PUBLIC CONTRACTS REVIEW BOARD

Case 1007 – CT 2027/2015 – Tender for the Supply of Cardiac Implants

The Publication Date of the Call for Tenders was 30 October 2015 whilst the Closing Date for Call of Tenders was 10 December 2015. The Estimated Value of the Tender, (Exclusive of VAT) was € 2,361,214.64.

Three (3) Bidders have submitted five (5) offers for this Tender.

On 17 October 2016, Charles de Giorgio Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to cancel Lot 1 of this Tender against a deposit of € 5,200.

On 15 November 2016, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Charles de Giorgio Ltd

Mr John Mallia	Representative
Dr Maxine Montanaro	Representative
Mr David Stellini	Representative
Dr Antoine Cremona	Legal Representative
Dr Clement Mifsud Bonnici	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Maria Cassar	Member, Evaluation Board
Ms Doreen Gouder	Member, Evaluation Board
Mr Stanley Iles	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Department of Contracts

Dr Christopher Mizzi	Legal Representative

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr Antoine Cremona, Legal Representative for Charles de Giorgio Ltd opened by saying that his clients were objecting on Lot 1 which concerned mechanical heart valves and that they were appealing on the decision of the Central Procurement and Supplies Unit on why the Tender was cancelled.

Dr Cremona agrees that both the current product used by the Contracting Authority, namely Carbomedics issued by Sorin whose product was offered for this Tender by another Bidder and the products manufactured by St Jude Medical who the Appellants are representing are the best in the market.

Dr Antoine Cremona continued by arguing that there were legal questions which led to the Appellants to file an Appeal before the Public Contracts Review Board and whether the Contracting Authority was right in the parameters of the Law and of the General Rules Governing Tenders version 1.13 dated 26 August 2015 particularly clause 18.3 which states:

"*Cancellation may occur where:*

(a) The Tender procedure has been unsuccessful, namely where no qualitatively of financial worthwhile tender has been received or there has been no response at all;

(b) The economic or technical parameters of the project have been fundamentally altered;

(c) Exceptional circumstances or force majeure render normal performance of the project impossible;

(d) All Technically Compliant Tenders exceed the financial resources available;

(e) There have been irregularities in the procedure, in particular where these have prevented fair competition;

(f) The duration of the evaluation has exceeded the stipulated time limit in article 8 of the General Rules Governing Tendering."

Dr Cremona felt that in this situation no one of these six clauses concurred with the situation. When asking why the Tender was cancelled, Charles de Giorgio Ltd got a reply saying that the Tender was cancelled on the Grounds of Clause 18.3 (b). This led the Appellants to get more confused on why the cancellation occurred since according to them there were no technical or financial alterations in the Tender.

Dr Cremona continued by saying that the valves offered by both Sorin and St Jude Medical will remain the same. The patients will still be operated in Malta at the same way while the distinction between the valves and the organic will stay there too. The Clause which the Contracting Authority used in cancelling the Tender is normally used in circumstances where the latter notices that the particular Tendered product was re-designed, when there are emergency budget questions but not for the simple buying of a technical solution, in this case an aortic valve which will remain the same.

Dr Cermona noted that there was a conflict between the Reasoned Letter of Reply dated 24 October 2016 and the reasons given to the Appellants in a letter dated 13 October 2016 which are:

- "*Using the previous valves for the last 15 years with best results (15 years study);*

- *To change to new valves involves rigorous training for a very long period of time (15 years).*"

In reality this was not true, continued Dr Cremona as there are many cardiac surgeons who when operating their patients use different products. He invited the Central Procurement and Supplies Unit can explain where the parameters were changed from Tender Stage to Cancellation Stage.

Dr Stefan Zrinzo Azzopardi, Legal Representative for the Central Procurement and Supplies Unit opened his submissions by requesting the Board to call Mr Alex Manche in order for him to explain where the difficulty from the part of his clients was. He also asked Dr Cremona to clarify the part in his Letter of Objection which said, "*the 'parameters' of the 'supply of cardiac implants' have been changed unilaterally mid-way through the evaluation process*".

Dr Antoine Cremona, Legal Representative for Charles de Giorgio Ltd replied that the parameters did not change and could not be changed. He was not aware that these were changed and even if they did change the changes were not allowed.

At this point, Mr Alex Manche, ID Card No 193057 M, a Cardiac Surgeon was summoned to witness under oath. A transcript of the Testimony made by this witness is attached with this decision.

Following Mr Manche's testimony, Dr Antoine Cremona, Legal Representative, Charles de Giorgio Ltd, asked the Board whether he can summon Dr Urban Lonn, a cardiac surgeon from Sweden to testify under oath. The Public Contracts Review Board has aceeded to Dr Lonn's request and the latter was called to testify. A transcript of the Dr Lonn's Testimony is also attached to this decision.

