



Arbitration CAS 2015/A/4355 J. & Anti Doping Denmark (ADD) v. International Paralympic Committee (IPC), award of 26 May 2016 (operative part of 18 March 2016)

Panel: Prof. Michael Geistlinger (Austria), President; Prof. Philippe Sands QC (United Kingdom); Mr Michele Bernasconi (Switzerland)

Paralympic shooting

Therapeutic Use Exemption (TUE) for carvedilol (beta blocker)

Particularities of the “state of health” of Article 4.1 b) WADA ISTUE in Paralympic sports

Applicable standards for determining the performance enhancing factors

Discretion of the CAS panel to grant a TUE under Article 4.1 ISTUE, criteria and burden of proof

- 1. In Paralympic sports, the relevant “state of health” is not one without any limitation and without any handicap. What is relevant is the difference of the state of health of a Paralympic athlete with or without the use of a medication needed for his or her particular, additional sickness.**
- 2. The applicable standard for determining the eventual factors enhancing performance is the “balance of probability” test, followings established CAS jurisprudence.**
- 3. All four criteria listed in Article 4.1 of the WADA International Standard for Therapeutic Use Exemptions (ISTUE), must be fulfilled for granting a TUE and the burden of proof lies with the athlete. The facts of any case are specific, to be evaluated on their own particular circumstances and on the basis of the evidence before the CAS panel. The introductory part of art. 4.1 ISTUE leaves it to the discretion of the CAS panel to grant a TUE, if the four criteria mentioned in this provision have been met by the athlete.**

I. THE PARTIES

- 1.1. Mr J. (the “Athlete”) is a male Paralympic shooter from Denmark, who suffers from muscular dystrophy, complicated by a dilated cardiomyopathy. He competes in the sport of Paralympic shooting in the R5 discipline (10 m air rifle prone, sport class SH2) and is, thus, *inter alia* entitled to use a shooting chair and an approved support stand to support the weight of the rifle.
- 1.2. Anti-Doping Denmark (the “ADD”) is the Government-funded Danish anti-doping organisation responsible for implementing as National Anti-Doping Organization (“NADO”) the World Anti-Doping Code (“WADC”) in Denmark.
- 1.3. The International Paralympic Committee (the “IPC” or the “Respondent”) is the global governing body of the Paralympic Movement. Its purpose is to organise the summer and winter

Paralympic Games and act as the International Federation for nine sports, including Paralympic shooting, supervising and coordinating World Championships and other competitions.

II. FACTS

- 2.1. The Athlete suffers from muscular dystrophy, complicated by a deterioration of left ventricular function (dilated cardiomyopathy). He was diagnosed with limb girdle muscular dystrophy type 2l in childhood and with cardiomyopathy resulting from the muscular dystrophy in 2009. Muscular dystrophy is a group of inherited genetic conditions that gradually cause the muscles to weaken. It leads to an increasing level of disability in a progressive manner and gets worse over the time. The Athlete's limb-girdle muscular dystrophy manifests itself in the form of increased fatigue and reduced muscle strength in the muscles closest to the body such as shoulders, upper arms, pelvic area, and thighs.
- 2.2. Cardiomyopathy is a disease of the heart muscle, which results in the progressive deterioration of the heart and can lead to heart failure and associated complications. The Athlete suffers from dilated cardiomyopathy with ejection fraction reduced to 25 percent.
- 2.3. The Athlete was first treated with Ramipril, but when this did not work, was also prescribed Carvedilol in the dose 25mg daily. The overall daily dose of 50mg, whilst considered minimal in amount, nevertheless serves to compensate cardiac rhythm and ventricular contraction and is considered to be essential to lessen the risk posed to the Athlete's life by his condition.
- 2.4. Carvedilol is used to treat heart failure and high blood pressure, is standard for severe heart disease, but prohibited in and out of competition in shooting.
- 2.5. Carvedilol is a third generation vasodilating non-cardioselective beta-adrenoceptor antagonist, which lacks intrinsic sympathomimetic activity ("ISA") and inverse agonism. ISA is characteristic of pindolol while inverse agonism is characteristic for the classical beta-adrenoceptor antagonist, propranolol, and the cardioselective drug, metoprolol. That Carvedilol lacks ISA and inverse agonism explains why it has less effect on heart rate at rest compared to pindolol, which increases heart rate, and propranolol, which reduces heart rate.
- 2.6. Carvedilol in addition to a blocking effect at beta1- and beta2-adrenoceptors antagonizes alpha1-adrenoceptors and is considered a strong antioxidant. It is more lipophilic than atenolol, but less lipophilic than propranolol. Although not compared head to head, the less lipophilic effect of Carvedilol results in less adverse central events, e.g. nightmare, depression and insomnia compared to propranolol.
- 2.7. It has remained undisputed that without the described treatment with Carvedilol the Athlete's life would be at risk, because he requires Carvedilol therapy to maintain cardiovascular stability and to maximise his cardiovascular protection. According to the doctors who diagnosed him, discontinuation of this medication for any length of time is detrimental to his wellbeing.

- 2.8. In view of his required and necessary use of Carvedilol, the Athlete has been granted a Therapeutic Use Exemption (“TEU”) since the beginning of his career as Paralympic shooter,
- 2.9. On 26 February 2010, the Athlete was first granted a TUE by the ADD for the use of Carvedilol.
- 2.10. On 21 August 2012, IPC refused to recognise the TUE granted by the ADD.
- 2.11. On 26 August 2012, the WADA Therapeutic Use Exemption Committee (“WADA TUEC”) granted a two-year TUE to the Athlete, authorising him to use Carvedilol in the dose of 25 mg twice daily for a period of two years (the “2012 WADA TUE”). This decision reversed the refusal by the IPC to recognise the TUE granted by the ADD. Following this decision the Athlete was able to represent Denmark at the London 2012 Summer Paralympics.
- 2.12. The Athlete took part in several IPC competitions in 2013 and 2014 using Carvedilol daily, in accordance with the 2012 WADA TUE.
- 2.13. On 29 April 2014, the Athlete was granted a new TUE by the ADD for the use of Carvedilol. The IPC was asked to recognise this TUE internationally.
- 2.14. On 22 December 2014, the IPC refused to recognise the TUE granted by the ADD.
- 2.15. On 3 July 2015, the Athlete was granted another TUE by the ADD for the use of Carvedilol and also this was followed by a request to the IPC for the international recognition of this TUE.
- 2.16. On 19 August 2015, the IPC decided not to recognise the TUE (the “Challenged Decision”). It held that the criterion of art. 4.1 (b) of the WADA International Standard for Therapeutic Use Exemptions (“ISTUE”) has not been met. It referred to the general performance enhancement benefit of beta-blockers for shooting and the precedents of CAS in the decisions in *Berger vs WADA* (CAS 2009/A/1948) and *ISSF vs WADA* (CAS 2013/A/3437). In these decisions the CAS determined that the use of beta-blockers in shooting remains prohibited due to the potential for systemic performance enhancement (both cardiac and, perhaps more importantly, non-cardiac). The IPC referred to the potential of beta-blockers to have profound systemic effects outside of just the cardiovascular system, to include skeletal muscle relaxation, reduction of tremor, and reduction of psychological stress/anxiety. However, the Challenged Decision also stated the following:

“Whilst it is noted that in the SH2 class, support stands and back rests are permitted, it cannot be assumed that the presence of these supports truly reduces the systemic performance benefit of the use of beta-blockers in the sport of shooting. Future studies supported by WADA are encouraged to determine if in fact a class-specific difference exists in the systemic impact of beta-blocker use”.
- 2.17. On 27 August 2015, the ADD requested WADA to review the IPC’s decision.
- 2.18. On 3 December 2015, a WADA TUEC, constituted according to art. 8 WADA International Standard for Therapeutic Use Exemptions (“ISTUE”), upheld the Challenged Decision. It

recognized that the “*treatment with a Beta-Blocker (e.g. carvedilol) and an Angiotensin Converting Enzyme (ACE) inhibitor (e.g. Ramipril) constitutes the accepted standard of care*”, that “*these agents are considered to be the cornerstone treatment for myocardial dysfunction secondary to muscular dystrophy*” and that Carvedilol has the effects of preventing or retarding the progression of cardiac dysfunction.

“*Considering that there is evidence that maximal cardiovascular stability is afforded by carvedilol and that acute withdrawal could put the Athlete at significant risk of morbidity and mortality from increased sympathetic activity leading to tachycardia, arrhythmia, rapid progression of left ventricular dysfunction and potential heart failure*”, and that the Athlete’s cardiac complications are a consequence of the underlying muscular dystrophy the WADA TUEC held that the conditions set forth in art. 4.1 a), c) and d) ISTUE were met.

The WADA TUEC saw little adrenergic blocking effect and modest other potential peripheral effects of Carvedilol as well as little bradycardic benefit for the Athlete. It considered that “*the putative effects of carvedilol on tremor are based only on extrapolation of clinical evidence available from studies employing other drugs classified as beta blockers*” and that the permission of the use of supporting devices for stabilizing the Athlete’s posture renders any such effect from beta-blockers negligible. Further to that, the WADA TUEC held that the heterogeneous manifestation of muscular dystrophies lets appear any performance-enhancing effect of Carvedilol as negligible in view of the categorization of shooters (category SH2 and subcategory A, B, and C). Besides, these classifications do not address the Athlete’s dilated cardiomyopathy. Nevertheless, the WADA TUEC found that despite of all that “*it is not possible to categorically exclude a potential beneficial effect of carvedilol on the shooting performance of this Athlete ... and that the condition set forth in Art. 4.1 b) ISTUE is therefore not met*”.

