IRISH SPORTS ANTI-DOPING DISCIPLINARY PANEL

IN THE MATTER OF ATHLETICS IRELAND AND IRISH SPORTS COUNCIL

AND

ATHLETE IS-3457

DECISION

1. INTRODUCTION

1.1 Mr. [...] ("**Mr.** IS-3457 ") is an elite sprinter and a member of Athletics Ireland ("**AI**"). As such he is subject to the Irish Anti-Doping Rules in force from time to time ("the **Rules**").

1.2 On [...] , 2014 Mr. IS-3457 was subjected to out of competition testing. He provided a urine sample and a blood sample, the latter of which was collected for analysis as part of the Athlete Biological Passport.

1.3 By letter dated 17th June, 2014 the Irish Sports Council ("**ISC**") informed Mr. IS-3457 of an alleged violation of the Rules namely, the presence of a Prohibited Substance or its metabolites or markers in the urine specimen provided. The Prohibited Substance was alleged to be a recombinant erythropoietin ("**rEPO**"), contrary to Article 2.1 of the Rules. Mr. IS-3457 was informed in that letter that as and from the date of that letter AI would provisionally suspend him in accordance with Article 7.6 of the Rules and that he would be notified to that effect by AI. By letter dated 20th June, 2014 Mr. IS-3457 was notified of such provisional suspension by AI. That provisional suspension operates to bar Mr. IS-3457 from participating in any competition prior to the final determination by the Irish Sport Anti-Doping Disciplinary Panel ("the **Panel**").

1.4 The Panel (Hugh O'Neill, Senior Counsel, Dr. Pat O'Neill, Medical Practitioner and Philip Browne, Sports Administrator) was duly constituted to adjudicate on the alleged violation of the Rules.

1.5 The alleged violation arose as a result of the analysis of the "A" sample of Mr. IS-3457's urine. Mr. IS-3457 has at all times maintained that he did not take rEPO (the same is administered by injection) and, as he was entitled to do under the Rules, called for the analysis of the "B" urine sample. This analysis was conducted by the Deutsche Sporthochschule Köln Institut Für Biochemie ("the **Cologne Institute**"), the same body which analysed the A sample. The B sample was opened and subsequently resealed in the presence, and to the apparent satisfaction[1], of Mr. IS-3457 on 7th July, 2014. The analysis of the Cologne Institute dated 9th July, 2014 purportedly reported the presence of rEPO in the B sample.

1.6 Both before and after the analysis of the B sample a considerable volume of correspondence passed between the parties in the course of which Mr. IS-3457 (through his representatives) challenged the alleged results of the analysis of the urine samples, the apparent anomaly between the results of the analysis of the urine and blood samples and the sequence in which the blood and urine samples were taken. In effect, Mr. IS-3457 was suggesting that either the analysis of the urine samples was incorrect or that those samples were not his samples. While Mr. IS-3457 was provided with the A and B sample laboratory documentation packs he sought access to further documentation and information to enable him, *inter alia,* have the samples subjected to DNA analysis. This request was considered by the Panel and refused for the reasons set out in the written decision of the Panel dated 12th November, 2014.

1.7 A preliminary hearing was conducted by the Chairman of the Panel (Hugh O'Neill, Senior Counsel) on 4th June, 2015 in the absence of the two other members of the Panel with the express agreement of the parties (AI, ISC and Mr. IS-3457). ISC, which had signified its intention to join the proceedings and attend the hearings of the Panel as a party (as it was entitled to do under Article 8.3.6 of the Rules), sought

[1] See B sample analysis – verification of sample identity dated 7th July, 2014.

liberty to adduce evidence at the substantive hearing by two of its intended witnesses by way of conference call. Mr. IS-3457 had no objection in principle to evidence being given by remote link but sought to have that evidence given by way of video conferencing by which the witness giving evidence could be seen and observed. The Panel indicated that it would be preferable if such evidence was given by video link, if that proved feasible.