At the end of Dr Lonn's testimony, Dr Antoine Cremona, Legal Representative for Charles de Giorgio Ltd said that despite the two testimonies, he was insisting that the question was a legal one. It was obvious that the market prefers the St Jude valves but Mr Manche has a personal preference with a competitive valve.

In the Appellant's opinion, the St Jude and the Carbomedics valves were the best found on the market. Dr Cremona wanted also to precise some issues brought forward by Mr Manche during his testimony regarding the paper which he has submitted and which his clients saw during Dr Lonn's testimony wherein nowhere in the paper the St Jude question was mentioned but it was comparing two other products which were not of St Jude.

Charles de Giorgio Ltd were excluded for two reasons. With regards the first reason, training when asked about it Mr Manche's answers continued to confirm that the Appellants were right in saying that the Contracting Authority gave them a frivolous answer. With regards the second reason, no one had still explained what was changed according to Clause 18.3 of the General Rules Governing Tenders. Nothing has changed except that the surgeons who worked in Malta advised the Evaluation Board that they prefer to stay put and work with the parts which they currently have.

Dr Cremona argued that this was not a valid reason as the European Courts of Justice said in their case 337.05 wherein Italy has tried unsuccessfully to make the same argument which the Central Procurement and Supplies Unit tried to make. The decision to keep the *status quo*

would have been acceptable if it was taken for a private hospital but when it comes to public spending, decisions must be taken according to the Public Procurement Regulations. A Tender has to be cancelled only if it concurs with one of the parameters of Clause 18.3 (b) of the General Rules Governing Tenders.

Dr Christopher Mizzi, Legal Representative for the Department of Contracts, said when Clause 18.3 (b) was mentioned, two points were given to substain the arguments. Those were not comments why the Appellant's bid was disqualified but were mere comments by the Evaluation Board.

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, asked why the Tender was cancelled for which Dr Christopher Mizzi, the Legal Representative for the Department of Contracts replied that the Technical Parameters.

The latter, as explained by Mr Manche, were changed in the sense that there were Technical Parameters which did not exist in the Tender Document. If you have a Tender Document which was published in a way, continued Dr Mizzi, and in reality there were Technical Parameters which should have been taken into consideration in the Tender Document, once these parameters are not in the latter, those are parameters which the Contracting Authority has to face, hence the change in parameters which were beyond those established in the Tender Document which constitutes a change, hence the Tender Cancellation.

Dr Mizzi continued by saying that even if these parameters were not taken into consideration, the fact that they exist and were not published gives leeway to the Contracting Authority to change them. Once proven in front of the Public Contracts Review Board that these parameters are fundamental to the Contracting Authority, these should constitute a change in the Technical Parameters.

Dr Antoine Cremona, Legal Representative for Charles de Giorgio Ltd said that if you look at page 18 of the Appellant's bid not only there wasn't what Dr Mizzi was saying but also it shows that both bidders who tendered for this offer qualify. It was not true that there were additional parameters.

Dr Christopher Mizzi, Legal Representative for the Department of Contracts, said that the Literature supplied by Mr Alex Manche goes beyond the Tender Document specifications.

Dr Antoine Cremona, Legal Representative for Charles de Giorgio Ltd concluded by saying that even the Literature submitted by Dr Urban Lonn show that the Technical Specifications were wide enough to address all brands.

At this stage, the Public Hearing was closed.

This Board,

Having noted this Objection filed by Charles de Giorgio Ltd (herein after referred to as the Appellant) on 17 October 2016, refers to the Contentions

made by the latter with regards to the award of Tender of Reference CT 2027/2015 listed as Case No 1007 in the records of the Public Contracts Review Board, awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellant: Dr Antoine Cremona

Dr Clement Mifsud Bonnici

Appearing for the Contracting Authority: Dr Christopher Mizzi (DoC)

Dr S Zrinzo Azzopardi (CPSU)

Whereby, the Appellant contends that:

a) **Their main objection represent the fact that although their offer was technically compliant, the Contracting Authority cancelled the Tender due to the alleged circumstance that "*The Technical Parameters of the Tender were fundamentally altered*" and this in accordance with Clause 18.3 of the General Rules Governing Tenders version 1.13 dated 26 August 2015.**

   In this regard, Charles de Giorgio Ltd maintains that this clause does not apply, simply due to the fact, that there was no alteration in design or utility of the product being tendered for.

b) Charles de Giorgio Ltd also contends that in is "*Letter of Reply*", the Contracting Authority stated that the reason for the cancellation was due to the fact that the present product gave excellent results for the last 15 years whilst at the same time, a change in the present product will involve training the surgeons for a very long period i.e 15 years.

In this regard, Charles de Giorgio Ltd is claiming that the reasons given by the Contracting Authority are not factual.

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 24 September 2016 and its verbal submissions during the Public Hearing held on 15 November 2016, in that:

a) The Central Procurement and Supplies Unit maintains that there were Technical Parameters which were not included in the Tender Document. These parameters constituted a change which led to the cancellation of the Tender.