III. PROCEEDINGS BEFORE THE CAS

- 3.1. In accordance with Articles R47 and R48 of the Code of Sports-related Arbitration (the “CAS Code”), the Appellants filed their statement of appeal on 21 December 2015.
- 3.2. In accordance with Article R51 of the CAS Code, the Appellants, having been granted an extension of the deadline, filed their appeal brief on 28 January 2016.
- 3.3. On 15 February 2016, the CAS Counsel recorded the Panel to resolve the dispute as composed by Mr Michael Geistlinger, professor in Salzburg, Austria, (President of the Panel); Mr Philippe Sands, QC, professor in London, United Kingdom, and Mr Michele Bernasconi, attorney-at-law in Zurich, Switzerland (arbitrators).
- 3.4. In accordance with Article R55 of the CAS Code, the Respondent having been granted an extension of the deadline, filed its answer on 9 March 2016.
- 3.5. On 11 March 2016, the Respondent, and on 14 March 2016, the Appellants signed an Order of Procedure.
- 3.6. On 16 March 2016, a hearing was held in Lausanne.

- 3.7. The Athlete was present in person, assisted by his father Mr P. The ADD was present by the scientific consultant Mr Jakob Morkeberg, by the program manager Ms Christina Friis Johansen, the legal manager Mr Jesper Frigast Larsen and the lawyer, Mr Mads Boesen. The Appellants were represented by two counsel, Mr Claude Ramoni and Ms Natalie St Cyr Clarke. The Panel heard as experts nominated by the Appellants Dr Jes Rahbek, specialist consultant in neurorehabilitation of the Danish Rehabilitation Centre for Neuromuscular Diseases, Prof. Ulf Simonsen from the Department of Biomedicine, Cardiovascular and Pulmonary Pharmacology of the Aarhus University, and Prof. Jacob Wienecke from the Department of Nutrition, Exercise and Sport of the University of Copenhagen by phone and Prof. Jérôme Biollaz from the Clinical Pharmacology Division of the Vaud University Hospital present in person. On behalf of the Respondent Ms Sarah Bond, IPC Shooting Manager, and Ms Anne Sargent, IPC Medical Manager, were present in person, and Mr Ferrol van Hoeven, IPC Head of Classification, was heard by phone. The Respondent was assisted by counsel Ms Elizabeth Riley. The Panel heard the witness nominated by the Respondent Prof. Harrison G. Pope Jr, MD, by phone.
- 3.8. At the beginning of the hearing, the parties confirmed that they had no objections as to the composition of the Panel. The Parties confirmed their submissions in writing.
- 3.9. The hearing focussed on the understanding of art. 4.1 b) ISTUE and the standard as well as object of proof to be fulfilled by the Athlete in order to meet the requirements set by this provision. The Appellants, by means of their experts, who all confirmed their statements in writing, tried to give such evidence. The Respondent, relying on its expert and questioning the experts of the Appellants, tried to argue that the Athlete could not show by a balance of probability that the Therapeutic Use of Carvedilol was unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.
- 3.10. The Appellants underlined the particularity of the specific facts of the present case. They compared the Challenged Decision with the 2012 WADA TUE and expressed concerns as to why the same disease, the same medication, in the same doses, used for dealing with such disease, and no changes in the state of science as to the effects of beta-blockers, led to two entirely different decisions in 2012 and 2015. At the same time, the applicable rules did not change in any material way. This goes against good faith. The Appellants emphasized that the standard of proof has changed since the cases CAS 2009/A/1948 and CAS 2014/A/3437. The ISTUE 2016, which also according to the Respondent is the ISTUE version to be applied on the present case, asks not anymore that the Athlete demonstrates that the use of Carvedilol would produce "*no additional enhancement of performance*", but reduces this standard to demonstrate that Carvedilol is "*highly unlikely to produce any additional enhancement of performance*". In the opinion of the Appellants, the ISTUE 2016 with the balance of probability test sets the lowest standard of evidence. It has to be proven that an additional performance effect is more likely than not. Two tests have to be made: Either the health condition does not affect the sport performance, or the health condition affects the sport performance. In the case at hands, the health condition negatively influences the sport performance. The medication allows the Athlete just to return

to a normal state of sport performance. It does not grant him an additional sport enhancement effect. WADA and the IPC used the “beyond reasonable doubt” standard of proof, which is a much higher standard of proof. Considering the impossibility to prove a negative fact, the applicable standard of proof and, because TUEs are part of the system, a TUE has to be granted once the Athlete meets the balance of probability test. The ratio of the TUEs lies in avoiding an unfair enhancement of the sport performance.

- 3.11. The Respondent held against that it never had issued or approved a TUE for Carvedilol. It did not attack the 2012 WADA TUE because of timing, economic and other considerations, including the proximity of the appealed decision to the 2012 Paralympics. The Respondent admitted that the Athlete is required to meet a deliberately high standard of proof, but this standard is justified by guaranteeing the fairness of the competitions. The Athlete, who bears the burden of proof, has not met this standard. The sport of shooting is a highly technical sport, where accuracy plays an eminent role. The margin between competitors is extremely narrow. Even a small support, provided by a prohibited substance, thus, can have a huge effect for the sport performance. In the case of the Athlete, there is a stand in his support, but still the rifle is not stable and, thus, the Athlete has to control it. Different beta-blockers have different effects on essential factors, in particular, heart rate, tremor, anxiety and motor restlessness. Measurements and results of physical examination shown by the Athlete were not enough to demonstrate that Carvedilol in his case was “*highly unlikely to produce any additional enhancement of performance*”. Since the IPC never has granted a TUE for Carvedilol for the Athlete, no good-faith expectation can be seen at the Athlete’s side. The Respondent explained that the Athlete has been categorized at class SH2 Ba according to Appendix One to the IPC Shooting Classification Rules & Regulations, version February 2014. The Athlete confirmed this and explained to more details which technical means of assistance are allowed according to this classification.
- 3.12. Prof. Jérôme Biollaz, specialist in internal medicine with particular expertise in pharmacological and pharmacokinetic studies on beta-blockers, and Prof. Ulf Simonsen, specialist in biomedicine, cardiovascular and pulmonary pharmacology, were heard and questioned at the same time. Prof. Biollaz expressed the opinion that Carvedilol treatment does not seem capable of providing to the Athlete an advantage in shooting performance. At best, Carvedilol may enable him to return his capacities to normal. Prof. Simonsen confirmed that he held that the effect of Carvedilol on muscle control in the Athlete is expected to be null. Carvedilol in his case is cardio-protective and, based on clinical studies, expected to delay the progression of the dilated cardiomyopathy and to prolong life expectancy. Due to the muscular dystrophy the Athlete will not have any other beneficial effects of Carvedilol. Even, if beta-blockers in general may cause a reduction in heart rate and have an influence on performance anxiety, there are differences between the various beta-blockers, and Carvedilol is to be preferred because of minimum effects. As to tremor and motor restlessness beta-blockers may have an effect in healthy athletes, but in the present case there is no sufficient muscle strength at the Athlete in order to create such effect. Prof. Biollaz confirmed the last statement of Prof. Simonsen and underlined that the variety between beta-blockers is significant, so that some beta-blockers lead to an increase of the heart rate, whereas others cause a reduction of the heart rate. Stress increases the Sympathetic Nervous System activity and, therefore, heart rate and tachycardic

muscle tremor. The increase in heart rate and tremor contributes to performance anxiety, which starts a vicious circle.

- 3.13. Both experts agreed that Athletes with heart failure do not have the same ability to decrease heart rate as do other Paralympic shooters. Beta-blockers in heart failure athletes simply compensate the disadvantages such athletes have in comparison to Paralympic athletes without heart failures. Prof. Biollaz recognised that he could not exclude the possibility of a small decrease in heart rate, but this would do no more than address the disadvantage the Athlete has by his heart failure in comparison to a Paralympic athlete without heart failure. The two heart measurements from 2010 and 2015, which exist for the Athlete, do not indicate anything with regard to his heart rate at a competition. A considerably lower heart rate measured in 2013 does not change his opinion, heart rates change frequently. Prof. Simonsen excludes a beneficial effect of beta-blockers on the heart rate in the Athlete, because the Athlete has already an increased heart rate. It would be different in other sports, other athletes and in particular healthy athletes. Prof. Biollaz concludes that on a balance of probability the effects on the heart of an Athlete suffering from a heart failure will do no more than balance the disadvantage such Athlete has. Prof. Simonsen would divide the disease of heart failure into stages. The use of beta-blockers could lead from stage 3 to stage 2 or 1 in the present case, but still a disadvantage would exist. Both experts agreed that muscle dystrophy must be taken into account as to tremor and Carvedilol has no effect on performance anxiety. Heart failure athletes have increased performance anxiety. Carvedilol is the best means to reduce this disadvantage.
- 3.14 Prof. Biollaz confirmed that the illnesses which were dealt with in CAS 2009/A/1948 and 2013/A/3437 were not at all the same as in the present case. In the ISSF case, the athlete suffered from Long QT Syndrome. Taking a beta-blocker was life-saving, but clearly gave the athlete an advantage as to enhancing performance. Prof. Biollaz, thus, agrees to CAS not having granted a TUE in that case. In the Berger case, the athlete was a hypertension patient and suffered from heart attacks. He was treated with beta-blockers, Prof. Biollaz does not remember exactly when, normally such treatment is being made over three years, but since the athlete had no medically indicated disadvantage he would have received an advantage as to sport performance when competing under influence of beta-blockers. Prof. Biollaz also in this case agrees to the decision of CAS from medical side. Both cases were different from the present case where the Athlete clearly has a disadvantage.
- 3.15. Prof. Simonsen was confronted with the statement in writing of the expert nominated by the Respondent, Prof. Pope *“I believe that Professor Simonsen’s speculations are fairly plausible, but in the final analysis they are mere speculations, rather than definitive conclusions regarding this Athlete. The fact remains that we still do not know precisely how beta blockers in general, or carvedilol in particular, exert their beneficial effects in patients with heart failure (Kaye et al., 2001). Moreover, even if we could show for certain that carvedilol has fewer beneficial effects on tremor, anxiety, and heart rate as compared to other beta blockers, we certainly could not conclude that carvedilol is devoid of such effects. In this context, I must reiterate that even a very subtle effect could easily be sufficient to substantially affect ranking in the very tightly packed field of shooters at the top of the sport”*. Prof. Simonsen stated that, as to the effects on the heart, there is plenty of documentation supporting the positive effects of treatment of cardiomyopathy with Carvedilol. Prof. Simonsen enumerated three positive effects, whilst accepting the need of

further research. Concerning the comparison of the effects, there are no big clinical trials as to tremor, because there are no life-saving effects as to this, which means there is not enough interest to invest in such studies. Therefore, there do not exist specific studies. Nevertheless, he concludes that it is highly unlikely that Carvedilol has beneficial effects on tremor, anxiety, and heart rate regarding this Athlete.