2. THE HEARING

2.1 The hearing took place at the Ormond Meeting Rooms, Ormond Quay, Dublin 7 on 22nd June, 2015. AI was represented by Mr. Gerry Dunne of O'Brien Dunne Solicitors. Ms. Louise Reilly, Barrister at Law instructed by Mr. Gary Rice and Aidan Healy of DAC Beachcroft appeared on behalf of ISC. Mr. IS-3457 was represented by Mr. C , Barrister at Law instructed by Mr. D and Ms. B of [...] Solicitors.

2.2 Each of the parties had prior to the hearing provided to the Panel and each other a list of the witnesses intended to be called, a summary of the evidence to be given by those witnesses and outline submissions. In addition, Ms. Reilly and Mr. Dunne made opening statements at the outset of the hearing.

2.3 From the written and oral submissions made on behalf of the parties, and the cases as presented, the following emerged as the central issues in dispute:

(i) The apparent inconsistency between the analyses of Mr. IS-3457 's blood and urine samples;

(ii) The sequence in which the blood and urines samples were taken from Mr. IS-3457 on [...] , 2014 and;

(iii) The interpretation of the results of the testing conducted by the Cologne Institute of the A and B samples.

Apart from challenging, by way of inference, the inconsistency between the results of the analysis of the blood and urine samples (suggesting that one or other may not be the sample of Mr. IS-3457), Mr. IS-3457 did not assert that there had been a departure from the World Anti-Doping Code International Standards for Testing and Laboratories. Under Article 8.5.2 of the Rules, WADA accredited laboratories are presumed to have conducted sample analysis and custodial procedures in accordance with the applicable international standard for laboratories. The Cologne Institute is a WADA accredited laboratory.

2.4 It is convenient to deal with each of these areas of dispute separately. However before so doing it is important to emphasise that Mr. IS-3457 , who gave evidence at the hearing, has consistently maintained that he has never taken (prohibited) drugs and in particular has not taken rEPO parenterally or otherwise.

Discrepancy between Blood and Urine Analyses

2.5 In his written submissions Mr. IS-3457 submitted that the hematocrit levels (proportion of red blood cells in volume of blood) identified in blood samples taken in [...] 2014 showed no evidence of any increase consistent with the use rEPO or any other EPO stimulating agent. These hematocrit levels were as follows:

[...] 2014... 50.8%
[...] 2014... 49.9%
[...] 2014... 52.1%.

2.6 Professor Brendan Buckley, a Consultant Endocrinologist and Chief Medical Officer of ICON (a company developing drugs on behalf of pharmaceutical companies) was called on behalf of ISC. Professor Buckley identified a number of positions he held, including the Chairmanship of the Anti-Doping Committee of ISC, membership of the UK Anti-Doping Scientific Advisory Committee and an invited participant to the US Anti-Doping Agency's Annual Scientific Meeting. He explained that EPO is a

hormone naturally produced by the kidney to cause the production of red blood cells to be increased should a person become anaemic. Professor Buckley expressed the view that the levels of hematocrit found in Mr. IS-3457 's samples were on or above the upper end of normal (normality being the level below which 95% of the population would fall) for healthy male individuals. He referred to what is described as the *"non-start rule"* where in 1997 competitive cyclists tested before a competition and having a hematocrit level of more than 50% were not permitted to participate in that competition/race. In his view Mr. IS-3457 's levels of hematocrit were compatible with the use of EPO. Professor Buckley was cross-examined by Mr. C who produced an extract from a textbook entitled *"Clinical Methods-The History, Physical and Laboratory Examinations"* (3rd Ed.-1990) which identified the normal hematocrit levels for men as being between 40% to 54%. Professor Buckley did not agree with this analysis although he did accept that for 5% of the population the hematocrit levels could be higher. Professor Buckley made it clear that he was not asserting that the levels of hematocrit found in Mr. IS-3457 's samples indicated the presence of rEPO; what he did assert was that those levels were not inconsistent with the presence of rEPO.

