QORTI TAL-APPELL

IMHALLFIN

S.T.O. PRIM IMHALLEF SILVIO CAMILLERI
ONOR. IMHALLEF TONIO MALLIA
ONOR. IMHALLEF JOSEPH AZZOPARDI

Seduta ta' nhar il-Gimgha 24 ta' Novembru 2017

Numru 4

Rikors numru 857/17

Cherubino Limited (C-3677)

v.

1.Dipartiment tal-Kuntratti
2.Central Procurement & Supplies Unit
3.Pharma-Cos Limited (C-2804)

Il-Qorti:

Dan hu appell imressaq fl-10 ta' Awwissu, 2017, mis-socjeta` rikorrenti Cherubino Limited wara decizjoni datata 21 ta' Lulju, 2017 moghtija mill-Bord ta' Revizjoni dwar il-Kuntratti Pubblici (minn hawn 'il quddiem

imsejjah “il-Bord”) fil-kaz referenza CFT 021/6059/2017 (kaz numru 1065).

Dan il-kaz hu marbut ma’ sejha ghall-offerti li hareg ic-Central Procurement & Supplies Unit fi hdan il-Gvern sabiex jigu suppliti “*radioactive iodine-131 capules*”. Ghal dan il-kuntratt intefghu diversi offerti, fosthom wahda mis-socjeta` rikorrenti u ohra mis-socjeta` intimata Pharma-Cos Limited. Il-kumitat ta’ evalwazzjoni ddecieda li s-socjeta` rikorrenti kienet l-offerent preferut, u l-offerta tas-socjeta` Pharma-Cos giet imwarba peress illi ma kienx gie pprezentat mal-offerta “*the package insert*”. Is-socjeta` Pharma-Cos ressqet oggezzjoni quddiem il-Bord, u dan iddecieda favur Pharma-Cos u ordna li din is-socjeta` terga’ tigi re-integrata fil-process ta’ evalwazzjoni. Id-decizjoni tal-Bord hija s-segwenti:

> “This Board,
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> “Having noted this Objection filed by Pharma-Cos Limited (herein after referred to as the Appellant) on 23 June 2017, refers to the Contentions made by the latter with regards to the award of Tender of Reference CFT 021-6059/17 listed as Case No 1065 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).
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> “Appearing for the Appellant: Dr Matthew Paris
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> “Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi
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> “Whereby, the Appellant contends that:
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> “*a*) The alleged reason given by the Central Procurement and Supplies Unit for discarding his offer was that Pharma-Cos Limited did

not submit the Package Insert for the product being offered, as per Article of Section 4 – Technical Specifications of the Tender Dossier.

"In this regard, the Appellant maintains that he has submitted all the necessary information for this type of capsule to be administered by specialists in the field, with particular reference to 2.1 of the Technical Specifications, wherein it was stated that:

"*Mock-Up and Package Insert for product being offered (Applicable for medicinal products excluding special medicines)*"

"b) The Appellant also maintains that he has submitted the necessary information in accordance with the Subsidiary Legislation 458/33, Medicinal Products Regulations issued on 30 October 2005 and the contents listed in their submissions following exactly the requirements as requested in the Tender Document.

"This Board also noted the Contracting Authority's "*Letter of Reply*" dated 30 June 2017 and its verbal submissions during the Public Hearing held on 13 July 2017, in that:

"a) The Central Procurement and Supplies Unit insist that the Tender Dossier requested two distinct documents, namely the "*Package Insert*" and the "*Summary of Product Characteristics*". However, Pharma-Cos Limited submitted two versions of the "*Summery of Product Characteristics*" but not the "*Package Insert*" and in this regard, the Evaluation Board had no other option but to discard the Appellant's offer;

"b) The Central Procurement and Supplies Unit also maintain that the Appellant's contention that he has abided by the "*Subsidiary Legislation 458/33, Medicinal Products Regulations*", has no bearing for the non submission of the requested information, as the quoted Legislation is applicable for the registration of medicine.

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

"1. Mr Michael Dalmas duly summoned by Pharma-Cos Limited;

"2. Mr Mark Zammit duly summoned by the Central Procurement and Supplies Unit.

"This Board has also taken note of the documents submitted by the Central Procurement and Supplies Unit which was a Package Leaflet Information for the User.

"This Board, after having considered the merits of this case and after hearing the testimonies of the Technical Witnesses duly summoned by both parties to this Appeal, arrived at the following conclusions:

"1. With regards to Pharma-Cos Limited's First Contention, this Board, after having heard length submissions both from the interested parties and the Technical Witnesses, first and foremost opines that one has to establish the type of information which was requested in the Tender-Document and that submitted by the Appellant.