- 3.16. Prof. Biollaz notes the generality of Prof. Pope's statement and that this specific Athlete has a huge disadvantage that will not be overcome compared to other athletes assembled in the same category of disabled shooters who do not suffer from additional cardiomyopathy. Prof. Biollaz and Prof. Simonsen both confirm that they hold that the condition of art. 4.1 b) ISTUE is met if the Athlete is compared to other SH2 Ba category athletes. The beta-blocker still would at an utmost compensate the disadvantage he has because of his additional heart failure.
- 3.17. Ms Sarah Bond, responsible for the administration of shooting within IPC, explained the classes in Paralympic shooting and their differences to each other. In class SH2 athletes have an impairment in the upper and lower limbs and, therefore, need a shooting stand to support the weight of the rifle. She demonstrated to the Panel, assisted by the Athlete himself, how the Athlete, using a weak spring with flexibility minimum 35 mm, can, to some extent, stabilize and move the rifle. She showed where the point of balance of the rifle is marked, described the scoring rings and scoring possibilities and stated by comparison of data of differently ranked Final-round performances in SH1 and SH2 10 m Air Rifle Prone events, which are all done indoor, that SH2 athletes still have to control the rifle and refine their aim using their upper limbs. The role of the spring is to transfer the weight of the rifle from the fore-arm to the bone. Success in target shooting depends on a micro scale of accuracy and precision, so that even the smallest variable can have a positive effect on the Athlete's performance and can therefore be considered a competitive advantage. In 10m Air Rifle Shooting accuracy is required down to tenths of a millimetre. At such a microscopic scale, any degree of additionally refined motor skills can have an advantageous effect on the Athlete's aiming hold and score. Therefore, even the most minimal effect of a beta blocker could have an impact significant enough to be the difference in the Athlete's performance between winning a medal or not.
- 3.18. Ms Bond explained that there was a rules change and that IPC took over the TUE authority from the National Anti-Doping Organizations. IPC is also running the TUE issue for Paralympic shooting. According to Ms Bond, the classification of athletes into class SH2 was not based on one or the same disease, but focussed on particular activity limitations. Thus, various diseases are assembled in the same class based on physical tests (e.g. tetraplegia, amputations, limb deficiency, impaired muscle power, impaired passive range of movement, hypertonia, ataxia, and athetosis). Being no medical expert, Ms Bond stated that she was not involved into the classification herself, but received the classes from the classification team. The categorizations are reviewed every year as well as upon request of the athletes. Currently there are several athletes suffering from muscular dystrophy, but Ms Bond did not know, whether any other athlete besides Mr J. suffers from additional heart failure. Ms Bond confirmed that the Athlete took part in previous IPC competitions.

- 3.19. The Athlete demonstrated his chair and how the table functions, which at competitions is separate from the chair. In his concluding words, he emphasized the role sport is playing for his survival, for his social contacts and for his life with his diseases. He confirmed, that he could not feel and control the heartbeat, but hear the pulse. He wondered how a TUE system in Paralympic sports could set up unreachable thresholds of proofs for affected athletes.
- 3.20. Mr Ferrol van Hoeven, Head of Competition and Officiating of the IPC Shooting Sport Technical Committee, described the support for SH2 athletes. He held the opinion that in principle the support only takes away the weight of the rifle. He confirmed that the Athlete could not hold the rifle himself on the stand, but that somebody must help him. This is normal for class SH2. Based on a comparison between SH1 and SH2 athlete scores in the same discipline, one can infer that the support gives a comparable competition. As to the design of the support stand, from a point of view of safety, the critical element is the 80mm pin of the upper part. The second element is the resistance against bending. The support must not entirely fix nor block the rifle. The opening of the Yoke must be 10mm wider than the stock of the rifle. The athlete controls the rifle with arms, body, and the hands.
- 3.21. Prof. Jacob Wienecke, associate professor at the Department of Nutrition, Exercise and Sport at the University of Copenhagen, is a neuroscientist dealing with motor skills; he works on animal and human models and elaborates how motor skills are generated, based on laboratory studies. Prof. Wienecke held that, as a general principle, beta-blockers can reduce tremors, to some degree also with the Athlete. There are, however, no studies to date examining the effect of Carvedilol on fine motor skills, which are to be differentiated from general motor skills. Prof. Wienecke confirmed that his analysis was made on the basis of the documents received from the Athlete, and not after an examination of the Athlete himself. Studies on the Athlete himself needed to be done, in order to exclude any positive effect of Carvedilol on the Athlete. He did not check the shooting support stand of the Athlete, but followed the shooting practice of the Athlete through video documentation, which gave him the impression that the shooting stand creates a stable fix-point for the Athlete. This creates a situation where the potential effects of Carvedilol on tremor would most likely be negligible, if they exist at all. Prof. Wienecke stated that it is unlikely that any potential effect of Carvedilol on tremor reductions would manifest in enhancement of the performance for the Athlete, but showed unable from scientific point of view to specify whether this could also mean *“highly unlikely”*. Chair, table, elbow, all contacts with the ground, the whole Athlete is considered to be a fix-point in the understanding of Prof. Wienecke’s expertise.
- 3.22. Prof. Wienecke was confronted with the written statement of Prof. Pope referring to Prof. Wienecke: *“However, upon examining the videotape of the Athlete performing shooting while using the stand, it is obvious that Dr. Wienecke is simply wrong, the stand uses a spring, such that the support of the gun is not fixed, but can move in all dimensions, Therefore, a slight deficit in motor performance while holding the butt end of the gun would cause a corresponding deficit at the barrel end, and the flexible and spring loaded stand would not erase that deficit. Consequently, it is not plausible that the presence of a stand would nullify a potential performance-enhancing effect of carvedilol”*. Prof. Wienecke stated that Prof. Pope needed to supply scientific evidence to substantiate this view, but accepted that the strength of a spring might have an influence on the motor skills. The more flexible a spring is, the more an influence

needed to be taken into consideration, but he does not know the strength of the spring used by the Athlete. He assumes that the spring was quite a strong one.

- 3.23. Dr Jes Rahbek, specialist in neurorehabilitation at the Danish Rehabilitation Centre for Neuromuscular Diseases, explained the diagnosis for limb girdle dystrophy 21, heterozygote and for cardiomyopathy in the Athlete. The first signs of the disease of the above type of dystrophy during childhood and until adult age have been visible from increased fatigue and reduced muscle strength in the muscles closest to the body, such as shoulders, upper arms, pelvic area, and thighs. The weakness resulted in problems in climbing stairs, getting up from chairs and the floor and caused the patient to walk slowly and with caution. There are many subtypes of this condition with different severity, age of onset, and features. Cardiomyopathy results from this disease and was diagnosed in the Athlete in 2009. Subsequently the disease has been followed at the Heart Diseases Ward at Aarhus University Hospital. The Athlete suffers from dilated cardiomyopathy with ejection fraction reduced to 25 percent. He was first treated with ACE inhibitor Ramipril and then supplemented with Carvedilol 25 mg x 2 daily. This treatment is life-long and must not be discontinued at any time, because this would cause an irreversible reduction of ejection fraction. Dr Rahbek holds that the dose of 50 mg daily is minimal, serving only to compensate cardiac rhythm and ventricular contraction.
- 3.24. According to Dr Rahbek, an objective physical examination of the Athlete revealed no signs of a performance-enhancing effect. Dr Rahbek based this statement on his own physical measurements of the force of the muscles. The strength in the shoulder and in the hands of the muscles in the Athlete measured by Dr Rahbek was between 2+ - 3, the Athlete has no tremor and cannot have a tremor. A tremor is excluded in case of a muscle dystrophy. From measuring the muscles, Dr Rahbek could see that beta-blockers have no influence on muscles. The heart rate in the Athlete has always been between 84 – 92 and this for the last 8 years. The Athlete was in Dr Rahbek's centre regularly since 2001 and also regularly in two other departments. The Athlete's disease is progressive. In 2001, the Athlete could run and walk, this became weaker and weaker and since 2009, the Athlete is bound to a wheelchair. At present, the Athlete is categorised as grade 2, and can only withstand gravity and move his hands up to the head, but not beyond the head. Dr Rahbek has set up a report as used in rehabilitation centres, but he did also receive twice a year a report from the cardiologic department of the university hospital, last time dating from October 2015. The Athlete regularly shows up there twice a year. There they do EKGs and other cardiologic examinations. The medical documentation on the Athlete dates back at least to 2008. Dr Rahbek was not aware that the Athlete was measured with a heart rate of 74 on one occasion in 2013.
- 3.25. Dr Rahbek was confronted with the statement of Prof. Pope saying that is not possible to rule out a potential performance enhancement effect of Carvedilol simply by a physical examination of the Athlete. Dr Rahbek holds that this statement of Prof. Pope is wrong, because the Athlete has muscular dystrophy, and that it is not possible or appropriate to compare such a case to a physical measurement of muscle power in a healthy person. A person with the same disease and health issues as the Athlete will never benefit in the muscles from beta-blockers. Accordingly, Dr Rahbek, following the exact health status of the Athlete since many years, was of the view that Prof. Pope was not addressing the right question. The question is that the Athlete should

have more power in the heart muscles. The Athlete cannot have more power in his very weak skeleton muscles. Dr Rahbek did not want to make a statement that any performance enhancing effects of Carvedilol can be ruled out in general, simply by a physical examination. He wanted simply to report what he had done and that according to these examinations of the present case and of the Athlete in particular, never a positive effect of a beta-blocker on the muscles in the case of muscle dystrophy could be measured.

