analogue and mimetic of the Prohibited Substance EPO.

4.2.2 The Respondent alleges that an analogue and mimetic may be identified by an existing test validated for an existing Prohibited Substance without the rigorous requirements of a scientific validation of a new test.

4.2.3 The Respondent moves the court to uphold the February 24, 2002 decision of the IOC Executive Board to:

- disqualify Muehlegg from the Men's 50 km Classical Cross-Country Skiing event;
- withdraw the medal and diploma; and
- exclude Muehlegg from the XIX Olympic Winter Games of Salt Lake City.

IV.3 Panel's Finding of Facts Regarding EPO

4.3.1 Erythropoietin ("EPO") is produced naturally in the human body. More than twelve years ago recombinant human Erythropoietin (rHuEPO hereinafter "r-EPO") appeared for sale in the commercial market place in the United States and elsewhere. In the year 2001, an improved version of this artificial form of EPO, darbepoetin alfa became available commercially and was marketed under the brand name Aranesp. Neither Aranesp nor r-EPO is naturally produced in the human body.

4.3.2 Erythropoietic products, such as r-EPO and Aranesp, must be administered exogenously and can be used by athletes as a means of "blood doping". When injected into the human body these substances stimulate the production of red blood cells that carry oxygen to the muscles and thereby increase aerobic capacity, which can enhance performance (particularly for endurance athletes). These products can also harm the health of a normal healthy person when used for non-medical purposes by increasing the viscosity of the blood thereby increasing the possibility of coronary and cerebral vascular occlusions and related medical conditions.

4.3.3 The existence of EPO, r-EPO and Aranesp in the human body can be determined by a urine test. The process for this test and its methodology are clearly set out in the recent CAS Award of *Lazutina* v. *IOC*[3] (hereafter "*Lazutina*").

4.3.4 As set out in *Lazutina* the methodology of the direct urine test involves four steps: sample preparation; isoelectric focusing; immuno-blotting; and visualisation. It is the last stage that requires some elaboration in this decision. There is no need to repeat the description of the methodology of the direct urine test in this award, as it was precisely the same in this case as described in *Lazutina*.

4.3.5 EPO in all its different forms produces an image or picture at the visualisation stage, which looks like rungs of a ladder without the side rails. Each rung or band as it is known in science is the visual isoform of electrically charged molecules. Through the isoelectric focussing process, the molecules migrate to their location on the electropherogram depending upon the substance that they constitute, i.e. EPO, r-EPO or Aranesp. The bands or isoforms can be in the acidic, neutral or basic areas of the electropherogram. To use the analogy of the ladder, the rungs may be high up on the ladder, in the middle, or towards the bottom of the ladder. These images of the ladder have been created by the emission of light, which has then been photographed by a special digital camera. It is this visual image which is used to evaluate the results of the lab analysis.

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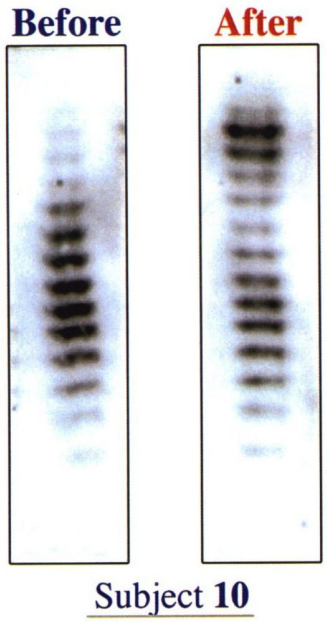
[3] CAS 2002/A/370 at paragraphs 10.9 to 10.23.

4.3.6 Essentially, at the end of the process an image is created that contains "finger prints" of the proteins in the analysed urine. This allows the laboratory to compare the protein "fingerprint" of an athlete's urine to fingerprints of control samples. In so doing the laboratory is able to assess what type of proteins are in an athlete's urine. Below is an example of the type of images that are produced.[4]



4.3.7 The comparison and study of the fingerprints of the different proteins from the ladder type image is the interpretation of the laboratory analytical results. Each fingerprint is within its own lane. In this instance, the higher up the ladder the more the ladder rungs (or isoforms as they are known) are within the acidic area. The varying acidity of the isoforms provides an indication of the type of protein present in the urine. When viewing an image various characteristics are considered to determine what protein is depicted by the isoforms:

- Position of the isoforms on the gel;
- Width of the isoforms;
- Density of the isoforms;
- Shape of the isoforms (meaning the shape surrounding the perimeter of a group of bands); and

[4] Images filed in connection with the expert report of Dr. Catlin related to study referred to at footnote 7.

- Number of isoforms.