The information supplied by the consultant surgeons goes beyond the Technical Specifications as dictated in the Tender Document, hence a change in parameters.

This same Board also noted the Testimonies of the witness namely:

i) **Mr Alex Manche duly summoned by the Central Procurement and Supplies Unit and**

ii) **Dr Urban Lonn duly summoned by Charles de Giorgio Ltd.**

The Transcript of the latter is herewith attached.

This Board, after having treated the merits of this case, arrived at the following conclusions:

1. **First and foremost, this Board justifiably notes that although extensive medical details were explained by both witnesses, this Board would treat the Charles de Giorgio Ltd's main contention from the legality point of view of the procedure adopted by the Central Procurement and Supplies Unit. However, the testimony of the witnesses has a valid bearing on the issue.**

   The reasons given by the Contracting Authority for the cancellation of the Tender was mainly due to a "*Change of Technical Parameters*" of the Tender.

In this regard, this Board notes that the offers made by both Bidders who tendered for this offer were considered technically compliant, so that a credible conclusion to this fact is that both bidders were within the technically parameters of the Tender, hence there was no change.

From the testimony of both witnesses during the Evaluation Stage, it was credibly established that Charles de Giorgio Ltd's offer was technically compliant and therefore there were no apparent alterations from the original Technical specifications.

With regards to technical matters, this Board has to rely on the Testimony given by both witnesses, who are experts in the field with proven success in their profession.

In this regard, this Board credibly notes that neither of these witnesses confirmed or asserted that there was a change of technical parameters of the product. There was no evidence or medical reasons delivered which show a change from the original specifications of the Tender Document.

This Board would like to refer to Clause 18.3 of the General Rules Governing Tenders v 1.13 wherein the circumstances are dictated when a Tender can be cancelled by the Contracting Authority and in

this regard, this Board does not find any proven evidence that the reasons for the cancellation of the Tender fell within any one of the circumstances mentioned in the said clause.

In this regard, this Board opines that the reason given by the Central Procurement and Supplies Unit, in its letter dated 7 October 2016, is not correct and proper and therefore, this Board upholds the Appellant's First Grievance.

2. **With regards to the Appellant's Second Grievance, this Board refers to the reasons given by the Contracting Authority in its "*Letter of Cancellation*" wherein the latter stated that the present product being deployed gave good results over the last fifteen years and a change to another product would involve fifteen years of training.**

This Board opines that from the testimony of Mr Alex Manche, it became evident that the present surgeons felt more comfortable to use the current product since it had a good and successful track record.

Although, this is a very sensitive health issue, this Board cannot but remark that this is a public Tender involving Public Funds and since

Charles de Giorgio's offer was proved to be technically compliant, the Tender process should have been continued.

From the same witness, it was also credibly established that the period of training was calculated to be one year, if the Central Procurement and Supplies Unit opted to choose the product which is different from the one presently being used. Therefore, the reason given in the "*Letter of Cancellation*", is not correct.

3. **On a general note, this Board is not disputing the witnesses' technical reasons for their choice of the product, but rather assessing the reasons why the Tender was cancelled.**

From the above conclusions and the witnesses' testimony, it is credibly evident that a change to a different yet technically compliant product requires an estimated training period of one year and not fifteen years as stated in the Contracting Authority's "*Letter of Cancellation*".

On a similar note, this Board opines that any medical reasons for an award of a Tender should be objected to and discussed after the award. In this particular case, there was no award, but a

cancellation of the Tender, the reason for which the latter was being contested.

In view of the above, this Board finds in favour of Charles de Giorgio Ltd, in that, the reasons given in the Contracting Authority's "*Letter of Cancellation*" were not correct. At the same instance, this Board recommends that:

i) The Tendering Process is to be continued, as the reasons for cancellation were not proven correct;

ii) The deposit paid by Charles de Giorgio Ltd should be fully reimbursed.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Lawrence Ancilleri Member

18 November 2016

PUBLIC CONTRACTS REVIEW BOARD

Today, 15 November 2016

PCRB Case 1007

Charles De Giorgio Ltd

vs

Central Procurement and Supplies Unit

Mr Alex Manche, ID Card No 193057 M summoned to testify under oath by the Central Procurement and Supplies Unit who said

Dr Stefan Zrinzo Azzopardi: Mr Manche, with reference to this particular Tender, which referred to particular needs, first of all can you please explain to the Board, your involvement in the Adjudication Process, if any?

Witness: My involvement would be to oversee the specifications that came out and make sure that they are compliant with our needs and then to review the products that had been brought forward to us and to try and make an assessment of how good or not so good these products are to our local population. That is very important that they fit in with our population.

Dr Anthony Cassar: When they say fit in what do you mean exactly, Mr Manche?

Witness: I will explain. First I will give an analogy. A Toyota is a good car. It might be the most popular car in the world but it isn't chosen by everybody because you might have countries where big cars are preferable or small cars are preferable.