- 3.26. Prof. Harrison G. Pope, Jr., professor of psychiatry at the Harvard Medical School was asked by the Respondent to comment on the expert opinions submitted by the Appellants. Asked for his specific expertise in cardiology, Prof. Pope referred to having dealt with heart diseases at training at medical school and currently being engaged in a study on heart diseases of athletes using anabolic steroids. He knows that the Athlete suffers from a heart disease and is aware of his reduced heart function. He has no specific expertise on muscular dystrophy, beyond general training obtained from medical school, and has not have the possibility to examine the Athlete himself. Prof. Pope stated that he was asked to answer two questions, a general one, namely, whether beta-blockers are beneficial for performance-enhancement in shooting sports, and a specific one, whether it is highly unlikely that Carvedilol has beneficial performance-enhancing effects at this Athlete. He was specifically asked by IPC to address the standard of proof of whether it was “highly unlikely” that the Athlete will receive a performance-enhancing benefit from using Carvedilol. He has been provided with the appeal brief and the opinions of each of the four experts used by the Appellants. He was aware of the 2012 WADA TUE, but had not read the text of that decision. He only knew that the WADA TUEC had granted a TUE for Carvedilol to this Athlete.
- 3.27. Irrespective of the views of the other three experts, Prof. Pope was unable to conclude that it could not be said that because of the specificities of the present case, it is highly unlikely that Carvedilol has any performance-enhancing effects on this Athlete. One could only say that Carvedilol might not affect the Athlete’s performance, or that there are less effects of Carvedilol on the Athlete’s performance than of other beta-blockers. In Prof. Pope’s view, the Athlete must show on a balance of probability that it is highly unlikely that Carvedilol has any effects on the Athlete’s performance. Prof. Pope did not know the ISTUE. His understanding of the criteria comes from the reading of the appeal brief, which quotes the four criteria from the ISTUE, three of which were clearly met. The criterion of art. 4.1 b) is the critical one and Prof. Pope addressed indeed this criterion. Most of the studies Prof. Pope is quoting in his statement are general studies on the effects of beta-blockers, on situations other than athletes. The studies specifically done on shooters are studies on healthy shooters. He does not know whether there is any study on shooters with muscular dystrophy. He recognised that the studies on shooters did not include any study on athletes with cardiomyopathy. Lacking such studies, he has extrapolated what is known with regard to healthy shooters on athletes with muscular dystrophy or cardiomyopathy. The information relating the medical status of the Athlete on which Prof. Pope relied is the one described in the appeal brief. Besides, IPC had sent to him two or three occasional heart measurement results of the Athlete, taken over the last years, but no further medical evaluations have been made available to him.

- 3.28. Prof. Pope agrees that the effect of a beta-blocker depends on its nature, on the person concerned and on the person's illness. Prof. Pope admits that it is not possible to extrapolate results from studies on healthy athletes to athletes with muscular dystrophy: such an extrapolation could be done with other healthy athletes, but not within the frame of Paralympic athletes. Prof. Pope holds, however, that the burden of proof, being with the Athlete, obliges the Athlete to demonstrate, on a balance of probability basis, that it is highly unlikely in his particular case that these effects are being given. Prof. Pope further states that there is no study proving that Carvedilol has or has not an effect on performance-enhancement on a shooter with muscular dystrophy. The only way of finding this out would be to exercise a rigorous placebo study, meaning that an athlete receiving Carvedilol is doing many, many shots, and then the same athlete is doing many, many shots while receiving a placebo. Both, the athlete, as well as the scientific observer must be blinded as to the receipt of Carvedilol and the placebo. In the absence of such study, there is no definite proof of whether Carvedilol has a performance-enhancing effect or not.
- 3.29. Prof. Pope holds that such study would be very difficult, even prohibitively dangerous in this particular Athlete, because it would mean that the life-securing Carvedilol needed to be replaced by a placebo. The difficulty of such study does not allow, from a scientific point of view, to assume in the absence of such study that Carvedilol has no performance-enhancing effect. Therefore, such double-blind study is the only way of proof in this particular Athlete and, once having been successful, grant a TUE. Such proof is even necessary given the wording of art. 4.1 a) ISTUE. The fact that the Athlete suffers from a progressive disease, which causes that he never will return to normal state of health in the sense of art. 4.1 b) WADA ISTUE, has no relevance for how to prove that it is highly unlikely that Carvedilol has any effect on shooting performance.
- 3.30. Prof. Pope does not doubt that it is very likely that Carvedilol is beneficial for dealing with the Athlete's disease. Prof. Pope also finds speculations of experts he had to review that from a pharmacological point of view it is less likely that Carvedilol will have any performance-enhancing effect in this particular Athlete than at healthy athletes or compared to other beta-blockers, plausible. But such plausible speculations do not mean more than assuming that it may be probable. "Probable", however, does not meet the high threshold of "highly unlikely". Prof. Pope believes, that the speculations have some merits, but they do not reach the "highly unlikely" requirement. Upon questions raised by the Panel, referring to the wording of art. 4.1 b) ISTUE, Prof. Pope confirmed that the standard he applied was whether it was highly unlikely that Carvedilol had any performance-enhancing effect on this particular Athlete.
- 3.31. Requested to answer a different standard meaning "*Would this prohibited substance taken by this Athlete produce an additional enhancement of performance under condition that by some mystery the disease he has would simply disappear?*", Prof. Pope holds that this could not be answered affirmatively or negatively, but it could also not be said that it is highly unlikely that Carvedilol has any additional performance-enhancing effect in such condition. Prof. Pope admits that it is speculative to assume what components of shooting performance result from the return to the normal state of health and what over and above from the use of Carvedilol. However, he was unable to

conclude that it is “highly unlikely” that the Athlete has any benefit over and above his return to his individual, very specific “normal state of health” from using Carvedilol.

- 3.32. In summary, Prof. Pope stays with his answer to the general question and finds that *“beta blockers unequivocally have beneficial effects on tachycardia, motor restlessness, tremor, and performance anxiety – symptoms that often occur in stressful situations, and that typically impair fine motor performance. Thus, there is no doubt that this family of drugs is performance enhancing in sports such as competition shooting, especially at the elite international competitive level, where differences in the leading competitors’ scores can be extremely small. ...”*.
- 3.33. As for the specific question, Prof. Pope stays with requiring to *“show under methodologically sound conditions that the Athlete experienced no beneficial decrease in his heart rate from carvedilol, one would need, at a minimum, to perform extensive, recorded monitoring of his heart rate, under actual anxiety-provoking competition conditions, both when taking carvedilol and when taking an inert placebo, under conditions where both the Athlete and the scientists conducting the experiment were blinded as to when he was receiving the active drug and when he was receiving the placebo (a so-called “double blind study”). If one could perform such a study and could show that there was no statistically significant improvement in the Athlete’s heart rate on carvedilol as compared to placebo, then – and only then – could one reasonably conclude that the athlete did not experience this particular benefit from this drug”*.
- 3.34. In their concluding remarks, the Appellants emphasized that the effect of not granting a TUE would be that the Athlete would be unable to participate at any organized training and sport, on a club, national and international level. They argued that the ISTUE is asking not for a scientific standard of proof, but for a balance of probability standard of proof. Such standard does not ask for a strict, scientific evidence. The issue of whether “it is highly unlikely” that Carvedilol has any additional performance-enhancing effect on the Athlete does not define the standard of proof, but is in fact an issue of proof. They hold that the evidence submitted by the Appellants is more convincing than the evidence submitted by the Respondent, which used a psychologist, who is not an expert in the relevant field and has not been provided with the full medical file. On one hand, the expert witness offered by Respondent did only extrapolate studies on healthy athletes to impaired athletes and set a standard of proof, which – reading art. 4.1 a) and b) ISTUE together – simply is impossible to meet. The Appellants’ experts, on the other hand, could demonstrate that the Athlete’s heart failure causes an additional disadvantage compared to other SH2 athletes, which is, at the upmost, compensated by using Carvedilol. They have demonstrated that the two CAS cases referred to by the Respondent deal with totally different medical facts. Reducing the heart rate does not automatically enhance sport performance. The Athlete cannot influence and use his heart rate, and he has no tremor, because his muscles do not react. Simply to extrapolate results from healthy athletes to impaired athletes is not sufficient. Otherwise, the Appellants confirmed their submissions in writing.
- 3.35. Also the Respondent in its concluding remarks particularly addressed the question of standard of proof and confirmed its submissions in writing. It is a two-stage test which is to be applied. The test is specific to this Athlete and there is no comparison to other athletes. It is the same test as it has been applied in the two CAS cases referred to earlier. In both previous CAS cases, it was looked at the possible enhancement in the performance, over and above the treatment

of the particular disease. In the case at hand, the question at stake is what needs to be done in order to treat the dilated cardiomyopathy of the Athlete. In the Respondent's view, the disease requires stabilization of the heart rate. "Highly likely" means less than "absolutely sure" and, thus, means less than asked for by the earlier ISTUE versions. But "highly unlikely" is more than just "unlikely" and sets a very high standard, which is justified in order to guarantee a level playing field. The burden of proof is with the Athlete. If he cannot fulfil the requirements, this simply means that he cannot receive a TUE. The Respondent tries to be inclusive, but not at any cost and, in particular, not at the expense of a fair competition. The letters of support by some athletes provided by the Appellants emphasize this requirement. The Respondent underlines that the Athlete did not meet the standard of proof.

- 3.36. At the end of the hearing, the parties confirmed that they had no objections to the manner how the Panel conducted the proceedings and the hearing.