4.3.8 Applying the above characteristics to the Muehlegg image (set out elsewhere in this Award) the panel finds:

- The position of the bands in Muehlegg's image are completely consistent with the position of the Aranesp controls.
- Width in combination with shape produces for human EPO a "cigar" like form with the wider bands in the centre and bands of decreasing width on each end. Aranesp has four bands of regular width which gives a "square" overall image. In the case of Muehlegg, the fingerprint's shape is completely consistent with the Aranesp typical shape. The fact that traces of human EPO have completely disappeared is consistent with the fact that Aranesp inhibits the production of human EPO and suggests the use of a rather high dosage.
- Density: It is the variation in intensity which is relevant. In human EPO, the intensity of the bands decreases from the centre. The pattern for Aranesp is that the two upper bands are more intense. Dr. Eliott described this as very typical. The Appellant's sample clearly fits that pattern.
- Number of bands: Human EPO has a number of bands ranging from the more basic to the more acid. Aranesp fingerprint shows 4 (3 clear and 1 usually fainter) bands. Again in this respect, the Appellant's sample corresponds to the Aranesp pattern.

Therefore, the image for Muehlegg without doubt establishes the use of Aranesp.

4.3.9 The bands of EPO and r-EPO may partly overlap with each other making it difficult to determine if the urine sample contains endogenous EPO or exogenous r-EPO. The image will only be considered to be r-EPO if more than 80% of the bands are in the basic range. This part of the EPO test methodology was the subject of discussion and conclusion in the CAS decision *UCI v/Hamburger*[5].

[5] CAS 2001/A/343 at p. 18.

4.3.10 The bands of Aranesp and r-EPO do not overlap as they are at opposite ends of the rungs of the ladder. Dr. Steve Elliot[6] in his expert testimony unequivocally established that the positioning of Aranesp on the acidic (top) area of the ladder was a deliberate decision of Amgen Inc., the manufacturer of the product. The product is manufactured in such a fashion that it will have such a particular fingerprint, which is unique on the electropherogram image.

4.3.11 The study of Aranesp is on-going. At the time of these proceedings in December of 2002 the unique fingerprint of Aranesp does not appear to overlap with natural EPO, unlike r-EPO. Therefore, there is no need for quantification and the calculation of a mathematical formula as there may be with r-EPO. Aranesp in larger than medical dosages for lengthy periods of time seems to cause the body to shut down the production of natural EPO. Thus, the fingerprint in Muehlegg's case does not appear to have any natural EPO bands. Other studies since the end of the SLC Games show that the natural bands can remain when the dosage is just over medical limits and the urine test is done within a couple of days of administration.[7] However, such an experiment does not equate to a larger dosage and regular use.

4.3.12 The Panel must conclude on all of the evidence before it that Aranesp has its own unique fingerprint which shows 4 bands clearly in the upper end of the ladder or in the acidic range.[8] It does so because the manufacturer uniquely made the product to have such a fingerprint. When Aranesp is injected into the human body it shows up on the electropherogram with the same distinctive fingerprint as the pure clinical form of Aranesp.

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[6] Expert witness of the IOC and the inventor of the active ingredient in darbepoetin alfa product

[7] Catlin et al "Comparison of the Isoelectric Focusing Patterns of Darbepoetin Alfa, Recombinant Human Erythropoietin, and Endogenous Erythropoietin from Human Urine" *Clinical Chemistry* 48, No 11, 2002

[8] It should be noted that the placing of the anode (positive pole) at the upper or top margin on the gel with the cathode at the bottom of the gel is a convention of the SLC lab. Other laboratories may use the reverse orientation thus creating a ladder, which is the exact opposite top and bottom. One must be careful looking at the image to ascertain which is the positive pole.

V. JURISDICTION AND APPLICABLE LAW

5.1 The CAS jurisdiction is founded upon Article 74 of the Olympic Charter, which states:

"*Any dispute arising on the occasion of, or in connection with, the Olympic Games shall be submitted exclusively to the Court of Arbitration for Sport, in accordance with the Code of Sports-Related Arbitration*."

5.2 These proceedings are governed by R58 of the Code and are to be decided according to the Olympic Charter and the OMAC.

VI. THE ISSUES

6.1 In these proceedings there is no issue between the parties that the sample was properly taken. There was also no dispute that there was a complete and proper chain of custody of the sample from the time of taking through to the analysis of it. The issues for determination are:

a) Does the absence of SLC Lab accreditation to carry out the r-EPO test nullify the results?

b) Is Aranesp an analogue and mimetic of r-EPO?

c) Do the indirect blood test and the direct urine test meet the prevailing standards of the scientific community with respect to the detection of Aranesp? This issue is further subdivided as follows:

   i) What is the proper role of the indirect blood test?

   ii) Is the direct urine test valid for the detection of r-EPO?

   iii) If so, is the direct urine test valid for the detection of Aranesp?

d) Was the urine test carried out by the SLC Lab properly executed?

e) Are the OMAC requirements for a doping infraction fulfilled?

VII. REASONS FOR THE DECISION

VII.1 Does the absence of SLC Lab accreditation to carry out the r-EPO test nullify the results?