2.7 Mr. IS-3457 did not present any evidence on this issue.

2.8 The Panel, having carefully considered the evidence adduced is satisfied, to a level beyond comfortable satisfaction, that the levels of hematocrit in Mr. IS-3457 's blood samples, including the blood sample taken on [...] , 2014 (the same day on which the urine sample was taken) are not inconsistent with the presence of rEPO in Mr. IS-3457 's urine sample taken on [...] , 2014.

Sequencing of Blood and Urine Samples

2.9 Mr. John Fogarty, a Doping Control Officer from ISC administered the taking of the blood and urine samples from Mr. IS-3457 on [...] , 2014. He produced to the Panel a doping control form dated [...] , 2014 signed by him, Mary Spain (the Blood Collection Officer) and Mr. IS-3457 which identifies the blood sample being

taken at 11:18am and the urine sample at 11:30am. Mr. Fogarty said that he had an actual recollection that the blood sample was taken before the urine sample although he could not at this remove remember the precise times at which those samples were taken.

2.10 Mr. IS-3457 gave evidence that he distinctly remembered giving the urine sample before the blood sample. On the morning of [...] Mr. IS-3457 had just finished an exam and needed to go to the toilet when he was met by Mr. Fogarty and his associate. Thus, when he went back to the apartment as he needed to go to the toilet he gave the urine sample first.

2.11 The Panel does not find it necessary to resolve this conflict in the recollection of the parties as it has not been suggested, let alone demonstrated, that the sequence in which the blood and urine samples were taken would have any impact on those samples and their subsequent analysis.

Analysis of A and B Urine Samples

2.12 The evidence of the two experts called by ISC, Philipp Reihlen and Christian Reichel, was given over the telephone. Before the hearing ISC had notified the Panel and the other parties that neither of these two gentlemen could give evidence by video link or Skype. This issue was explored by Mr. C in cross examination of each of these witnesses. Mr. Reihlen, who is a member of the Cologne Institute, said that all evidence theretofore given to hearings had been given via telephone and that neither webcam nor Skype had been installed at his office. He conceded that smart mobile phones and tablets are fitted with cameras and can be used for Skype and other similar applications and that he had access to such phones and tablets. Dr. Reichel of the Seibersdorf Laboratories said that in similar circumstances evidence was normally given by Seibersdorf representatives by telephone because the Skype connection in the laboratory was bad with resulting interruptions in connection.

2.13 Apart from the foregoing cross examination, the issue about the manner in which the evidence by these two individuals was given was not pursued further by Mr. IS-3457 or his legal representatives. Having heard the evidence via telephone the Panel does not believe that any injustice is or was caused to any of the parties in the manner in which the evidence was given even if that evidence could have been provided by video link.

2.14 Mr. Reihlen is a biochemist and head of the EPO Department in the Cologne Institute, a WADA accredited laboratory. He is a co-author of the current WADA Technical Document for analysis and reporting of recombinant EPO and on a panel to provide second opinions of analyses of samples for the presence of rEPO. Since 2009 Mr. Reihlen has analysed approximately 21,000 urine samples for the presence of rEPO.

2.15 Mr. Reihlen and his colleagues conducted the analysis of Mr. IS-3457's A and B urine samples. The WADA technical document – TD 2013 EPO calls for an initial testing or screening procedure using either isoelectric focusing ("**IEF**") or sodium *N*-lauroylsarcosinate ("sarcosyl") polyacrylamide gel electrophoresis ("**SAR-PAGE**"). The initial screening test was conducted on the A sample using SAR-PAGE and was reported as suspicious for the presence of rEPO. The further definitive testing as required by the WADA technical document, calls for testing by IEF and either SAR-PAGE or sodium dodecyl sulphate polyacrylamide gel electrophoresis ("**SDS-PAGE**"). The A sample was subjected to IEF and SAR-PAGE testing. According to Mr. Reihlen, each of these tests is capable of differentiating between endogenous EPO and recombinant EPO; in the case of IEF recombinant EPO has a different isoform. SAR-PAGE (and SDS-PAGE) distinguishes recombinant and endogenous EPO by mass, recombinant EPO having a higher molecular mass than endogenous EPO.