IV. SUBMISSIONS OF THE PARTIES

- 4.1. The Parties agree as to the jurisdiction of the CAS, based on art. 13.4 read together with art. 4.4.6.2 of the IPC Anti-Doping Code and the last paragraph of the decision of the WADA TUEC of 3 December 2015. The IPC regulations, in particular the 2015 IPC Anti-Doping Code and the 2016 ISTUE shall be the applicable rules (cf. CAS 2010/A/2178, para. 12). The 21-day deadline for the statement of appeal and the two times prolonged deadline for the appeal brief as well as the prolonged deadline for the answer of the Respondent have been met. As to the costs art R65 of the CAS Code applies.

- 4.2. The parties also agree that art. 4.1 of both the 2015 ISTUE and the 2016 ISTUE list the conditions to be met in order for an athlete to be granted a TUE. This provision reads as follows:

"a. The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.

b. The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.

c. There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method.

d. The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use".

- 4.3. The Challenged Decision and the WADA TUEC decision find that the condition of art. 4.1 (b) ISTUE is not met.

a. The Appellants

- 4.4. As mentioned above, the Appellants contest this finding and start their argument from the 2012 WADA TUE, where the WADA TUEC concluded, on 26 August 2012, that the use of Carvedilol would not produce any “*additional enhancement of performance other than might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition*”. The decision, which the Appellants argue, was accepted by the IPC, covered the London 2012 Paralympics and IPC competitions of 2013 and 2014. The Appellants quote from this decision inter alia the following:

“The use of Carvedilol and Ramipril is clinically appropriate, as they are the cornerstone of the treatment of myocardial dysfunction and there are data supporting their use in muscular dystrophy (...)”

and

“There is evidence that acute withdrawal of a beta-blocker could put this individual at significant increased risk, resulting in increased morbidity and mortality. Withdrawal symptoms can occur due to increased sympathetic activity, likely a reflection of adrenergic receptor up regulation during the period of sympathetic blockade, resulting in increased heart rate, arrhythmia, more rapid progression of left ventricular dysfunction and a risk of heart failure. In summary, this athlete requires Carvedilol therapy to maintain cardiovascular stability and to maximize his cardiovascular protection. Discontinuation of this medication for any length of time is detrimental to his wellbeing”.

- 4.5. Given the current medical condition of the Athlete, the Appellants wonder why in view of an identical medical condition, an identical medical treatment of the Athlete, and a stricter wording of the respective provision of the then applicable 2011 ISTUE, a TUE was granted then and has not been granted in 2015. Whereas the 2011 ISTUE had required that the “*Therapeutic Use of the Prohibited Substance or Prohibited Method would produce no additional enhancement of performance*”, the 2015 or 2016 ISTUE require that the “*Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance*”. Thus, under the 2011 ISTUE the Athlete had to prove the absence of performance enhancing effect. Under the 2015 and 2016 ISTUE it is sufficient for an Athlete to demonstrate on a balance of probability that a performance enhancing effect is highly unlikely.
- 4.6. The Appellants conclude from the above comparison that based on the legal principles of fairness, good faith and prohibition of *venire contra factum proprium*, as regularly applied by CAS (notably CAS 2002/O/410, CAS OG 02/006, CAS 2008/O/1455), legitimate expectations have been created on the part, or in favour, of the Athlete. Thus, the Respondent and WADA are barred from changing their course of action to the detriment of the Athlete. The Athlete became an international-level Paralympic athlete in good faith and is now forced by the Challenged Decision confirmed by WADA, to end his sporting career. This fact violates the above mentioned principles.
- 4.7. According to the Appellants, art. 4.1 of the 2016 ISTUE sets the balance of probability standard for proof and followed a respective advice by CAS in CAS 2013/A/3437. The previous versions

of the ISTUE did not provide for a clear rule to this end. The 2016 ISTUE in the opinion of the Appellants brought no deviation, but a clarification in view of the CAS recommendation. For the case that the Panel would rule that the 2015 ISTUE is the applicable regulation on the present case, the application of the balance of probability standard of proof follows from the principle *contra proferentem* and from the *lex mitior* rule.

- 4.8. The Appellants hold that in the Challenged Decision and in the WADA TUEC confirmation, a “beyond reasonable doubt” standard was applied, when the Athlete was required to categorically exclude a potential effect of Carvedilol on his shooting performance. This represents the highest standard of proof, usually utilised in criminal trials. Both organisations erred in applying this *beyond reasonable doubt* standard in the context of art. 4.1 ISTUE.
- 4.9. The Appellants quote from CAS 2009/A/1987, CAS 2009/A/1844 and CAS 2006/A/1385 as definition for the balance of probability standard: *“The balance of probability means that the athlete alleged to have committed a doping violation bears the burden of persuading the judging body that the occurrence of a specified circumstance is more probable than its non-occurrence”*.
- 4.10. The Appellants argue that the WADA TUEC would have granted the Athlete a TUE, if it was cognisant of had applied the correct standard of proof.
- 4.11. In the opinion of the Appellants, the Respondent and WADA did also not realise that since 1 January 2015 it was not to demonstrate anymore that the use of the otherwise prohibited substance would produce *“no additional enhancement of performance”*, but *“that it is highly unlikely to produce any additional enhancement of performance”*. The difference between both rules lies in that under the 2015 and 2016 ISTUE, even if a performance enhancing effect is possible, a TUE must be granted, if the effect is highly unlikely. Under the previous ISTUE versions in such a case a TUE had to be denied. The Challenged Decision did not realise this difference and continued to apply the former versions. They applied the “no performance enhancing effect” standard instead of the “highly unlikely” standard.
- 4.12. The Appellants argue that the CAS decisions CAS 2009/A/1948 and CAS 2013/A/3437, which the Challenged Decision refers to, do not constitute “precedents” to decide the present matter, because medical treatment must be analysed on a case by case basis, because the ISTUE standard to be applied has changed since then, because there was no previous TUE already granted for the same substance before in these cases, and because in difference from the present case both cases did not address the case of an athlete allowed to use a rifle support. Besides, the CAS decisions in both cases were heavily criticized by prominent legal scholars as the result of these awards contradicts to the fourth Fundamental Principle of Olympism contained in the Olympic Charter.
- 4.13. The Appellants demonstrate, why, on a balance of probability, the Athlete has fulfilled all four criteria of art. 4.1 ISTUE. Art. 4.1 (a) has been fulfilled, because the Athlete has been diagnosed with muscular dystrophy with associated deterioration of left ventricular function and has been prescribed Carvedilol and Ramipril, which are considered to be a standard of care. Art. 4.1 (c) has been fulfilled, because there is clear evidence that both prescribed substances are the

cornerstones of the treatment of myocardial dysfunction and there are data supporting their use in muscular dystrophy. Carvedilol is one of three beta-blockers significantly improving the heart function, morbidity and mortality. There is evidence that the acute withdrawal of a beta-blocker could put the Athlete at significant risk, resulting in increased morbidity and mortality. The Athlete requires Carvedilol to maintain cardiovascular stability and to maximise his cardiovascular protection. Discontinuation of this medication for any length of time is detrimental to the Athlete's wellbeing. As to Art. 4.1 (d), it is clear that the Athlete's cardiac complications are a consequence of the underlying muscular dystrophy and not of the prior use of a substance or method prohibited at that time. Thus, also this provision has been fulfilled.

- 4.14. Discussing the criteria of art. 4.1 (b), the Appellants argue that the Challenged Decision makes no reference to the specific facts of the case at hands and does not apply the applicable standard of proof. In the opinion of the Appellants, *"the Athlete has to demonstrate that it is more probable than not that the use of Carvedilol is highly unlikely to produce any performance enhancing benefits over and above what might be anticipated by the Athlete's normal state of health"*.
- 4.15. The Appellants analyse the Challenged Decision and its confirmation by WADA as to which peripheral effects could affect shooting performance and list for the Respondent cardiovascular benefits, skeletal muscle relaxation, reduction of tremor, and reduction of psychological stress/anxiety, and for WADA neuro-hormonal changes, motivation, hydration, electrolyte balance and nutritional status.
- 4.16. The Appellants see four possibilities of defining the Athlete's normal state of health. Considering the wording of the provision, the Appellants exclude the options *"the state of health of a healthy adult male of the Athlete's age"* and *"the state of health of a male of the Athlete's age suffering the same conditions, namely muscular dystrophy and/or dilated cardiomyopathy"*. Since the Athlete has suffered from muscular dystrophy with dilated cardiomyopathy since childhood, since both diseases cannot be cured, but can only be prevented from rapidly worsening, and since the Athlete has always competed in the SH2 category with the need for Carvedilol, it can also not be *"the state of health of the Athlete prior to any ailment"*, but only the understanding *"the state of health which allows the Athlete to live"*. The Athlete can only live with daily use of Carvedilol.
- 4.17. The Appellants admit that the Athlete has to prove, on a balance of probability, that the use of Carvedilol is highly unlikely to have an additional performance enhancing effect. The Athlete has the difficult task of proving a negative fact, he faces an "evidence calamity". For such a situation, the CAS Panel in the Contador case (CAS 2011/A/2384 & CAS 2011/A/2386) had held *"that while there is no re-allocation of the burden of proof, such cases will result in a "duty of cooperation" of the contesting party"*. This rule applied on the present case means in the view of the Appellants, that the Athlete only needs to show that the facts alleged by him are possible. The Respondent must substantiate and explain in detail why the facts alleged by the Athlete are wrong.
- 4.18. The Appellants argue, that the Athlete has no chance to meet the requirements of WADA, laid down in its TUE Guidance for Cardiovascular Conditions. This Guidance, which includes an Algorithm for assessing a TUE application for beta-blockers, states that *"it may be necessary for an athlete to go beyond clinical assessments of treatment success and include systematic measurements of physiological*

and performance parameters before and after medication in their application". In the present case, this requirement could only be fulfilled at the risk of life of the Athlete.