7.1.1 Chapter V of the OMAC and Appendices B & D as amended govern the process for a laboratory to obtain IOC accreditation. These provisions have been amended by the "Modifications to the Olympic Movement Anti-Doping Code regarding the replacement of the norm ISO Guide 25 by the norm ISO Guide 17025"[9]

7.1.2 The procedures for EPO testing at the Games were set out in the "Blood Testing Statement" prepared by the Salt Lake City Organising Committee and the accompanying flow chart"[10]

7.1.3 The national accrediting body for the United States issued its accreditation certificate for the UCLA lab on 6 June 2002. The certificate is valid until the end of 2003.[11] That accreditation includes the testing procedure used in the SLC Lab known as Test Method 9001 "*Urinary Glycoprotein by Isoelectrophoresis*". This is the test procedure being challenged in this arbitration. The equivalent documents of certification for the SLC Lab issued 18 November, 2001 and valid until 31 May, 2002 did not include Test Method 9001. On this basis it was argued by the Appellant that the testing procedure was without accreditation and the presumption that testing and custodial procedures were properly performed, as contained in Chapter III, Article 2 of the OMAC, fails. Accordingly, the Appellant submits that the IOC bears the burden of proving that the testing procedures employed were in accordance with the prevailing standards of the scientific community, and it failed to do so.

7.1.4 The testing for r-EPO is fairly recent. It began prior to the Summer Olympic Games in Sydney in 2000. The oral testimony of Dr. Catlin the Director of the SLC Lab explained that the SLC Lab did not have ISO accreditation for Test Method 9001 at the time of the Games. It was only after the Games that the UCLA Lab obtained this

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[9] Distributed by the letter of the then Chairman of the IOC Medical Commission 11 October 2001. Exhibit IOC-19

[10] Exhibit IOC-21

[11] Exhibit IOC-35

accreditation and it was the first lab in the world to do so. Dr. Catlin was quite candid and expressly stated: "let me be very clear. We did not have the last item at the time of the Games."[12]

7.1.5 The Panel also notes that despite the lack of ISO accreditation Dr. Catlin adamantly believed that the r-EPO test method had been validated. He stated:

"…I think it was validated at the meeting of August of 2000 before Sydney. At the meeting there were 40 or so experts… the decision was made to approve the test… the IOC approved it and it was implemented in Sydney… the two years since then the validation has gotten stronger."[13]

7.1.6 The Panel notes that the OMAC contemplates the possibility of laboratories employing testing methods not expressly incorporated in the OMAC. Appendix D, Article 1.1(d) provides:

"The laboratory must have written protocols for their screening procedures…

(3)…

…For other peptidic hormones: specific techniques and methodologies will be needed following the evolution of scientific knowledge on [sic!] this field. Refer to the IOC Medical Commission for updated information." [*Emphasis added*]

7.1.7 The SLC Lab was accredited for the Games. The fact that the accreditation for the isoelectric focusing test {Method 9001} came after the Games does not mean the SLC Lab was not capable of conducting the r-EPO test. Appendix D, Article 1.1(d) specifically provides for the evolution of scientific knowledge and testing procedures. What must be established to the comfortable satisfaction of the Panel is that the testing procedure as carried out was in accordance with the prevailing standards and practices of the scientific community.

7.1.8 The SLC Lab and UCLA Lab, under the guidance of Prof. Catlin have established written protocols that they follow for the isoelectric focusing tests. The SLC Lab protocol has been adopted and it has modified the protocol established by the "Inter-Laboratory Report".[14] The SLC Lab did so in accordance with and using the document agreed to by five participating IOC accredited laboratories. The

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[12] CAS Recorded Transcript December 10 at 10:32:00
[13] CAS Recorded Transcript December 10 at 10:25:00

Appellant's expert failed to convince the Panel that the process used by the SLC Lab was not in accordance with scientific practice. They did establish that the process was not in accordance with the so-called "French" urine test. However, the SLC Lab was using a more advanced and sophisticated procedure than that to which the experts for the Appellant were referring and basing their testimony on. The fact that ISO accreditation had not yet been obtained is not fatal. The Panel finds that the testing was in accordance with the scientific community's practices and procedures, indeed the SLC Lab was leading in the establishment of those very practices and procedures. Therefore, the Panel rejects the contention that the SLC lab was not capable of conducting the r-EPO test. The absence of accreditation does not affect the results.

VII.2 Is Aranesp an analogue and mimetic of r-EPO?

7.2.1 This issue was raised in the Appellant's brief but not focused on during the hearing. This is a threshold issue as to whether the substance identified by the SLC Lab was a Prohibited Substance and needs to be determined before considering the issues surrounding its identification, regardless of how it was identified. In an abundance of caution the Panel, being unsure if the Appellant has abandoned the argument, elected to provide its reasons on this issue.

7.2.2 Appendix A of the OMAC sets out various prohibited classes of substances. Class E "Peptide Hormones, Mimetics and Analogues" includes, as an example in clause 6, EPO. The provision states that Prohibited Classes of Substances, like EPO, that are listed as examples in Class E include "their analogues and mimetics".