"From examination of the relative documentation, the Tender Document requested two documents, namely a "*Package Insert*" and a "*Summary of Product Characteristics*". From the submissions and examination of documentation, it is hereby being credibly established that Pharma-Cos Limited submitted a "*Detailed Summary of Product Characteristics*" and another copy of the same document in a slightly different form.

"This Board has also justifiably established that the "*Summary of Product Characteristics*" is intended for the use of the medical professional or specialists applying the treatment while the "*Package Insert*" is purely intended for the user; in this case the patient.

"It has been also credibly established that this type of capsule is only applied on patients in hospitals, administered by a highly qualified specialist, so that it has also been asserted that this type of capsule cannot be purchased or administered by the patient himself and is not available from pharmacies.

"The sole purpose of the "*Package Insert*" is for the user to be aware of the type of medicine and its contents. This Board is conscious of the fact that this medical procedure can only be administered in hospitals so that, awareness to the patient of the purpose and use of the same capsule can only be communicated through the specialist applying the latter. This procedure is well known and forms part of the protocol in the medicine field.

"In this regard, this Board finds that from the testimonies of the Technical Experts, this capsule can be considered to be a "*Special Medicine*" which in accordance with Clause 2.1 should be exempted for submitting a "*Mocking-Up and Package Insert*".

"At the same instance, this Board considers that the non-inclusion of a "*Package Insert*" in this particular case, for this type of specialised capsule does not inflict any harm or discomfort to the patient and as the medical treatment is being administered in hospitals only, the patient is pre-advised of the procedure and the effects of such medication.

"Needless to mention the fact, that this is not a situation where the patient has to provide for the capsule himself and in reality, the patient relies on the advice and awareness given to him by the specialist.

"This Board is by no means eliminating or minimising the importance of the submission of the dictated information in a Tender Document, but rather considering the merits of this particular case in the rejection of the Appellant's offer, in these special circumstances.

"This Board, justifiably noted that Pharma-Cos Limited submitted all the information necessary for the application of this capsule and this same Board also takes into consideration the fact that since the supply and application of the capsule can only be administered in hospital by specialists in the field, the latter is obliged to explain to the patient the use and effects of this capsule, which in most cases, such information is clearer than when one reads the instructions and side effects in a package insert. In this respect, the Appellant submitted the appropriate information for the administrator of this capsule.

"At the same instance, this Board is credibly convinced that the non inclusion of the "*Package Insert*" in this particular case and under these circumstances, will not deprive any rights which the patient has to be aware of the medication he is undergoing as the specialists advice, prior to the administration of this capsule, is sufficient enough for the patient to be fully aware of the effects of the procedure itself.

"On the other hand, this Board heard convincingly, from the submissions made by the Technical Witnesses, that enough information was submitted by Pharma-Cos Limited to enable the applicator of the medical procedure to administer the capsule. It was also clearly stated by the Technical Witness that the capsule package is not given to the patient, so that the latter does not have access to the package and tablet or the insert.

"This Board applies the principle of "*Substance over Form*" and "*Proportionality*" and is credibly convinced that the non inclusion of the "*Package Insert*" does not have any bearing effect. Neither on the application of this tablet nor on the well being, comfort and safety of the patient. In this regard, this same Board upholds Pharma-Cos Limited's First Contention.

"2. With regards to Pharma-Cos Limited's Second Grievance, this Board refers to the Subsidiary Legislation 458/33, Medicinal Products Regulations Issued on 30 October 2005 and would like to respectfully point out that this legislation, in actual fact refers to the requisites for any type of medicine to be registered and thus can be on the market.

"In this regard, this Board opines that it is credibly convinced that the Appellant's product is registered and on the market but the issue at stake is the non-submission of the "*Package Insert*", so that this same Board does not see any relevance to this legislation in the particular casw.