- 4.19. The Appellants hold the opinion that, irrespective of this difficulty, the evidence actually provided by the Athlete is sufficient to satisfy the balance of probability. They point at the differences in profiles and effects of beta-blockers and give the evidence of expert opinion holding that as to Neuro-hormonal changes, Carvedilol's use in congestive heart failure has limited effect on heart rate. At two separate measurements under treatment with Carvedilol, the Athlete's resting heart rate was nearly the same and remained at the upper end of the scale for a normal resting heart rate. The Athlete also had a normal blood pressure. There was no beneficial slowing of the heart measurable, which would produce a performance enhancing effect. On a balance of probability, the Athlete does not enjoy any performance enhancing benefit beyond to return to a normal state of health vis-à-vis cardiovascular function.
- 4.20. As to tremor reduction and muscle relaxing, according to the Appellants it needs to be considered that the Athlete is permitted to use a support stand for his rifle. Tremors, thus, are not critical for the SH2 class. An eventual effect is mediated via the bradycardiac effect of beta-blockers, fatigue increases physiological tremor and, therefore, stands against, as does the less lipophilic nature of Carvedilol compared to other beta-blockers like Propranolol. The Athlete's use of Carvedilol is long-term and he has always competed with using it. Thus, there are no additional benefits over and above his normal state of health.
- 4.21. As to stress and anxiety reduction, the Appellants argue that even, when taking Carvedilol, the Athlete's heart rate remains relatively high. This fact, together with the support stand eliminates any advantage gained by a possible reduction in tremor. Carvedilol does not serve to reduce the physical effects of stress and anxiety on the Athlete.
- 4.22. As to motivation, the Appellants admit that, in general, beta-blockers may lead to less stress, but it cannot be argued that such an effect has to be considered a performance enhancer.
- 4.23. As to hydration, the Appellants argue that by improving cardiac function and by decreasing the renin-angiotensin-aldosterone system as an effect of Carvedilol, at best a return to a normal function could happen. Therefore, on a balance of probability, it is more likely that Carvedilol does not have a performance enhancing effect on the Athlete's hydration.
- 4.24. As to the electrolyte balance, the Appellants state that Carvedilol tends to impair the entry of potassium into the cells, the clinical effect on the plasma potassium concentration is however minor. It is not expected that the effects on potassium enhance the performance of the Athlete, but they play a preventive role against cardiac arrhythmias.
- 4.25. As to the nutritional status, the Appellants hold, that Carvedilol may lead to weight gain. This may happen, however, as a consequence of either deterioration in heart failure or an improvement in cardiac function. The first effect would be detrimental for performance, the second would result in more or less a return to a normal state.

4.26. Summarizing, the Appellants hold that *“the Athlete has shown that, on a balance of probability, his use of carvedilol is highly unlikely to produce performance enhancing effects over and above his normal state of health. The normal state of health must be looked at subjectively and consider the particular circumstances of the Athlete. Thus, given that the Athlete can only be alive with the use of carvedilol and that there will be no “return” to a former state of health, the normal state of health of the Athlete is him taking carvedilol to avoid serious heart failure. Even so, the Athlete has proven that carvedilol has, at most, negligible effects on him”*. The absence of a performance-enhancing effect is confirmed by the 2012 WADA TUE and the experts Professors Biollaz, Simonsen, and Wienecke. The Athlete, thus, has discharged his burden with the best available evidence he had in order to prove a negative fact. Besides, to treat him today differently from the 2012 WADA TUE in 2015 would be highest unfair. The Athlete has the support of other competitors.

4.27. The Appellants submit the following Prayers for Relief:

- “1. The decision of the International Paralympic Committee Medical Committee dated 19 August 2015, upheld by the decision by the WADA Therapeutic Use Exemption Committee dated 3 December 2015, is set aside.*
- 2. J. is granted a Therapeutic Use Exemption permitting him the use of Carvedilol 25mg taken twice daily for a period of four years.*
- 3. The International Paralympic Committee shall bear all costs of this arbitration, if any, and shall reimburse any and all advances of costs paid by J. and Anti Doping Denmark, including the minimum Court Office Fee of CHF 1,000.*
- 4. IPC shall be ordered to compensate J. and Anti Doping Denmark for the legal and other costs incurred in connection with these proceedings, in an amount to be determined at the full discretion of the Panel”*.

b. The Respondent

4.28. The Respondent emphasizes that all parties agree that the Athlete meets the conditions of art. 4.1 (a), (c), and (d) ISTUE. The only issue to be determined by the CAS Panel is whether the Athlete has met his burden under art. 4.1 (b) ISTUE *“of showing, on the balance of probabilities, that his use of Carvedilol is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to his normal state of health following the treatment of his medical condition”*. The Respondent and WADA say that he has not.

4.29. The Respondent underlines that beta-blockers, including Carvedilol, are prohibited both in and out of competition in the sport of shooting. The Athlete, therefore, has the burden of establishing, on the balance of probabilities, that the requirement of art. 4.1. (b) ISTUE, as condition for obtaining a TUE permitting the use of Carvedilol, has been met. The Respondent admits that the WADA TUE regime is tight. If the Athlete does not meet his burden of proof, he cannot be granted a TUE. Behind the system stands the efforts to strike a balance between the need for a TUE process and the need to maintain a level and fair playing field. The underlying rationale for the Respondent’s classification rules is the need to ensure that athletes are able to compete on a level playing field, where the outcome is determined by the skills and abilities of the athlete and not by his/her impairment. Thus, the athlete and the coach, that wrote letters in support of the Athlete, wanted to see athletes to be allowed to compete using

Carvedilol, *“if there is clear indication that their use of medicine due to their disability is not giving them an advantage”*.

- 4.30. The Respondent acknowledges that the result of the Challenged Decision for the Athlete is very unfortunate, but refers to the same consequences of the CAS decisions in the cases CAS 2013/A/3437 and CAS 2009/A/1948 for the respective shooters.
- 4.31. The Respondent holds that it has met the requirements ensuing from the Appellants’ difficulty to prove a negative fact or from the *“evidence calamity principle”*. The Respondent believes that it has fully complied with any duty of cooperation ensuing from this principle. Relying on the case CAS 2011/A/2384 & 2386 at para 255, the Respondent holds the view, that such duty of the opposing party consists in substantiating and explaining why it considers that the facts submitted by the other party are wrong. The Respondent holds that it has made available to the Athlete all relevant information within its control and has instructed an independent expert, Professor Pope, to review the further evidence submitted by the Athlete in support of his appeal. It has provided an expert report and made the expert available for questioning at the hearing.
- 4.32. The Respondent holds that the Athlete has not established that his use of Carvedilol is highly unlikely to produce any additional enhancement of performance. Since beta-blockers do not necessarily enhance performance for all athletes in all circumstances and do not all produce the same effects, it is necessary to carry out a case-by-case assessment. The burden of proof relates to the particular athlete and his case. The Athlete has to show why he in particular would not be experiencing a benefit from his particular beta-blocker, given that beta-blockers in general benefit precision sports and there is overwhelming evidence for that.
- 4.33. The Respondent underlines that the fact that the Athlete might have done all that he can to try and meet his burden is not enough and refers to CAS 2013/A/3437 at paras 325-326. There the Panel stated that the *“issue for the Panel however is not whether the Athlete has done all that she could do to provide evidence but whether the evidence which she has actually provided is sufficient to establish that the criterion in 4.1 (b) is satisfied. The Panel concludes that it is not”*.
- 4.34. The Respondent holds further, that the Athlete cannot rely on the doctrine of legitimate expectation. This doctrine means in the understanding of the Respondent that *“where the conduct of one party has induced legitimate expectations in another party, the first party is then estopped from changing its courses of action to the detriment of the second party”*.
- 4.35. The Respondent argues that it has consistently taken the view that the Athlete does not meet the criteria for the grant of a TUE for Carvedilol throughout the Athlete’s career. It has refused three separate TUE applications by the Athlete (21 August 2012, 22 December 2014, 19 August 2015). Also the fact that the Respondent did not appeal the 2012 WADA TUE does not contradict such consistent behaviour of the Respondent. There were only five days between the decision and the start of competition of the Athlete at the 2012 London Paralympics, which was not enough time to consider and prepare a proper appeal. Also cost considerations played

a role in view of the Respondent's very limited anti-doping budget. The Respondent never made any appearance on the Athlete that it would grant or recognise a TUE for him.

4.36. The Respondent submits the following Prayers for Relief:

*“(a) to dismiss the appeal brought by Mr J. and ADD;
(b) uphold the IPC’s decision of 19 August 2015 not to recognise the TUE granted to Mr J. by ADD for use of Carvedilol;
(c) order that Mr J. and ADD bear the costs of this arbitration, if any; and
(d) order that each of the parties bear their own legal and other costs”.*

V. CAS JURISDICTION AND ADMISSIBILITY

5.1. The jurisdiction of the CAS follows from art 13.4 read together with art 4.4.6.2 IPC Anti-Doping Code. These provisions read as follows:

“Art. 13.4

TUE decisions may be appealed exclusively as provided in Article 4.4 above”.

“Art. 4.4.6.2

Any TUE decision by the IPC (or by a National Anti-Doping Organisation where it has agreed to consider the application on behalf of the IPC) that is not reviewed by WADA or that is reviewed by WADA but is not reversed upon review, may be appealed by the Athlete and/or the Athlete’s National Anti-Doping Organisation exclusively to CAS in accordance with Article 13”.

5.2. Additionally, number 3 of the WADA TUEC decision dated 3 December 2015 advised the Appellants to submit such appeal to the CAS within 21 days from receipt of that decision.

5.3. The jurisdiction of the CAS and the admissibility of the appeal are undisputed and have been confirmed by both parties upon signature of the Order of Procedure.

5.4. It follows that the CAS has jurisdiction to decide the present case and that the case is admissible.

VI. APPLICABLE LAW

6.1. Article R58 of the CAS Code provides as follows:

“The Panel shall decide the dispute according to the applicable regulations and, subsidiarily, to the rules of law chosen by the parties or, in the absence of such a choice, according to the law of the country in which the federation, association or sports-related body which has issued the challenged decision is domiciled or according to the rules of law the Panel deems appropriate. In the latter case, the Panel shall give reasons for its decision”.