7.2.3 An "analogue" means a similar function within the body irrespective of structure.[15] A "mimetic" means a substance that imitates behaviour.[16] These requirements are similar to that of the "related substance" test in other parts of the OMAC. In the

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[14] Exhibit Appellant-9

[15] "Analogue" means an analogous or parallel thing. H. W. Fowler and F. G. Fowler, The Concise Oxford Dictionary of Current English, Oxford, 1976.

[16] "Mimetic" means imitation. H. W. Fowler and F. G. Fowler, The Concise Oxford Dictionary of Current English, Oxford, 1976.

context of this case the Panel must be comfortably satisfied that Aranesp is similar in its effect on the human body to r-EPO, which is undeniably a Prohibited Substance.

7.2.4 Aranesp is a substance, which has the effect of artificially boosting the oxygen in the blood by the introduction of a greater number of red blood cells, and for an elite performance athlete these additional red blood cells translate into enhanced stamina. The natural hormone EPO and r-EPO have precisely the same physiological effects. On the evaluation of all of the evidence and the expert reports related thereto we conclude that Aranesp is an analogue and mimetic of r-EPO. Therefore, Aranesp is an analogue and mimetic of a Prohibited Substance.

VII.3 Do the indirect blood test and the direct urine test meet the prevailing standards of the scientific community with respect to the detection of Aranesp?

VII.3.1 What is the proper role of the indirect blood test?

7.3.1.1 During this proceeding the Appellant did not directly take issue with blood testing being used to screen those samples that should be subjected to a urine test. However, the Appellant does take issue with the blood test being used to support a positive finding of doping arising from a urine test. The Appellant's assertions with respect to the blood test relate to its reliability.

7.3.1.2 The Appellant's expert Professor Jordi Mallol opines that the "Parisotto"[17] method for detecting the use of r-EPO has not been sufficiently validated in a definitive manner. He further states that the method has not been validated for Aranesp. It is the IOC position that it does not have to be validated when applying the indirect blood test to an analogue of EPO.

7.3.1.3 Professor Mallol suggests that the cut-off level for further inquiry by urine analysis is suspect. First, because the subjects used in the Parisotto et al study to establish the on-score threshold were few in number and not professional athletes but amateurs. Second, even the authors of the study suggest that the cut-off level they have found is

[17] Exhibit Appellant-8 Parisotto et al (Haematologiac, 2001, 86: 128-137).

a provisional value subject to changes that may be observed when increasing the size of the studied population.

7.3.1.4 The Respondent's expert Prof. Donald Catlin asserts that:

> "I disagree with the statements of Professor Mallol and Ballarty that the 'on-score' indirect blood test is somehow unsuitable to screen for the use of darbepoetin. It is certainly the case that darbepoetin and rHuEPO have different pharmacokinetics…however, these effects are minor and irrelevant… The differences do not alter the integrity and value of the 'on-score'…Any errors that Professor Mallol alleges to be present in the 'on-score' (see page 9 of his report) can only work to the benefit of the athlete, not to the athlete's detriment."

7.3.1.5 In addition, Dr. Catlin is quick to note that the 'on-score' in no way determines whether a doping infraction has occurred, rather it only serves as a screening process in determining which samples should be subjected to a urine test. It is the urine test that definitively proves a Prohibited Substance is in an athlete's body.

7.3.1.6 The indirect blood test is used to determine if there is elevated erythropoietic activity in the blood. It is merely used as a screen to send a sample on for urine analysis. It is not used to overrule a negative urine analysis. Therefore, it is valid for its purpose, which is to reduce the number of direct urine analysis tests conducted by the SLC Lab.

7.3.1.7 The more difficult question, and the major objection of the Appellant, is whether the indirect blood test can be used as evidence in support of a urine analysis that finds Aranesp. In answering questions from the Panel, Dr. Catlin explained that the indirect blood test suggests that there has been some form of blood manipulation. A high "on-score" reflects the use of some substance that elevates the erythropoietic activity.

7.3.1.8 We agree with the Appellant's submissions that no greater certainty is achieved by the blood test on score in connection with a urine analysis. The Panel is of the view that the urine test is an independent test that does not require the validation of an abnormally high 'on-score' for a finding that a doping infraction has been

committed.[18] The test is merely used to determine if a direct urine test will be undertaken. That test then must stand on its own and does not need to take support for a positive finding from the high on score in the blood test.

VII.3.2 Is the direct urine test valid for the detection of r-EPO?

7.3.2.1 Professor Mallol asserts that the inter-laboratory reproducibility for detecting r-EPO is in reality a trial and is not really a validation of the capacity of the method for determining the criteria for deciding that a case is positive for doping with r-EPO.

7.3.2.2 The Panel has already determined in section 7.1 that the absence of an accreditation for conducting the "*Glycoprotein electric focusing"* test {Method 9001} does not invalidate the lab results.