In Malta we have a population of quite small people, small in stature and the problem we're facing especially in Aortic Valve implants is that not all valves fit easily into our small oscillation and we have employed several strategies over the years to try to make up or choose the most appropriate device that we felt, by we I mean the three cardiac surgeons in conjunction, to fit our patients.

There are several valves on the market and we've been particularly sticking with the small sizes because a small patient is not going to be able to have a large valve put in because it won't fit. And there are several designs of smaller sizes and over the years we have chosen particular models which will fit not only fit into the small size but when the valve opens, it would give a nice flow or allow a nice flow of blood.

In order to constraint on this particular problem that we face in Malta we have actually opted to use the designs for smaller patients but in larger patients we didn't have a particular preference so we had a much larger choice for the larger patients.

This matching up of valve design for particular size is to be very well studied in the Literature and it is known as Prosthesis Patient Mismatch. In other words we have to try to match the valve design for the size of the patient.

Coming on to the Prosthesis Patient Mismatch, there is a lot of Literature but obviously within this word literature, there are word profanities and I would like to hand a seminal paper by Pibarot and Dumesnil which I can hand copies of. It's a paper that discusses this in vast depth and it's a paper that has been circulated for hundreds of times and everybody refers to this research.

(***At this point, the article "Hemodynamic and Clinical Impact of Prosthesis – Patient Mismatch in the Aortic Valve Position and its Prevention" by Philippe Pibarot and Jean G Dumesnil has been submitted to the Public Contracts Review Board)***

In the research, I can perhaps quote you just a little sentence which says:

"*Unfortunately, there are often important discrepancies between the actual prosthesis ring outer diameter and the manufacturer's labelled valve size (109-111).*"

So, when you have a world authority telling you, "I'm going to buy, for example, a bra size. I'm going to buy a B but is it the same if I had to buy it from this company or that?"

I don't want to trivialize but this is a very important point. In this paper which is backed up by references, when you buy a size 19, for example Carbomedics valve, is it the same as the size 19 St Jude?

I have another passage I can give you its literature later on of papers, you can tell from the title, "*Accuracy of sizers for aortic valve prostheses*". "*Discrepancies between labelled and actual dimensions of prosthetic valves and sizers*" and finally "*Why aren't valve sizers and prostheses labelled accurately?*" So this sets the tone for my argument as to why we were unhappy to change from the valves that we were using to something that was purportedly as good and cheaper.

When we make comparisons, we used the Literature of the companies so I have brought with me the Literature of the Company that has put in the Tender, the St Jude Medical Company and for example they produce charts. These charts are not complicated; all they're doing is defining the Prothesis Patient Mismatch.

In other words they are saying that their valve is far superior according to their sizes to the valve that we produce nowadays. But if you look in the small print, you will find that they are not comparing orange juice with orange juice because they are comparing their latest valve to a valve produced by the company that we use which we don't use anymore. It has been superceded before the Millenium by another valve. So we are comparing a new valve to an older valve.

If then, you compare the new to the new, then the sizes are better than the valve which we are using now. What happens if for example, the surgeon is faced with a valve that he is going to try and put on a patient? The heart as we know all pumps blood so we want the blood to flow without obstruction or minimal obstruction into the circulation.

So we want to put the largest possible valve into that space in the heart to allow what we call a very good hemodynamic; a good flow of blood. There are instances where a St Jude valve, this is the one which we came to adjudicate, has been put in

a say size 19 but because it was forced because the seizer is not the same as a valve, the force of distorting the valve make the leaflets entrapped.

Perhaps I can give you an example, if you look behind you there is a door, a frame, if you squeeze the frame into the wall, it can actually obstruct the opening and closing of the door. Now this is a rare occurrence but it has happened in the Literature, it is reported in the Literature of the St Jude valve but never in the Carbomedics which is the one we've been using for many years.

I will just read a sentence for you from a paper which says, "*In the hands of senior cardiac surgeons performing numerous aortic valve replacements (AVRs) per year, 3 patients had their prostheses explanted immediately during the operation as a result of leaflet arrest."* Arrest means sticking like the door sticking. *"The prostheses were replaced with a smaller-sized valve of the same type in 1 patient,* (the St Jude), *and Carbomedics valves of similar size in 2 instances*".

So what are we saying? The 19 St Jude didn't work it was explanted and the 19 Carbomedics worked well so clearly there is a difference between the sizing of the valves.

Dr Anthony Cassar: Are we saying that the valves which you use now are more appropriate?

Witness: For our population, that's what I am saying.

Dr Anthony Cassar: But the Appellant's question was why the Tender was then cancelled?

Dr Antoine Cremona: That's not for Dr Manche to reply. This is irrelevant in my opinion.

Dr Stefan Zrinzo Azzopardi: Mr Manche is explaining the Technical Parameters.

Dr Anthony Cassar: Yes, but there must be a connection why the parameters have been cancelled.