> "However, it is noted that the information given by the Appellant with regards to the "*Summary of Product Characteristics*" conform to the requisites of this Legislation.
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> "3. On a general note, this Board, in arriving at its deliberations, took great consideration with regards to the Technical Testimonies and also the documentation related to this Appeal. It must be emphasised that in no way, the decisions taken by this Board undermine the importance and obligation which a Bidder should apply in submitting and adhering to the dictated conditions of the Tender.
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> "However, one must also consider the particular circumstance and the particular reason for a discarded offer. In this respect, this Board, apart from applying the principles of "*Substance over Form*" and "*Proportionality*" has also considered the practical mode of the application of this capsule, mainly in that, at no time will the package and the capsule will be in the patient's possession, so that the latter's right for information regarding this medical procedure must be forthcoming from the specialist performing such procedure.
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> "In view of the above, this Board finds in favour of Pharma-Cos Limited and recommends that:
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> "i) The decision to award the Tender is to be temporarily revoked;
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> "ii) Pharma-Cos Limited's offer is to be reintegrated in the Evaluation Process;
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> "iii) The deposit paid by Pharma-Cos Limited is to be fully refunded".

Is-socjeta` Cherubino Limited appellat mid-decizjoni li ha l-Bord ghal quddiem din il-Qorti u ressqet aggravju principali fis-sens li darba li s-socjeta` Pharma-Cos ma pprezentatx il-*package insert*, kellha titqies bhala *technically non-compliant*, kif fil-fatt kien iddecieda l-Kumitat ta' evalwazzjoni.

Wara li semget it-trattazzjoni tad-difensuri tal-partijiet u rat l-atti kollha tal-kawza u d-dokumenti esebiti, din il-Qorti sejra tghaddi ghas-sentenza taghha.

Ikkonsidrat:

Illi qabel xejn din il-Qorti trid tqies l-eccezzjoni tad-Dipartiment tal-Kuntratti li huwa mhux il-legittmu kontradittur f'dawn il-proceduri. Fil-fatt, hu car li s-setgha pubblika meritu ta' dan l-appell kienet immexxija mis-Central Procurement & Supplies Limited u mhux mid-Dipartiment tal-Kuntratti u dan minhabba l-valur tal-Kuntratt li huwa inqas minn €135,000 u dana, skont il-ligi ma jitmexxiex mid-Dipartiment. Darba li l-kuntratt pubbliku meritu ta' dawn il-proceduri ma kienx jaqa' fir-responsabbilita` tad-Dipartiment tal-Kuntratti, id-dipartiment appellat ma kellux ikun parti f'dawn il-proceduri (ara **Clintec Limited v. Direttur tal-Kuntratti et** deciza minn din il-Qorti fis-27 ta' Ottubru, 2015). Dan id-Dipartiment qieghed ghalhekk, jinheles mill-osservanza tal-gudizzju.

Trattat issa l-meritu tal-appell, din il-Qorti tara li s-socjeta` appellant ghandha ragun fl-ilment taghha.

Fid-dokument ghas-sejha kien jidher car li l-offerta kellha tikkontjeni l-"*package insert*" u "*summary of product characteristics*" u s-socjeta`

Pharma-Cos naqset milli tipprezenta tal-ewwel, u resqet zewg verzjonijiet tat-tieni. Dawn ma humiex l-istess haga. Kif gie spjegat mis-Central Procurement & Supplies Unit, "*the summary of product characteristics is intended to provide information to health care professionals; on the other hand, the package insert is a document that is intended to provide information for patients*". Darba li z-zewg dokumenti kienu mitluba, kellhom jigu pprezentati t-tnejn, u la dokument minnhom ma giex ipprezentat, l-istess offerta kellha titqies mhux teknikament konformi. Il-Bord ma kellux jidhol biex jiddeciedi li l-*package insert* ma kienx bzonnjuz, ghax in-nuqqas, skont hu, "*does not inflict any harm or discomfort to the patient*". Din mhux bicca tieghu li jidhol fiha, u darba dak id-dokument kien mitlub fis-sejha ghall-offerti, kellu jigi pprezentat, u n-nuqqas ta' offerent li jressaq dokument espressament mitlub, kellha twassal ghas-skwalifika tieghu. Huwa principju, anke ta' dritt kostituzzjonali, illi pazjent irid jinghata l-informazzjoni kollha relatata mat-trattament li jkun ser jinghata, u dan il-*Package Insert* jew *leaflet* huwa mehtieg precizament ghal dan l-iskop.

Kif osservat din il-Qorti fil-kaz **SR Environmental Solutions Limited v. Dipartiment tal-Kuntratti** deciz fis-6 ta' Frar, 2015:

> "*Ghandu jinghad in principju li kull min huwa involut fil-process ta' sejha pubblika, inkluz ukoll dawk li huma mghobbija bl-oneru li jiggudikaw is-sejha, huma kollha marbutin bil-kundizzjonijiet li jkunu mnizzla fid-dokumentazzjoni tas-sejha*".