7.3.2.3 The Appellant's expert raised many issues with respect to the on-going development of the direct urine testing procedure. It may well be that the Inter-Laboratory Report of the IOC raised various areas of study that should be continued with respect to r-EPO testing. However, the fact that the laboratories wish to improve their testing methods, and further improve the r-EPO test, does not result in the test being invalid. For example, it may be that through further studies the IOC Medical Committee will be able to lower the threshold test for when an r-EPO positive will be found. Such work in progress does not make the use of the test in current circumstances invalid.

7.3.2.4 A number of studies on the validity of the direct urine test in respect of r-EPO test have been published, as is indicated in the appendices to Professor Catlin's Expert Report. The test has been the subject of scrutiny at scientific meetings in Lausanne in August 2000 and in November 2001.[19] The test was used in the Sydney Olympic Games and has been accepted in at least two CAS proceedings in *UCI* v. *Hamburger* (CAS 2001/A/343) and *Meier* v. *Swiss Cycling* (CAS 2001/A/345. Furthermore, it was very recently accepted and the subject of comment in *Lazutina/Danilova* v. *IOC* (CAS 2002/A/370 & 371) The Panel is unable to accept an assertion that the direct urine test is not valid for the detection of r-EPO.

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[18] See Meier v. Swiss Cycling CAS 2001/A/345 at page 15 {English translation}.
[19] See minutes of the five-laboratory validation study minutes in IOC Exhibit-36.

VII.3.3 Is the direct urine test valid to detect Aranesp?

7.3.3.1 In this decision up to this point the indirect blood test has been upheld as a valid screen. It has further been held that the direct urine test for r-EPO test is valid to detect r-EPO and determine that a doping infraction has occurred. What remains to be determined is whether the direct urine test can reliably be used for the detection of Aranesp.

7.3.3.2 The major issue here is whether the test is valid for Aranesp given that a threshold, similar to the one established for r-EPO, has not been put in place to account for overlap of Aranesp with endogenously produced EPO. The threshold is used to statistically reduce the possibility of a false positive. The Appellant asserts that the test cannot distinguish between Aranesp and endogenous EPO and therefore proper epidemiologic and statistical studies must be undertaken. The expert witness for the Appellant, Dr. Mallol testified that the possibility of natural EPO being contained almost entirely in the acidic region (where the fingerprint of Aranesp is located) could not be excluded. Accordingly, scientific study needs to be undertaken to ensure that false positives will not occur and, if necessary, a threshold test similar to the one employed with respect to r-EPO should be established for Aranesp.

7.3.3.3 The IOC claims that such studies are unnecessary because the molecular make-up results in a clear and identifiable fingerprint and the Appellant is utterly unable to provide an explanation for why a human being would produce EPO that was almost entirely acidic. Further, Dr. Elliot testified that endogenous EPO will always have a different fingerprint than Aranesp because of the fashion in which it is manufactured. The reply of the Appellant's expert is that there are no scientific studies provided and thus, the possibility of overlap could not be excluded without them.

7.3.3.4 The Panel accepts that the possibility Aranesp may overlap with endogenous EPO cannot be absolutely excluded. However, based on all of the evidence presented the Panel is comfortably satisfied that it is unlikely that there will ever be any significant overlap. Dr. Catlin conducted two studies post the Salt Lake Olympic Games and these studies indicated that the results matched with the scientific understanding of the method. Further, Dr. Steve Elliott, the inventor of Aranesp, predicted where it

would appear on the visualisation of the result of the urine test based upon his knowledge of the urine test and the attributes of Aranesp. Dr. Elliot communicated the distinctive band pattern that he expected Aranesp to produce on the urine test to Dr. Catlin of the IOC-accredited laboratory in Salt Lake City prior to the Olympic Games. The results obtained from the Athlete's urine test matched the prediction of Dr. Steve Elliott. Third, Dr. Catlin has studied the use of the EPO test for detection of Aranesp subsequent to the Olympic Games.[20] While the sample sizes of the studies were small, Dr. Catlin was able to conclude that the EPO test is capable of detecting Aranesp at 0.4ug/Kg. Furthermore, while there was variability in the density of bands in the Aranesp region, there was no variability in the presence of the bands – all Aranesp-positive subjects produced bands in the upper part of the ladder exactly where one would expect to find Aranesp.

7.3.3.5 Furthermore, as the Panel noted earlier the fingerprint of Aranesp is distinctive and was engineered to be so. See Part IV.3 Panels Finding of Facts Regarding EPO. The Appellant's results from the SLC Lab reflect that unique fingerprint. Therefore, there can be no doubt that the Appellant used Aranesp. It is a Prohibited Substance and can not be produced naturally unlike r-EPO that has an overlapping fingerprint with EPO and can cause doubts as to whether the isoform is natural or artificial in nature. Therefore, it does not matter that there may be overlap with the natural bands of EPO as there can be no doubt that there was use of Aranesp and its source can not possibly be that of the human body.

7.3.3.6 For all of the foregoing reasons the Panel concludes that the direct urine test employed to detect r-EPO can also be applied to detect Aranesp. The notable difference between the two applications is that Aranesp does not require a threshold safety margin to protect against false positives because of overlap, as does r-EPO.