Dr Antoine Cremona: 100%

Dr Stefan Zrinzo Azzopardi: With regards to the Evaluation that was being carried out, was it limited to documents? Or did you have access to the actual valves

Witness: No, we had no access to the actual valves. Obviously, when we've been using a model for the last fifteen years, you don't need a sample. But if you're going to buy something different you need to not only see it in your hand, you need the company to send doctors to help you do the first few and then when you're happy that everything is all right with the transition, then it is possible to change otherwise we would never change.

I would ask the panel, if you had to buy something important in your life like buying a car, you wouldn't buy it from the adverts but you'd want to have a test drive and we will never allow in this Tender the test drive for the new valve.

I have to add also that when I came to Malta in 1995, which is a long time ago, we had a stock of these very St Jude valves, admittedly a slightly older version but the one which is still on the market and I did try to use up the stock because they cost a

lot of money and I did encounter problems. It wasn't the first time that I tried to put the St Jude valve and had to take it out and use the Carbomedics valve of the same size.

This is not only detrimental to the patient and the surgeon making a long and complicated operation but also not cost effective and that is the time when I made the transition to the valve, the Carbomedics valve that I have been using throughout my training in England.

I have to say that when my colleagues came from England, from different centres they also used this valve for their operations. The Carbomedics valve actually produced the St Jude valve for St Jude so they are serious manufacturers. The Carbomedics have never changed their design; however the St Jude has changed their design because there were problems. They have even changed their sewing brand recently which allowed the cloth pit that allowed to stitch the valve of the heart.

I don't want everyone here to go away with the impression that one valve is fantastic and the other one is hopeless because in fact the St Jude is the most one used in the world. However, I keep saying that for our particular population of small people with small roots the Carbomedics valve is very much more suited to our population.

Dr Stefan Zrinzo Azzopardi: I have no further questions.

Dr Antoine Cremona: Mr Manche, just a couple of questions. I'm the lawyer representing St Jude Medical. First of all I want to understand a bit better your role in the adjudication. These reservations which you had including the Patient Prosthesis Mismatch and the past history which you had, how they are communicated with the Evaluation Board? In the form of a report? In the form of a phone call? In the form of a meeting?

Witness: Well what I did was first sat down with my two colleagues, because after all...

Dr Antoine Cremona: The Cardiac surgeons

Witness: It's not right for me as a Chairman to say, "*Well, from tomorrow you are going to use this valve*", so we sat down together and we went through the Evaluation and it was the opinion of the three of us that what we are served with, is the best for our patients.

The others didn't have as such, one colleague had quite a lot of experience with the St Jude at Liverpool, the other person in Sheffield had very little experience with the St Jude so myself, having had the experience with both, another surgeon having experience with both and the other surgeon have no experience.

Dr Antoine Cremona: In older products.

Witness: In older products. In fact I have to say that there are always advantages of certain models. The region for example with the St Jude valve has come out brilliantly in the Literature and given the opportunity to try the Size 19, for example I would have to try and make an opening for that because I was actually pushing for this.

However, the way the Tender is, you either take all or nothing and I was very reluctant to lose for example....

Dr Antoine Cremona: I agree with you

Witness: The 21 and the 23 top heads, to try the 19.

Dr Antoine Cremona: So just to get back to my question, after you met with your fellow colleagues, how was then your reservation, the collective reservation communicated to the Board? Did you meet? Did you sent an e-mail? Did you draft a report?

Witness: After having this meeting, we wrote a joint letter in the Tender File, which is saying that we believe that the Carbomedics valve Tophead is the best cheapest valve for our patients, and we were very reluctant to make a change on the basis of being the first cheapest.

Dr Antoine Cremona: So am I right in saying that you did not at any point in time, find the St Jude Medical offer as Technically Not Compliant?

Witness: No, I think I have made this quite clear to the Board that it was compliant with the specifications.

Dr Antoine Cremona: In all fairness, before you came in, I have exhibited two papers from a journal which I did not give you a copy of, which make a comparative Analysis specifically of the two products. Am I right in saying that the peculiarities of the Maltese population, which you described as small does not arise from any scientific study or publications to date?

Witness: Well it does.

Dr Antoine Cremona: It is obviously a matter of experience.

Witness: We actually published our results.

Dr Antoine Cremona: Can you point out from where in the paper.

Witness: I can give you a copy of the paper.

(At this point, an article called "Does Aortic Valve Replacement Restore Normal Life Expectancy? A Twenty-Year Relative Study" by the Witness himself together with Liberato Camilleri and Dorothy Gauci was submitted to the Public Contracts Review Board)

We have published a twenty year study using the Carbomedics Brand throughout the mechanical study. We also have a biological one. What we have shown in our population is that after twenty years we have restored normal life expectancy to older people receiving our valves.

Dr Antoine Cremona: My question is related to the peculiarities of the Maltese stature. Can you point it out?