2.16 Mr. Reihlen referred the Panel to the GASepo Analysis Report in respect of the "A" sample. He reported that both the IEF and SAR-PAGE analyses confirmed the presence of rEPO. Mr. Reihlen said the data for the A sample was also checked by his colleagues, Raoul Kempkes and Dr. Hans Geyer who, according to Mr. Reihlen, confirmed those analyses.

2.17 Mr. Reihlen also referred to the GASepo Analysis Report in respect of the "B" sample showing the results of the SAR-PAGE testing.[2] He again expressed the view, supported by Mike Blobel and Dr. Wilhelm Schänzer of the Cologne Institute, that the SAR-PAGE analysis of the B sample confirmed the presence of rEPO.

2.18 Mr. Reihlen was cross examined closely and in detail in relation to the results of the SAR-PAGE testing and the conclusions to be drawn therefrom. Positive and negative controls, namely, samples with and without rEPO, are used to determine how a positive and a negative appear. The tests are calibrated by ESA-mix standards showing different generation epoetins and from which a *"cut off"* line can be identified with, broadly speaking, endogenous EPO appearing below the line and recombinant EPO above the line. However, the analysis of the result of the test depends not only on the presence of the *"blot"* above or below this line but also on the band shape of that blot. It was suggested by Mr. C in cross examination that part of the blot on the negative control appeared above the line (coloured blue), thus indicative of the presence of rEPO and that, consequently, the test, and the location of the blue line was incorrect and invalid. Mr. Reihlen agreed that the presence of rEPO in the negative control would invalidate the test but was of the view that the negative control did not demonstrate the presence of rEPO even though part of the signal traversed the blue line.

2.19 A similar discussion took place between Mr. C and Mr. Reihlen in respect of the analysis of the B sample. Again, in respect of the negative control used in the analysis of the B sample, Mr. Reihlen disagreed that that negative control demonstrated the presence of rEPO.

2.20 It was suggested to Mr. Reihlen that the interpretation of the results of the various tests was *"a matter of impression"*. Mr. Reihlen did not agree and expressed the opinion, as an expert, that the samples clearly showed the presence of rEPO.

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[2] The technical document – TD2013 EPO requires the "B" sample to be subjected to either IEF, SAR-PAGE or SDS-PAGE testing.

2.21 Dr. Christian Reichel is a scientist and the Head of Proteomics and Analytical Biochemistry in the Austrian Institute of Technology – Sieberdorf Laboratories, Doping Control Laboratory, a WADA accredited laboratory. He has been involved on behalf of the laboratory in the EPO analysis since 2003 over which time the laboratory has analysed approximately 10,000 samples. Dr. Reichel is a member of the WADA EPO Working Group, one of whose purposes is to draft the WADA Technical Document. He has also been involved in training laboratories in EPO testing.

2.22 The WADA Technical Document – TD2013 EPO requires the provision of a second opinion before any adverse analytical finding for rEPO is reported. Dr. Reichel is one of the eight experts designated under those Regulations to provide such an opinion[3].

2.23 Dr. Reichel received the raw data in respect of the A and B samples and analysed them with GASepo software. Having analysed the data he expressed the opinion that both the IEL and SAR-PAGE tests on the A sample and the SAR-PAGE test on the B sample all clearly disclosed the existence of rEPO in those samples. In relation to the negative control used in the SAR-PAGE test the witness said that while there was some signal above the blue line that did not signify recombinant EPO because EPO is composed of different glycoforms of different molecular masses and that endogenous EPO contains a low amount of this higher molecular mass. Consequently, the blue line is not a strict cut off line whereby anything above the line is recombinant and anything below is endogenous.