7.3.3.7 The fact that Aranesp does not require a safety margin is particularly true given that where Aranesp is used in high dosages the natural production of EPO is curbed. This results in the electropherogram depicting bands that are only in the region where

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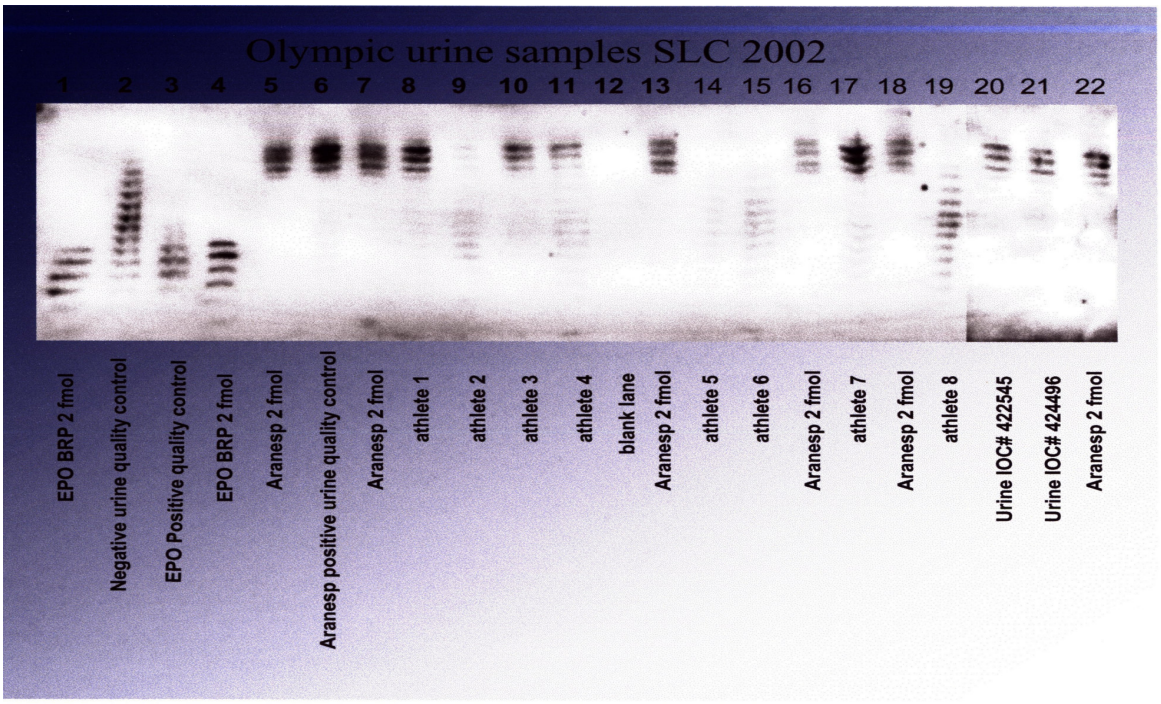
[20] Don H. Catlin, M.D., Preliminary Report to the IOC: Darbepoetin Study I, June 28, 2002; Don H. Catlin, M.D., Report to the IOC on Darbepoetin: Darbepoetin Study II, September 23, 2002. Don H. Catlin *et al*, Comparison of the Isoelectric Focusing Patterns of Darbetpoetin Alfa, Recombinant Human Erythropoietin, and Endogenous Erthropoietin from Human Urine, Clinical Chemistry 48, No 11, 2002 at 2057.

Aranesp is located. This was precisely the case with Muehlegg's sample. Below is the electropherogram that relates to the Appellant test: It very clearly reveals that the isoforms are in the upper portion of the ladder. Thus, the predicted unique fingerprint is present.



7.3.3.8 Muehlegg's sample is contained in lane 20 of the image above. Looking at this image in comparison to the Aranesp control standard in the final lane and the athlete urine control standard two lanes to the left in lane 18 it is very easy to see the clear and distinctive Aranesp qualities appearing in the Muehlegg sample.

VII.4 Was the Urine Test carried out by the SLC Lab properly executed?

7.4.1 The Appellant argued that the specific procedures employed in the analysis of Muehlegg's urine did not follow the appropriate process. First, the Appellant claimed the SLC Lab did not follow the standard protocol set out in the Inter-Laboratory Report, which provided the proper protocol for isoelectric focusing method.

7.4.2 The Panel acknowledges that the SLC lab did not follow the protocol established in the Inter-Laboratory Report. Indeed, during cross-examination Dr. Catlin candidly admitted that he had not read the standard protocol. However, the Panel is not of the view that this necessarily means that the SLC Lab used an improper or unreliable method. In fact, Prof. Catlin testified that the protocol employed by the SLC lab was superior to the one set out in the Inter-Laboratory Report. Prof. Catlin indicated that his laboratory learned the testing method through several means and then established its own standard operating procedure.