Witness: The population characteristics are all in data.

Dr Antoine Cremona: Am I right in saying that even from WHO reports, and I'll put it to you that there is no difference of any significance in the population structure, and I will exhibit further documents, between the Maltese population and the Southern European?

Witness: I have to disagree with you.

Dr Antoine Cremona: Can you point it out?

Witness: We are not in that paper but you will find in the Eurostat that we have the fattest men and the second fattest women in Europe but we are not the tallest or second tallest.

Dr Antoine Cremona: I don't think we need a paper to confirm that.

Witness: This is a basic problem which we face in that people who are perhaps overweight still have a smaller aortic route. The paper, for the body surface area, in fact the Patient Prosthesis Mismatch is calculated by dividing the body surface area of the patient.

Dr Antoine Cremona: But am I right in saying that the Prosthesis Patient Mismatch is not significantly more of a problem with the St Jude equipment compared to the Carbomedics or to others and is not statistically proven for sure that there is a higher incidence of such a mismatch in any one brand compared to the other? The legal brand at least.

Witness: That is a difficult question to answer. Patient Prosthesis Mismatch it has been shown to be detrimental in less regression of hypertrophy, the vegetarian remoras and the quality of life. Some papers are in favour and some papers are actually against. So that it still a contentious issue.

Dr Antoine Cremona: But if I were to mention the four top, I have statistics here which show the interventions of mechanical heart implants, I would be correct now in stating that the problem is equally of a problem or a non problem to St Jude, Sorin, Metronic and Onex. It is not particularly prelevant in any one brand.

Witness: No. However, I would agree with you. This is not an easy choice. But having had now a long term survival of the last twenty years in the particular valve doing extremely well, would you as a surgeon take the jump to try a different prosthesis in a small population where you have an excellent valve already with the tophead design and if I predict whether in twenty years we were going to be in the same happy situation? This is the problem that we face.

Dr Antoine Cremona: But there are statistics at least for the past thirty-four years from St Jude from 1977 at least, which is more than thirty-four years.

Witness: Not on the region.

Dr Antoine Cremona: Not on the region. And this is the one being offered.

Witness: You can't have the long term survival.

Dr Antoine Cremona: That paper which I have just produced, indicates that the survival rate is fairly the same or most identical. What would be your reaction to that?

Witness: Part of the reaction is positive but the title says that it is a ten year follow up whilst ours is a twenty year follow up. But yes, I would need to see the patients' characteristics with regards to sizes.

Dr Antoine Cremona: But we are in agreement that the Patients Prosthesis Mismatch is not a problem particularly present or relating to St Jude Medical's roots?

Witness: I would take issue with you that our population is short and is obese. This is the problem which we have in the short Aortic route.

Dr Antoine Cremona: My last question. How would one product therefore in your opinion, in your professional opinion, be better than another product in the particular setting of the Maltese population as you have put it here?

Witness: It would have to be that when you are putting it in a tight situation, many times it is tight, that the distortion of the gate is not going to cause an entrapment, one of the worries that I have...

Dr Antoine Cremona: But do the St Jude ones cause entrapment?

Witness: I've given you the papers. I have given you the actual references where there is also a study which shows that the distortion in a Lab required to entrap a St Jude leaflet is much lower than to entrap a Carbomedics cause the Carbomedics has to retain to reinforce.

Dr Antoine Cremona: I beg to differ and I produce a study which shows exactly the opposite, but are you explaining, apart from you being familiar with what has been there for the past fifteen years, what is another comparing reason why the Carbomedic products should be preferred in the realities of the population?

Witness: In reality, my best answer to you would be that for the last twenty years we never had a mechanical failure, we have very good survivor studies, we have small sciences, we have Prosthesis Patient Mismatch which is equal to other instances in all over the world but the survival rate has been extremely good.

Dr Antoine Cremona: So would my saying that this is a fear of change being a correct statement?

Witness: Yes, it is partially correct, yes. After all we are dealing with the patients, we are surgeons. There is a fear of change when things are going well. When things are not going so well, we are more adventurous for change but when things are going well, and then there is fear of change.

Dr Stefan Zrinzo Azzopardi: One final question. Mr Manche, earlier on you were explaining, that the only information you had regarding the compiling of a report, was the documentation presented with the Tender...

Witness: Confrontational case of the products.

Dr Stefan Zrinzo Azzopardi: Exactly. Your evaluation of matters, if you had access to the samples, would that have made things in a different manner?

Dr Antoine Cremona: I don't want to object for the scope of objecting but we weren't disqualified for the sampling.

Dr Anthony Cassar: No.

Dr Stefan Zrinzo Azzopardi: There wasn't a sample obligation but I wanted him to mention it as a clarification point.

Witness: I think the sample is a small portion, I think the sample has to come with proctoring and a lab incur. Nowadays, we don't just use a product without the company actually producing the tools how to use a product. We do use samples, in a situation when we are unhappy with it.