- 6.2. In the present matter, the parties have agreed, that the IPC regulations - in particular the IPC Anti-Doping Code, the IPC Shooting Classification Rules and Regulations and the IPC Shooting Technical Rules and Regulations - are primarily applicable to this matter.
- 6.3. Art. 4.4 IPC Anti-Doping Code refers as to the details of TUEs to the WADA International Standard for Therapeutic Use Exemptions (“ISTUE”). Even though the Challenged Decision was issued under the legal effect of the 2015 ISTUE, the 2016 ISTUE, which entered into force on 1 January 2016, applies on the present matter. The Panel follows the established jurisprudence of the CAS holding that technical or procedural regulations enter into force forthwith (see e.g. CAS 2010/A/2178 at para 12). Both parties have accepted the “balance on probability” standard as to the criteria under art. 4.1 ISTUE, formally introduced by the version 2016 of the ISTUE.
- 6.4. WADA, thereby, implemented a recommendation set by the CAS in CAS 2013/A/3437 at para. 298 and followed its own argumentation in that case against the opinion of the ISSF, which contended for “comfortable satisfaction” (see at para 293). The Panel in that case did not see a need to resolve this issue, but recommended WADA in any revision of the ISTUE to address it specifically.
- 6.5. The ISTUE 2015, which was in force, when the ADD granted the TUE at stake (3 July 2015), and the Challenged Decision (19 August 2015) as well as the WADA TUEC confirmation of non-recognition of the TUE (3 December 2015), did not yet implement this recommendation. The introductory part of art 4.1 read as follows:
- “4.1 An Athlete may be granted a TUE if (and only if) he/she can show that each of the following conditions is met: ...”.*
- 6.6. The introductory part of art. 4.1 ISTUE 2016 reads as follows:
- “4.1 An Athlete may be granted a TUE if (and only if) he/she can show, by a balance of probability, that each of the following conditions is met: ...”.*
- 6.7. The wording of the further text of the two versions of the ISTUE is virtually identical. There was, however, a comment to art. 4.1 in the 2015 version, which has not been included in the 2016 version. This comment read as follows:
- “[Comment to 4.1: When a TUEC is deciding whether or not to recognize a TUE granted by another Anti-Doping Organization (see Article 7, below) and when WADA is reviewing a decision to grant (or not to grant) a TUE (see Article 8, below), the issue will be the same as it is for a TUEC that is considering an application for a TUE under article 6, below, i.e., has the Athlete demonstrated by a balance of probability that each of the conditions set out in article 4.1 is met?].”.*
- 6.8. It follows from the above comment that in line with WADA’s argumentation in CAS 2013/A/3437 already under the 2015 ISTUE the applicable standard of proof was “by a balance of probability”. Since the fact that the quoted comment has not been adopted in the 2016 ISTUE is of no legal relevance (because the comment explained a legal fact, which was self-

evident under the 2015 ISTUE and remains self-evident under the 2016 ISTUE, whether explicitly mentioned or not), the Panel considers that the 2015 ISTUE and the 2016 ISTUE as to art. 4.1 are – at least for the matters at stake in the present proceedings – materially identical as to their substance. Thus, none of the parties suffers from the fact that the 2016 ISTUE wording is more precise than the 2015 ISTUE and the Panel, in line with CAS 2010/A/2178, finds the 2016 ISTUE being the applicable regulation.

6.9. Subsidiarily, German law, as the law of the seat of the IPC, applies.

VII. MERITS

1. The Object to Prove under Art. 4.1 (b) ISTUE

- 7.1. Since both parties explicitly agree that the criteria of art. 4.1 (a), (c), and (d) ISTUE (for the text see para. 4.2 above) have been satisfied by the Athlete, and considering that indeed the discussion with the experts at the hearing has confirmed this finding, the Panel has no need to address the respective analysis of these aspects made by the Appellants in their appeal brief. The Panel restricts itself to addressing the single issue on which the parties disagree: is this Athlete able to show, by a balance of probability, that the therapeutic use of a prohibited substance is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition? If yes, he fulfils the requirements of art. 4.1 (b) ISTUE; if no, he does not.
- 7.2. The Panel expresses its appreciation to all the experts, for the reports and for having made themselves available at the hearing. Their professional and independent contributions have helped the Panel understand the particular medical condition of the Athlete, and the effects of his medical treatment.
- 7.3. The Panel agrees with the parties that art. 4.1 (b) as applicable to this particular Athlete at the time reads as follows: *“The Therapeutic Use of Carvedilol ... is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of his dilated cardiomyopathy”*.
- 7.4. In light of the evidence at the hearing, and the submissions of the parties, the Panel concludes that the disease of “dilated cardiomyopathy” had no influence on the classification of the Athlete in the category SH2. Ms Bond explained that the further underlying disease in the Athlete, which is “muscular dystrophy”, was decisive to associate this Athlete with other athletes suffering from other diseases which led to a comparable activity limitation (see para. 3.19 above) in the same class for Paralympic shooting. Ms Bond and other representatives of the Respondent were unable to state to the Panel whether athletes other than Mr J. suffering from muscular dystrophy and included in the category SH2 also suffered from dilated cardiomyopathy. They were also unable to indicate to the Panel whether athletes suffering from other diseases (e.g. amputations and the like), assembled in the same SH2 class, suffered from dilated cardiomyopathy. Lacking such information, the Panel concludes that the complication

of “dilated cardiomyopathy” gives this Athlete an additional disadvantage in comparison to the other athletes of the SH2 class. Whereas his muscular dystrophy puts him on equal ground with the other SH2 category shooters, his dilated cardiomyopathy puts him in a position that is worse than the other athletes of his category.

- 7.5. In the course of the hearing all the experts agreed that the dilated cardiomyopathy in the Athlete is irreversible and cannot be cured. Thus, the last part of the sentence of art. 4.1 (b) ISTUE (“*return to the Athlete’s normal state of health following the treatment of his dilated cardiomyopathy*”) is a situation that must take into consideration the concrete state of health of the Athlete and cannot refer to an abstract, impossible to reach, state of health without any “handicap”. In other words, in Paralympic sports in particular, the relevant “state of health” is not one without any limitation and without any handicap. What is relevant is the difference of the state of health of a Paralympic athlete with or without the use of a medication needed for his or her particular, additional sickness. In this case: the dilated cardiomyopathy. The sentence, thus, is premised on a fictional situation, inviting a decision-maker to assume the possibility that the Athlete could be returned to a state of health without dilated cardiomyopathy following the treatment with Carvedilol. Assuming that this would and will be the case, it appears that the object to be proven is that it is highly unlikely that the use of Carvedilol will produce any additional enhancement of performance by this Athlete who would compete against other Paralympic athletes of his class.
- 7.6. In order to apply that standard, the Panel considers it to be significant that the experts have agreed that Carvedilol does not treat the underlying muscular dystrophy. If there were to be any therapeutic effect of Carvedilol for the treatment of the muscular dystrophy in this Athlete, the object of proof would have to be re-visited. None of the experts submitted that Carvedilol might have any therapeutic effect on the disease of muscular dystrophy in the Athlete. They disagreed, on the other hand, as to whether Carvedilol might interfere with the disease of muscular dystrophy, thus, additionally enhancing his otherwise performance as a shooter of category SH2 (Prof. Biollaz, Prof. Simonsen and Dr Rahbek expressed one view, albeit in differing respects, and Prof. Pope expressed a contrary view). The difference of opinion appears to be premised on the different areas of expertise: in particular, Prof. Pope, who is professor of psychiatry at the Harvard Medical School, does not deal directly with dilated cardiomyopathy and/or muscular dystrophy.

2. The Eventual Factors enhancing Performance

- 7.7. The respective discussion at the hearing led to a focussed assessment of three dominant aspects. The experts in line with the WADA TUE Physician Guidelines “Cardiovascular Conditions: The Therapeutic Use of Beta-blockers in Athletes” focussed on discussing the possible effects of Carvedilol on (1) heart rate, (2) tremor, and (3) anxiety and motor restlessness of the Athlete. These elements were identified as influencing performance in shooting as a highly technical sport, where without any doubt accuracy plays a key role (see at para 3.12 above). Ms Bond and Mr van Hoeven demonstrated to the Panel, assisted by the Athlete and shown by the Athlete himself, that due to a weak spring with flexibility minimum 35 mm, used by the Athlete, irrespective of a support stand, the rifle is not fixed. In this way they asserted that Carvedilol’s

effects on heart rate, tremor, and/or on anxiety and motor restlessness might have an influence on his shooting performance. The Panel accepts that view.

- 7.8. The Panel held that the opposite expert opinion of Prof. Wienecke suffered from the fact that he was only able to rely on videos showing the Athlete in shooting. The videos together with the lack of knowledge of the technical rules and erroneous assumptions as to the strength of the spring, led to a conclusion which the Panel has not been persuaded by.
- 7.9. As to the standard, the Panel applies a “balance of probability” test, followings established CAS jurisprudence (see para 4.9 above, the correct decision, however, the quotation emanates from, is: CAS 2009/A/1817 & 1844 at para 50). The Panel holds, that it is more probable than not that the Athlete has some control over the rifle.