7.4.3 The Panel finds that the protocol employed by the SLC Lab was accurate and reliable. The SLC Lab was, as noted previously, capable of conducting the validated test and it did so in accordance with its own protocol, which was properly followed during the analysis of Muehlegg's urine sample.

7.4.4 The Appellant's second allegation is that the various control standards used by the SLC Lab were not sufficient to ensure the reliability of the test result.[21] The Panel rejects these allegations as it does not find, nor has the Appellant demonstrated, that this impacts the reliability of the analysis of Muehlegg's urine.

7.4.5 Third, the Appellant argued that the control samples were not adjusted to a uniform value so that they would be consistent with the density of Muehlegg's urine. Muehlegg's urine had a specific gravity of 1.002 meaning that it was very diluted. Dr. Catlin explained that adjustments are performed in order to dilute samples with high specific gravities, otherwise they will be too dense and the image produced will be a blur that cannot be properly assessed. It would, however, make no sense to dilute the control standards. The Panel also must reject this contention.

7.4.6 Finally, the Appellant raised an issue at the hearing with respect to the photocopy of the electropherogram shown above that depicted the analysis of Muehlegg's sample. The Appellant suggested that it appeared that two separate membranes had been pasted together to generate the electrophergram provided to them. During the hearing Professor Catlin displayed the original electropherogram computer image on

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[21] The Appellant took issue with the fact that the quality control standard for Aranesp was purchased from a drug store; the quality control standard for Aranesp contaminated urine was obtained from a female cancer patient; and the standard for non-contaminated urine was obtained from a pool of 4 individuals (which is

a screen in the hearing room. This image of the electropherogram did not have the distortion that existed in the photocopies provided to the Appellant and the Panel and reproduced herein. From the computer image it was clear that only one membrane had been used. However, it was also clear to everyone in the hearing room that the bands corresponding to Muehlegg's urine were fainter on the original image. On this issue, the Panel concludes that someone at the SLC Lab or in the IOC manipulated the photocopy of the electropherogram in order to make the bands relating to the Muehlegg's sample appear darker. The Panel doubts that this was done to intentionally mislead. It was most probable that the manipulation was done with the intent of assisting the Panel in viewing the location of the bands in Muehlegg's urine. In any event, it is apparent that this manipulation caused the photocopied electropherogram to look as if two separate membranes were used. Having viewed the original computer image the Panel concludes that a single membrane was used to produce the electropherogram and that the location and characteristics of Muehlegg's bands were still clearly identifiable. Nonetheless, the Panel strongly suggests that any future manipulation, regardless of the good intentions that may bring it about, should be avoided. Presentation of the computer image is the clearest and most appropriate way in which to view and examine the results.

7.4.7 For all of the foregoing reasons the Panel rejects all of the Appellant's claims that an improper procedure was used in the specific analysis of Muehlegg's urine. The Panel is more than comfortably satisfied that the procedures employed in the analysis of Muehlegg's sample by the SLC Lab were scientifically acceptable and within the protocol under which the lab operated.

VII.5 Are the OMAC Requirements for a Doping Infraction Satisfied?

7.5.1 The Panel finds that:

(a) Aranesp is an analogue and mimetic of r-EPO and therefore a Prohibited Substance ;

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different than the standard used in the Inter-Laboratory Report and then the SIGMA standard used in the "Nature 2000" publication.).

(b) the direct urine test is valid for the detection of r-EPO;

(c) the direct urine test is valid for the detection of Aranesp;

(d) the SLC Lab was accredited generally and capable of performing the r-EPO test; and

(e) the urine test performed on Muehlegg's sample was properly conducted.

7.5.2 Therefore, on 23 February 2002 the laboratory analysis performed on Muehlegg's urine sample revealed the presence of the Prohibited Substance Aranesp. Therefore, pursuant to Chapter II, Art. 2(2) of the OMAC Muehlegg committed a doping infraction. The Panel concludes that the IOC Executive Board properly found Muehlegg to have committed a doping infraction and hereby upholds that decision.

VIII. The Sporting Sanction for an Out of Competition Doping Infraction?

8.1 Chapter II, Article 3(3) of the OMAC does not apply directly because Muehlegg's test was performed out-of-competition. Therefore the applicable provision is Chapter II, Article 3(5) of the OMAC, which provides:

"5. *The penalty for an offence committed by a competitor and detected on the occasion of an out-of-competition test shall be the same, mutatis mutandis, and shall take effect from the date the positive result was recorded or the date on which the final judgment further to an appeal is pronounced, whichever is more recent."* (emphasis added)

8.2 The underlined portion of Chapt. II Article 3(5) deals with the consequences of a doping infraction. The balance of the provision after the words "*mutatis mutandis*" addresses the timing of such consequences. Dealing first with the consequences the Panel finds that the words "… the same" refers back to Article 3(3) which provides:

"Any case of doping during a competition automatically leads to an invalidation of the result obtained (with all its consequences, including forfeit of any medals and prizes)…"