For example, in very old patients, now we are using rapid deployment valves which shorten the operation but we didn't require a valve off the market. We went to many meetings, we've got to operation theatres, we've got doctors who come and do the cases with us so yes samples are a step but then there are several steps which we do also.

Dr Antoine Cremona: One final question, Mr Manche, I mean we can agree that if you and your teams were to start using the Regent St Jude mechanical valves, you wouldn't need fifteen years of training?

Witness: I hope not.

Dr Antoine Cremona: Thank you.

Witness: Just to give you an idea the newer valves we've been using them since 2007, however with the new valves we only have a proctor for about a year.

This was the witness of Mr Alex Manche' before the Public Contracts Review Board.

Dr Anthony Cassar
Chairman
Public Contracts Review Board

I declare that I have transcribed the recording honestly and faithfully and to the best of my knowledge and abilities.

Antonello Abela
Principal
Public Contracts Review Board

PUBLIC CONTRACTS REVIEW BOARD

Today, 15 November 2016

PCRB Case 1007

Charles de Giorgio Ltd

vs

Central Procurement and Supplies Unit

Dr Urban Lonn, summoned to testify under oath by Charles de Giorgio Ltd who said

Witness: My name is Urban Lonn and I'm a cardiac surgeon from Sweden, working now as a Medical Director for St Jude Medical in their clinical affairs department.

Dr Antoine Cremona: Dr Lonn, I am going to ask you a couple of questions and then my colleagues have the right to ask you in cross examination. So, can you please describe the product with which St Jude Medical submitted this bid, the history of the product and any market data you have in terms of market share and in terms of patient survival rates after being implanted with this mechanical valve?

Witness: This valve brought by St Jude, Bioleaflet Mechanical Part Valve was constructed and introduced in 1977. Since then it has become a little bit what we call the Gold Standard because all other valves coming out of the market has been using the St Jude valve as a reference.

There are five different Bioleaflet Mechanical Part Valves in the market. When it comes to Sorin and Sorin Tophead that was coming in about ten years later on the market. All these five valves are very good valves, they reproduce the work that they are supposed to do and so there is a survival benefit. There is no big difference in these valves. They work as they should.

I think there are two publications and journals that compare the Carbomedics valve with the St Jude Bioleaflet Valve, which I have a copy here and they say that there is no real difference in the valve.

From an implantation point of view, every skilled cardiac surgeon with licence, you don't have to be especially skilled in putting any of these valves. It's a standard procedure in just sort of passing through the tissue of the heart and pass it through the complex of the valve...

Dr Anthony Cassar: You don't have to describe the articulation.

Dr Antoine Cremona: Ok, I am making reference to a particular point which Mr Manche before you gave evidence on; the Patient Prosthesis Mismatch. From your vast experience and from market data which has been collected, would you say that there is any prevalence from the Patient Prosthesis Mismatch in any one particular product or does St Jude medically fare any worse than the others?

Witness: There is a very nice publication looking at the performance of these five commercially valves out there and it states very clearly that the performance of the St Jude valve is still the best because it has the opportunity, all of them, that the angles of the leaflets to take a degree. I think also this is the reason why we are still, the St Jude valve in market the leader. Already in 2011, there were ordered 2 million of these valve implants.

Looking at the market value, in the first quarter of 2016, St Jude has a market value of 57.1 % in the United States, where Sorin has 10.1 %. When it comes to Western Europe, St Jude has 47.2% and Sorin has 27.7%. So there is reason that we still are considered as the best and that is still built on enormous publications and performances of the St Jude valve. There are, I don't know how many thousands of papers written on this valve throughout the years.

Dr Antoine Cremona: Dr Lonn, would you say your supplies, the St Jude supplies are restricted to one type of population that is for example, you know, Scandinavian males, Caucasian males and females or do you supply across the world in various populations, in various statures, sizes, races?

Witness: Of course, you know when we do this type of surgery, we take out the old valve and then there are quite a few anatomical differences in populations, I mean we see some in Asia that have a bit more of Bioleaflet valves that we see in some other countries but it has no influence on the procedure itself.

I also say that there are some small instances, for example if you going to do a double valve replacement, which is about 7% of all the cases that you can mainly prefer a Sorin tophead model instead of the...

Dr Antoine Cremona: The other way round.

Witness: Yes, so these are quite a small number of patients compared to the big volume we are doing today of single valve replacements.

Dr Antoine Cremona: Now specifically with respect to the 19mm one, how would you say that the two models, now I'm not referring to the other brands, I'm restricting myself to the Sorin Carbomedics and to the St Jude one. How would you say that the two compare with specific case to the 19mm valve?

Witness: I have to refer to this very nice paper that was published from the Heart Lab in Padua, in Italy under the guidance of Prof Dino di Rosa, who's a big authority on the Part valves in general, both mechanical and biological valves where he states exactly what it counts to function on these valves, the 19, the small valve size which is very important for patients with small aortic routes.