2.24 Dr. Reichel said that Dr. Günter Gmeiner, the head of the Scibersdorf Laboratories, cross-checked the data for the A and B samples and confirmed the findings that the two tests on the A sample and the one test on the B sample all established the presence of rEPO in those samples.

[3] In 2014 Mr. Reihlen was added to the list of designated experts.

2.25 In cross-examination Dr. Reichel was asked about the results of the initial screening as shown on the GASepo Analysis Report (page 16 of the documentation package for the "A" sample) and the relevance of the discrepancy noticed by Dr. Kwasowski of in the region of 2mm between the datum point (blue line) in the 3 control lanes. Dr. Reichel was of the view that such measurement was irrelevant and unscientific and that no scientist/biochemist would measure the gel electrophoresis result with a ruler.

2.26 Dr. Peter Kwasowski gave evidence on behalf of Mr. IS-3457 . Mr. Kwasowski graduated from the University of Surrey in the United Kingdom in 1979 with an honours degree in biochemistry. For the past twenty years he has described himself as an immuno-technologist as most of his work is involved in making antibodies similar to those used in assaying techniques.

2.27 Dr. Kwasowski gave evidence that in respect of the initial (screening) analysis the GASepo Analysis Report showed a difference of approximately 2mm between the blue line plotted in respect of the three controls which could have a bearing on the position of the blue line in respect of the A sample. As this blue line could thereby move up no part of the signal on the A sample might appear above the blue line. Consequently, he was of the view that one could not interpret the A sample as being *"suspicious"*. As to the evidence given by Mr. Reihlen that the location of the blue line was governed by the analysis in the closest control lane (in this case lane 16) Dr. Kwasowski compared that to choosing the answer that you want. He did not elaborate further on this.

2.28 Dr. Kwasowski was asked to comment on the subsequent SAR-PAGE testing of the A sample. He stated that the samples (page 34 of the documentation package for sample A) appeared *"fuzzy"*, perhaps due to too high a concentration of the relevant antibody used in the testing, whereas the boundaries (of the signals) should be clearly defined.[4] Dr. Kwasowski said *"I just don't like the whole data set"* and would have had the test redone. He also expressed the view that certain aspects of the testing were sub-

[4] It is noted by the Panel that at figure 3 to the WADA Technical Document – TD 2013 EPO – the blots on the SAR-PAGE image are likewise fuzzy. Other figures showing SDS-PAGE images, a test which the Panel is told is broadly similar to the SAR-PAGE test show the various blots as being equally fuzzy.

optimal. However, Dr. Kwasowski was clear in stating that he was not suggesting that the testing carried out was not carried out in accordance with the WADA International Standards.

2.29 Dr. Kwasowski did not say that the SAR-PAGE testing on the A sample did not disclose the presence of rEPO; rather he said that *"the degree of veracity which is being suggested...goes a little further than probably the outcome could be trusted to give"* and that there is an element of subjectivity, and room for disagreement, in the interpretation of the results. It is worth noting that Dr. Kwasowski had never used the GASepo software, had never done a western blot and had not received any specific training in EPO analysis.

2.30 Dr. Kwasowski was referred by the Panel to the IEF testing of the A sample. He expressed the view that the results of that testing (page 23 of the documentation package for the A sample) did a *"better job"* of persuading him of the presence of rEPO in Mr. IS-3457 's A sample but that it did not necessarily get him *"fully on board"*.

2.31 Dr. Kwasowski did not specifically address the testing or analysis of Mr. IS-3457 's B sample.

2.32 Having carefully considered all of the evidence adduced on this issue by the parties, the Panel is satisfied that the analysis of the results of IEF and SAR-PAGE testing is not a subjective analysis although, of course, it is an analysis that can only properly be carried out by suitably qualified and experienced experts. The determination of whether a sample, including controlled samples, contains rEPO is not simply a question of determining whether any part of the signal appears above or below the blue line but is also related to the shape of that signal. The Panel is also satisfied that not only were the various tests on the A and B samples properly carried out but that they establish the presence of rEPO in Mr. IS-3457's A and B samples.