8.3 Therefore, Article 3(5) operates at least prospectively to invalidate all the results obtained and the forfeiture of any medals or prizes with the necessary adjustments being made (*mutatis mutandis)* by referring the reader back to Chapt. II Article 3.3. The effect of the underlined portion of the Article is to treat the matter as if it were an in-competition test and doping infraction. An in-competition infraction results in the application of the strict liability concept and because of the possibility of having held an unfair competition with the doped athlete competing the medal will be stripped as was the case in *Baxter* v. *IOC* CAS 2002/A/376. This will be the result despite the fact the sample was given out-of-competition. The closing words of Article 3.5 then indicate that where an athlete commits an out-of-competition doping offence, at least all the results obtained after the date the sample was taken shall be invalidated.[22]

8.4 The Panel has some difficulty with the proper interpretation to be ascribed to the second portion of the Article. It could be construed as limiting the invalidation of results to those results that were achieved after the later of the date the positive result was recorded or the date final judgment on the issue is rendered. This interpretation would result in the absurdity that an athlete could compete up until the final adjudication of a doping infraction and not have any results obtained in the interim period invalidated. This is contrary to the purpose of the OMAC and such an interpretation cannot be accepted. The Panel finds that this section operates not to determine what results will be invalidated, but the date on which the invalidation of results, that occur pursuant to the first part of the provision, is effectively imposed. Therefore, the latter part of the Article reinforces the conclusion derived in determining that a medal should be stripped by reference to the same effect as an in-competition test.[Art. 50 of the Olympic Charter supports this interpretation]

8.5 Based on all of the foregoing the Panel finds that the IOC Executive Board properly exercised its authority under the Olympic Charter and the OMAC to invalidate Muehlegg's results in the 50km classical cross-country event, withdraw the gold medal obtained, and exclude him from the Games.

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[22] It is the Panels opinion that the necessary adjustments that need to be made for an out-of-competition positive are the invalidation of the subsequent results obtained. This provision provides the Panel with the discretion to make such adjustments.

IX. COSTS

9.1 The decision as to costs is based on R 65 of the CAS Code and Chapter III Article 5 of the OMAC. Pursuant to the OMAC the Panel can award costs if it finds that the proceedings have been judged to be vexatious, frivolous, dilatory or otherwise abusive. In the instant case the Panel notes the lack of accreditation of the SLC Lab and that this was the first positive test result for Aranesp. Accordingly, the Panel believes that the Appellant had a legitimate case to bring forward. Therefore, there is no jurisdiction to award costs under the OMAC.

9.2 Pursuant to R65.3 of the CAS Code, the costs of the parties and therefore particularly of the witnesses are to be advanced by the parties. It is then up to the Panel to decide which party is to bear the costs ultimately. In so deciding the Panel must take into account the outcome of the proceedings, as well as the conduct and financial resources of the parties.

9.3. The Appeal is dismissed in full; the dismissal is essentially based on the fact that the interpretation of the test results, on which the Appellant appealed, took considerable explanation in these proceedings. It only transpired during the course of the appeal hearing that the method of evaluating the test results in the areas at issue needed careful attention to be sufficiently established. There was a full and substantial case to be argued here. The Appellant's lawyers carefully and constructively pursued the Appellant's case. There were real and significant differences of opinion between the experts. There is a basis for granting a contribution to the costs of the IOC but only a contribution. The IOC received significant costs in the Russian cross-country skiing cases. In *Lazutina* it was CHF 25,000 and in *Danilova* it was CHF 25,000. The preparation for those proceedings had many parallels to the preparation for the Mühlegg case. Furthermore, if this case had been heard at the Games rather than through the regular Appeals proceedings there would have been no cost to the athlete. Finally the IOC in its reply brief specifically requested all costs for the period from April through to the filing of the Appeal brief in August on the basis of the alleged misconduct of the Appellant's lawyers. The Panel by the completion of the hearing was of the view that there had not been misconduct on the part of the lawyers for the

Appellant in this period. It also became clear to the Panel that some documents were only being revealed to the Appellant at the time of filing Dr. Catlin's expert report. Bearing all these matters in mind the Panel therefore considers that the Appellant should bear a limited portion of the costs of the Respondent in the amount of CHF 12,000 as a contribution to the costs of the IOC.

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DECISION

The Court of Arbitration for Sport rules:

1. The appeal filed by Johann Muehlegg on 16 March 2002 is dismissed.

2. The decision of the Executive Board of the International Olympic Committee of 24 February 2002 is upheld.

3. The award is pronounced without costs, except for the court office fee of CHF 500 (five hundred Swiss Francs) paid by Johann Muehlegg which is kept by the CAS.

4. Johann Muehlegg is ordered to pay the sum of CHF 12'000.-- (Twelve thousand Swiss Francs), to the IOC in contribution towards its legal costs.

Dated in Lausanne, 24 January 2003

THE COURT OF ARBITRATION FOR SPORT

President of the Panel:

Professor Richard H. **McLaren**

Arbitrators:

Dr. Dirk-Reiner **Martens**

Jean-Pierre **Morand**