Hekk ukoll din l-istess Qorti, fil-kawza **Transport Services for Disabled Person Co-Operative Limited v. Id-Direttur Generali tal-Kuntratti et** deciza fl-24 ta' Gunju, 2016, kienet osservat hekk:

> "*Jibqa' l-fatt pero`, li ghalkemm il-vetturi offruti kienu "the best value for money", ma humiex konformi ma' dak mitlub. Din il-Qorti, f'kazijiet simili, mhux l-ewwel darba li ikkonfermat il-principju li offerent, anke jekk joffri prodotti ahjar, ghandu jkun skwalifikat jekk il-prodott offrut ma jkunx skont kif indikat fis-sejha. Il-principju ta' trasparenza jrid li l-kumitat ta' evalwazzjoni jimxi mad-dettalji teknici kif imnizzla fid-dokumenti tas-sejha, u mhux jiddeciedi li jaghzel liema li jidhirlu li hi l-ahjar offerta*".

Dan hu principju importanti *in subjecta materia* u huwa mehtieg f'gieh it-trasparenza li ghandha tirrenja f'dawn il-kazijiet. Offerent ghandu obbligu josserva r-regoli tas-sejha meta jaghmel offerta, u jekk dokument rikjest ma jigix sottomess, dik l-offerta m'ghandhiex titqies bhala wahda valida.

Is-socjeta` appellanti tilmenta li d-dokument tas-sejha talab *Package Insert*, li ma jezistix, u mhux *Package Leaflet*. Apparti l-fatt illi s-Sur Marcel Mifsud, ghas-socjeta` appellanti, xehed quddiem il-Bord li dawn iz-zewg dokumenti jezistu, u flimkien mas-*Summary of Product Characterisations*, jinsabu fuq il-*website* tal-Malta Medicine Authority, jekk is-socjeta` kellha xi dubju dwar dak mitlub kellha dritt titlob kjarifika, pero`, ma setghetx taqbad u tinjora dak li gie specifikament mitlub fis-sejha ghall-offerti.

L-istess socjeta` appellanti tghid ukoll li ghall-medicina taghha kellha *market authorisation* u l-medicina kienet tissodisfa l-htigijiet tal-Avviz Legali 393 tal-2005, ir-Regolamenti dwar it-Tqeghid ta' Tikketti u Ppakkettjar ta' Prodotti Medicinali (legislazzjoni sussidjarja numru 458.33). Dan jista' jkun minnu u dan juri li l-prodott jirrispetta l-ligijiet kollha nostrani u dawk tal-Unjoni Ewropea u li l-prodott huwa wiehed approvat. Dan ma jfissirx, pero`, li l-offerta li saret mis-socjeta` kienet konformi ma' dak mitlub fis-sejha. Il-prodott jista' jkun konformi mal-ligijiet, pero`, l-offerta ma kinitx konformi mas-sejha. Is-socjeta` appellanti ma kellhiex tforni dokumenti jew informazzjoni biex turi li l-prodott kien konformi mal-ligi, izda d-dokumenti espressament mitluba fis-sejha, u ma jidhirx mill-atti li l-informazzjoni li tinsab fil-*Package Leaflet* inghatat mal-offerta – almenu zgur mhux fil-forma semplici li riedet is-sejha peress illi dak id-dokument hu intiz li jinqara u jinftiehem minn pazjenti.

Ghaldaqstant, ghar-ragunijiet premessi, tiddisponi mill-appell ta' Cherubino Limited billi fl-ewwel lok, tillibera lid-Dipartment tal-Kuntratti mill-osservanza tal-gudizzju, u billi tilqa' l-istess, thassar u tirrevoka d-decizjoni tal-Bord tal-21 ta' Lulju, 2017, tordna li d-depozitu li ghamlet is-socjeta` Pharma-Cos ghal dak l-appell jintilef, u tichad l-appell li Pharma-Cos ressqet ghal quddiem il-Bord u tiddeciedi li l-offerta li din l-ahhar socjeta` ghamlet ma hijiex "*technically compliant*".

L-ispejjez ta' dawn il-proceduri jithallsu kollha mis-socjeta` appellata Pharma-Cos Limited, hlief ghal dawk tad-Dipartiment tal-Kuntratti li ghandhom jithallsu mis-socjeta` appellanti Cherubino Limited.

Silvio Camilleri Prim Imhallef	Tonio Mallia Imhallef	Joseph Azzopardi Imhallef

Deputat Registratur
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