3. CONCLUSIONS

3.1 The WADA Technical Document TD 2013 EPO requires for an Adverse Analytical Finding a positive result in respect of each of the tests carried out, namely, IEF and SAR-PAGE testing on sample A, and SAR-PAGE testing on sample B. The evidence led before the Panel establishes to the comfortable satisfaction of the Panel that each of the confirmatory tests carried out on the A and B samples identify the presence of rEPO, a Prohibited Substance.

3.2 The alleged violation of the Rules in the present case is the presence of a prohibited substance or its metabolites or markers in Mr. IS-3457 's A and B samples. Under Article 2.1.2 of the Rules proof of:

> *"2.1.2.2 The presence of a Prohibited Substance or any of its Metabolites or Markers in the Athlete's A Sample, where the Athlete's B Sample is analysed and such analysis confirms the presence in the B Sample of the Prohibited Substance or any of its Metabolites or Markers found in the A Sample"*

to the comfortable satisfaction of the Panel is sufficient to establish an anti-doping rule violation under Article 2.1 of the Rules.

3.3 In determining whether an anti-doping rule violation under Article 2.1 has occurred it is not necessary that intent, fault, negligence or knowing use on the part of the athlete be demonstrated.

3.4 The determination of the Panel is that proof of an anti-doping rule violation under Article 2.1 has been established to the comfortable satisfaction of the Panel.

4. SANCTION

4.1 Under Article 10.1 the period of ineligibility (as defined in the Rules) for a first violation of Article 2.1 shall be two years unless the conditions for eliminating, reducing or increasing that period as provided for in Articles 10.3, 10.4 or 10.5 are met. Article 10.3 does not apply as rEPO is not a Specified Substance. It is not suggested there are any aggravating circumstances which would bring Article 10.5 into play.

4.2 Article 10.4 provides for an elimination or reduction of a period of ineligibility based on no fault or negligence (Article 10.4.1) or no significant fault or negligence (Article 10.4.2). To avail of either of those provisions the athlete must demonstrate how the Prohibited Substance entered his or her system. No such evidence has been adduced in the present case; indeed Mr. IS-3457 has consistently denied that he administered to himself (or had administered) any recombinant EPO. In the circumstances, the elimination or reduction of the period of ineligibility provided for in Article 10.4 does not arise. The subsequent provisions of Article 10 do not, and are not claimed to, apply in the present case.

4.3 The Panel has outlined above (paragraph 1.3) the circumstances in which Mr. IS-3457 was provisionally suspended following the alleged violation of the Rules. While the authority conferred by the Rules to suspend an athlete is vested in this case in AI, which duly suspended Mr. IS-3457 by letter dated 20th June, 2014, the wording of the letter dated 17th June, 2014 from ISC could reasonably be interpreted as applying the suspension from that date (17th June, 2014). In the circumstances, ISC and AI have agreed that the provisional suspension should be treated as having run from 17th June, 2014. Mr. IS-3457 is entitled under Article 10.7.3.1 of the Rules to receive credit for any period of provisional suspension against the period of ineligibility which may ultimately be imposed.

4.4 In the circumstances, the Panel declares that Mr. IS-3457 shall be ineligible to participate in any capacity in any competition, event or activity of the nature identified in Article 10.8.1.1 of the Rules until 17th June, 2016.

5. CONCLUDING COMMENTS

5.1 The day after the Hearing the Panel learnt of the untimely death of Dr. Kwasowski. The Panel would like to express its sympathy to Dr. Kwasowski's family and friends. May he rest in peace.

5.2 Finally, the Panel would like to thank its secretary, Ms. Nicola Carroll for all her assistance during the course of these drawn-out proceedings. The Panel would also like to thank the parties, their legal representatives and witnesses for their assistance in the proceedings.

Dated this 16th day of July, 2015.

Signed on behalf of the Panel
by Hugh O'Neill, SC
Chairman