Dr Antoine Cremona: Would you say that from the results of the Padua Heart Lab, in your professional experience, would you say that it would need some sort of restructuring and reshaping between the Italian population and the Maltese population?

Witness: No, I think that the conclusion of the investigation which they had done in this valve, I mean they mentioned here that the worst results named the Highest heart

loss obtained with the Carbomedics Tophead and ATS valves compared with the St Jude Regent and Sorin Biopart Carbon Slim Line Prosthesis.

So, I mean it is a difference in the valve and it has to do with the size of the valve how the leaflets is opening and how much it is exposed or effective in this area is. The Top Plus is a very good valve and has a very good functioning valve and it's due to work but you cannot say that one valve is absolutely much better than the other.

Dr Antoine Cremona: Just one final question, if someone with the huge experience of Mr Manche or yourself as a cardiac surgeon, but if I were, you know Mr Manche with at least thirty years, twenty years of experience, using the Carbomedic valve, how long would it take in terms of training to start using the St Jude valve?

Witness: You know, it would take him five minutes. I mean, it's the same procedure as you do with most of these Bioleaflet valves. It just had to be acquainted to the valve itself and it's every licensed cardiac surgeon in very big volume centres we have many valves that we just switch between depending on which valves we have on the shelf.

Dr Antoine Cremona: So there are cardiac surgeons which use both simultaneously?

Witness: Absolutely, I mean like Dr Manche with his vast experience it'll be a walk in the park.

Dr Antoine Cremona: Thank you, Dr Lonn.

Dr Stefan Zrinzo Azzopardi: Mr Manche, in his wise-giving evidence, referred to a paper published by the Journal of the American College of Cardiology, which states and I will quote, "*Unfortunately, there are often important discrepancies between the actual prodthesis ring outer diameter and the manufacturer's labelled valve size.*" With regards to the smaller sizes, particularly the size 19, such a discrepancy, would it be detrimental to the success of an operation utilizing this particular valve?

Witness: You can compare the 19mm St Jude valve with the 21mm Carbomedic Tophead so the reason why Tophead was constructed was to be able to place supra annular.

Dr Antoine Cremona: You will need to describe that because you will be losing everyone.

Witness: It's a question of trying to increase the effective surface area to have a better hemodynamic flow. In this paper from Padua, they actually looked very carefully to the 21mm Tophead compared to the 19mm St Jude valve and still the St Jude valve comes out to a better degree and the reason for this is that the St Jude valve opens 85 degrees when the leaflet goes up like this. The Tophead opens about 78 per cent and it makes a difference between the effective orifice area.

An effective orifice area has a direct co-ordination with pressure radiance. Pressure radiance is a thing that we don't like when we surgeons switch out valves and pressure radiance and effective orifice compose the Patient Prosthesis Mismatch.

Dr Stefan Zrinzo Azzopardi: Are you saying that, the 19 of one company is to be compared to the 21 of St Jude valve?

Dr Antoine Cremona: It's the other way round.

Witness: No, the 19mm St Jude was compared here with the 21mm Tophead. I have the exact measurements here. So an external diameter of 19mm Regent is 19mm. The external diameter of a Carbomedics Tophead is 21.8mm. When it comes to the inner diameters is 17.8 for the Regent and 16.7 for the Carbomedics and then when it comes to opening angles, Regent valve 85%, Carbomedics Tophead 78%.

Looking at the effective orifice area, how the opening is it? St Jude Regent is 2.39mm and compared to Carbomedics Tophead is 2.07mm so there is a big difference in 21mm Tophead to 19mm St Jude valve and it has to do with opening angles and the pressure radiance in the St Jude valves.

Dr Stefan Zrinzo Azzopardi: With regards, is there a difference in your opinion from the information you have in hand that Mr Manche pointed out that if the outer ring is although indacted as 19 but possibly having to be forced into the place where it has to be located, excuse my limited biological knowledge, I come from a family of doctors but it stops there, that it would affect the mobility of the valve itself since the way it is placed would be potentially hindered to the flow as it is supposedly to be designed?

Witness: When it comes to the Bioleaflet valves it is all a question about the correct sizing. We as cardiac surgeons learned from when we were in school that when you try to put in a superior valve as you can to make the flow easier.

But with this kind of biological mechanical valves, if you try to squeeze them down in the area where they should be it can be a possibility that you can have a problem with one leaflet but then it's not a problem with the valve. It's a problem with the surgeon because then you try to do something that you should not do. It's all very well known because it had been described in the Literature that with over sizing Bioleaflet valves.

Dr Stefan Zrinzo Azzopardi: Thank you Dr Lonn. No further questions.

This was the witness of Dr Urban Lonn before the Public Contracts Review Board.

Dr Anthony Cassar
Chairman
Public Contracts Review Board

I declare that I have transcribed the recording honestly and faithfully and to the best of my knowledge and abilities.

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