A. *The Heart Rate*

- 7.10. The Athlete provided evidence in expert opinions of Prof. Biollaz and Prof. Simonsen to show that the Athlete does not have same propensity to a decreased heart rate as other SH2 shooters. The effect of Carvedilol is to compensate as much as possible the disadvantages of this Athlete in comparison to other SH2 shooters. According to Prof. Biollaz, on a balance of probability, the effects of Carvedilol on the heart of the Athlete will not eliminate the Athlete’s disadvantage. Prof. Simonsen holds the opinion that Carvedilol could lead from stage 3 to stage 2 or 1, but that would still be at a disadvantage as compared to other Athletes. Even if the two experts hold a slightly different opinion, they agree that Carvedilol in the Athlete does not lead to an additional enhancement of performance by decreasing his heart rate. The Athlete explained that he can hear the pulse and listen to his heart but is not able to influence his heart rate.
- 7.11. The Panel took note of the evidence of Prof. Pope (see paras 3.29 – 3.34 above) and the reactions thereto of Profs Simonsen and Biollaz (see para 3.16 and 3.17 above). Prof. Pope concludes that it is highly unlikely that performance-enhancing effects on the Athlete’s heart rate can be excluded. The Panel notes that Prof. Pope has had to extrapolate his conclusions from studies made on healthy shooters and on beta-blockers in general, and that he has indicated the need for a double-blind study in order to prove to the requisite standard the effect of Carvedilol on the Athlete’s heart rate (see paras 3.29 and 3.30 above).
- 7.12. The Panel notes that such a study would be prohibitively dangerous to carry out, as it would mean that the life-securing Carvedilol needed to be replaced by a placebo. The study would put the Athlete at risk to life. In fact, this risk has remained undisputed.
- 7.13. In the opinion of the Panel, to ask for scientific evidence, which cannot be adduced, would impose an impossible burden on the Athlete. With regard to heart rate, the Panel finds that there is no further evidence that could reasonably be adduced by the Athlete to establish that the additional benefit (on heart rate) is “highly unlikely”.
- 7.14. On the basis of the evidence before it, and in particular taking into due consideration the very specific, individual state of health of the Athlete, the Panel concludes that it is highly unlikely

that Carvedilol would cause any additional performance enhancing effects through decreasing heart rate. The Panel is satisfied that the effect of Carvedilol on the Athlete's heart rate could not go beyond removing any disadvantage by reference to other athletes in the SH2 category.

B. Tremor and Anxiety/Motor Restlessness

- 7.15. The Panel holds that the same general evidentiary arguments as discussed above in paras. 7.11 – 7.14 are relevant for the analysis of an additional performance-enhancing effect of Carvedilol through action on tremor and on anxiety and motor restlessness in the Athlete.
- 7.16. As for tremor, the Panel finds particularly convincing the evidence of Dr Rahbek, who relied on his own physical measurements of the force of the Athlete's muscles, in the period since 2001. He has personally observed the progress of the Athlete's diseases and has received twice a year a report from the cardiological department of the Aarhus University Hospital (see paras. 3.24 and 3.25 above) to the effect that the Athlete has no tremor - and basically cannot have a tremor. This statement was not contradicted by any other evidence before the Panel. Dr Rahbek explicitly excluded tremor in case of muscle dystrophy. Confronted with the statement of Prof. Pope that it is not possible to rule out a potential performance enhancement effect of Carvedilol simply by a physical examination of the Athlete, Dr Rahbek stated that Prof. Pope is wrong, because the Athlete has a muscle dystrophy and that it is impossible to compare a physical measurement of muscle force in an athlete with muscle dystrophy to a physical measurement in healthy persons. Dr Rahbek stated that a person with muscle dystrophy will, according to his measurements, never obtain any benefits in the muscles from beta-blockers.
- 7.17. Lacking any contradictory statement of any other expert, the Panel, on a balance of probability, holds that it is highly unlikely that any additional performance enhancing effect through action on tremor is produced by the Therapeutic Use of Carvedilol in the Athlete beyond what might be anticipated by a return to his specific state of health (*i.e.* muscular dystrophy without dilated cardiomyopathy).
- 7.18. As to anxiety and motor restlessness, Prof. Simonsen, supported by Prof. Biollaz, explained to the Panel that, whereas in healthy athletes beta-blockers may likely have an influence, this is excluded in this Athlete because there is no sufficient muscle strength in the Athlete in order to create such an effect (see paras. 3.13 and 3.14 above). The Panel associates this reasoning with that of Dr Rahbek's analysis of the physical measurements of the muscle power in the Athlete (see para 3.26 above). Taken together, this evidence convinces the Panel, on a balance of probability, that it is highly unlikely that any additional performance enhancing effect through action on anxiety and motor restlessness is produced by the Therapeutic Use of Carvedilol in the Athlete beyond what might be anticipated by a return to the Athlete's state of health (*i.e.* muscular dystrophy without dilated cardiomyopathy).
- 7.19. On this basis, and having regard to the three factors identified by the Respondent as potentially indicating the enhanced performance of the Athlete, the Panel concludes that the Athlete has successfully discharged his burden of proof and demonstrated to the Panel, by a balance of probability, that he has satisfied the requirements of art. 4.1 b). In the opinion of the Panel, the

Athlete has shown, on a balance of probability, that the Therapeutic Use of Carvedilol is, in the specifics of his case, highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the specific Athlete's state of health following the treatment of the acute or chronic medical condition.

3. Consistency of This Finding with CAS 2009/A/1948 and CAS 2013/A/3437

- 7.20. The Panel asked Prof. Biollaz to explain to the Panel whether there is a difference as to the medical facts of the cases CAS 2009/A/1948 and CAS 2013/A/3437. Prof. Biollaz stated that the illnesses dealt with in these cases are not at all the same as in the present case. In the case 2013/A/3437, the athlete concerned suffered from Long QT Syndrome. According to the expert opinion of Prof. Biollaz, taking a beta-blocker other than Carvedilol did give the athlete an advantage as to enhancing performance. Prof. Biollaz, thus agreed, from medical point of view, with the decision of the CAS Panel in that case not to grant a TUE. The same goes for the case 2009/A/1948, where the athlete was a hypertension patient who suffered from heart attacks. The athlete was treated with beta-blockers, which also were not Carvedilol, but because the athlete had no medically indicated disadvantage, he would have received an advantage as to enhancing performance when competing under the influence of beta-blockers. The crucial difference between this case and the two others is that only in this one is the Athlete in a situation of disadvantage that will not be removed entirely.
- 7.21. The Panel emphasizes that it followed the previous CAS Panels in holding that all four criteria must be fulfilled and that the burden of proof lies with the Athlete (see CAS 2013/A/3437 at para 292). The facts of any case are specific, to be evaluated on their own particular circumstances and on the basis of the evidence before the Panel.
- 7.22. In this case, the Panel concludes that the WADA TUEC misdirected itself as to the correct standard to be applied under art. 4.1(b). It was not required to determine, as it did, that potential beneficial effects of Carvedilol were to be "categorically excluded" (supra., para. 2.18). Rather, the correct test to apply was whether such benefits were "highly unlikely". Having applied that standard, the Panel is satisfied, on the basis of the evidence before it, that the Athlete has met that standard. In this regard, the Panel draws comfort in its conclusion from the fact that the WADA TUEC also so found in its 2012 decision, and that in the interim the drug taken and the dose have remained the same, the Athlete's condition is not improved, and no evidence has been tendered to show any change in the state of scientific knowledge since 2012.

4. Compliance of Challenged Decision with Fairness, Good Faith and Prohibition of Venire contra factum proprium – Doctrine of Legitimate Expectation

- 7.23. Given the above finding of the Panel, the Panel sees no need to determine whether the Respondent and WADA are estopped from departing from their previous practice by the Challenged Decision and WADA by confirming the non-recognition of a TUE by the Respondent. It is true, as the Respondent argues, that on several occasions (21 August 2012, 22 December 2014 and 19 August 2015) the Respondent has refused to grant or recognise a TUE for the use of Carvedilol by the Athlete. On the other hand, the Panel notes the manifest

contradiction between the 2012 WADA TUE and the Challenged Decision of 3 December 2015. As noted above, the Panel takes comfort in its decision by noting the discrepancies between the ISTUE decisions. The Panel decision, however, is based on the above considerations.

5. Conclusion

7.24. The introductory part of art. 4.1 ISTUE leaves it to the discretion of the Panel to grant a TUE, if the four criteria mentioned in this provision have been met by the Athlete. For the reasons set out above, the Panel considers that the requirements of art. 4.1 have been met in this specific case. The decision maintains consistency with the 2012 WADA TUE.

7.25. The Appellants have requested the issuance of a TUE for a period of four years. Art 6.9 ISTUE, which is the relevant provision in the ISTUE, reads as follows:

Each TUE will have a specified duration, as decided by the TUEC, at the end of which the TUE will expire automatically. If the Athlete needs to continue to Use the Prohibited Substance or Prohibited Method after the expiry date, he/she must submit an application for a new TUE well in advance of that expiry date, so that there is sufficient time for a decision to be made on the application before the expiry date.

The provision leaves it to the TUEC to determine the specified duration. In the case at hand, thus, it is the duty of the Panel to determine the specified duration. All experts heard by the Panel agreed that the dilated cardiomyopathy in the Athlete is progressing and cannot be stopped or reversed. The use of Carvedilol in the Athlete is life-saving, maintains cardiovascular stability and maximises his cardiovascular protection. Dr Rahbek described how the disease is progressing in the Athlete (see at para. 3.25 above). Given these medical facts, the Panel can see no reason not to accede to the request of the Appellants.

7.26. Accordingly, the Panel holds that the Challenged Decision upheld by the WADA TUEC by decision of 3 December 2015 shall be set aside and a TUE permitting the Athlete to use Carvedilol in a dose of 25 mg taken twice daily for a period of four years shall be granted.

ON THESE GROUNDS

The Court of Arbitration for Sport rules:

1. The appeal filed on 21 December 2015 by Mr J. and Anti-Doping Denmark against the decision of the International Paralympic Committee of 19 August 2015, upheld by the WADA Therapeutic Use Exemption Committee by decision of 3 December 2015, is upheld.

2. The decisions of the International Paralympic Committee of 19 August 2015 and of the WADA Therapeutic Use Exemption Committee of 3 December 2015 are set aside.
3. Mr J. is granted a Therapeutic Use Exemption permitting him the use of Carvedilol 25 mg taken twice daily for a period of four (4) years.
4. (...)
5. (...)
6. All other motions or prayers for relief are dismissed.