



MALTA

**QORTI TA' L-APPELL**

**ONOR. IMHALLEF**

**EDWINA GRIMA**

Seduta tad-29 ta' April, 2015

Appell Civili Numru. 53/2012

**V.J.SALOMONE PHARMA LIMITED**

**VS**

**(1) DIRETTUR TAD-DIPARTIMENT TAL-KUNTRATTI**

**(2) CHERUBINO LIMITED (C3677)**

**(3) BORD TA' REVIZJONI DWAR IL-KUNTRATTI PUBBLICI**

**(4) BORD TA' EVALWAZZJONI**

**(5) CENTRAL PROCUREMENT AND SUPPLIES UNIT (CPSU)**

**(5) MINISTRU GHAS-SAHHA, L-ANZJANI U KURA FIL-KOMUNITA  
ghal kull interess li jista' ikollu**

Il-Qorti;

Rat id-decizjoni moghtija mill-Bord ta' Revizjoni Dwar il-Kuntratti Pubblici fl-14 ta' Novembru 2012, fejn giet ipprounzjata is-segweni decizjoni fl-ismijiet premissi:-

*“This Board,*

- *having noted that the appellants, in terms of their ‘letter of objection’ filed on 14<sup>th</sup> May 2012 and also through their verbal submissions presented during the hearing held on the 23<sup>rd</sup> July 2012, had objected to the decision taken by the pertinent authorities;*
- *having noted all of the appellant company’s representative’s claims and observations, particularly, the references made to the fact that (a) by letter dated 8<sup>th</sup> May, 2012 the contracting authority had informed the appellant company that its tender submission was not successful since it could not “be confirmed whether the product offered is compliant with published specifications regarding bioavailability since section 4.2 of SPC submitted states that patients should not be transferred to or from other oral formulations of Cicloporin without appropriate close monitoring...” and ‘...that substitution of Deximune capsules for other formulations may lead to alterations in cicloporin blood levels’, (b) the case under reference and the previous ones were quiet similar, with the main difference being that, this time, the contracting authority also stated in its letter of rejection that “Following recommendations by Clinical Section, DPA have review specifications. Item is not according to the new updated specifications (due to the nature of product, in the updated specifications, the bioequivalence clause has been removed and the originator ‘Neoral is requested”, (c) it, therefore, followed that this call for tenders was issued with the bioequivalence clause, (d) since the tender specifications allowed bidders to offer generic products then the appellant company’s offer was compliant and should not have been disqualified, (e) if anything the contracting authority might have cancelled the tender – as was the case with GHPST/410/11 – and not recommend award to the bidder who offered the originator product and excluded the appellant company for offering a generic product as requested in the tender document, (f) given this scenario, one had to question the purpose for contracting authority to issue a call for tenders when only the originator product would be requested, (g) both this tender and tender Ref. No. with GHPST/410/11 had been issued with the bioequivalence clause with the difference being that the contracting authority had recommended the cancellation of the latter whereas the same contracting authority was recommending this tender for award to VJ Salomone Pharma Ltd, (h) the technical specifications at page 30 allowed bidders to offer generic products and, accordingly, the appellant company offered a generic product together with the required bioequivalence evidence and the contracting authority did not rule out the appellant company’s product for not being bioequivalent but it stated that it was not successful since it cannot be confirmed whether the product offered was compliant with published specifications regarding bioavailability...namely the same reason quoted with regard to the previous tender procedure (GHPST/410/11), (i) at the hearing held in connection with calls for tenders’ reference numbers GHPST/410/11 and GHPST/928/11, it had been greed that one had to establish whether the appellant company’s product was bioequivalent or not (j) one had to share the Public Contracts Review Board’s view that one should await the independent technical advice sought by the Public Contracts Review Board and it would result that the appellant company’s product was*

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*bioequivalent then its offer should be reinstated even in the case of this tendering procedure and if it would result that the appellant company's product was not bioequivalent then its disqualification out to be confirmed in both cases;*

- *having considered the contracting authority's representatives' reference to the fact that (a) the preferred bidder offered the originator product and, as a result, the offer was compliant with or without the bioequivalence clause, (b) when the adjudicating board was evaluating the tender submissions it noted that the offers submitted referred to both the originator product and to a generic product and, as a consequence, it referred the matter to the Clinical Section which, in turn, declared that the generic product was not acceptable and recommended a revision of the specifications to remove the bioequivalence clause and (c) this call for tenders did include the bioequivalence clause but future calls for tenders for the same product would be issued without that clause thereby requesting only the originator 'Neoral (R) Novartis';*
- *having considered the recommended tenderer's representatives' reference to the fact that (a) the technical specifications at page 30 of the tender document were, in a way, rather contradictory in the sense that, whereas the second paragraph allowed bidders to offer a generic product, the previous (first) paragraph, clearly and specifically, requested Cyclosporin 25mg soft gelatine capsules in a microemulsified formulation (Neoral (R), Novartis) and no alternatives were mentioned and (b) although the recommended tenderer was the only distributor in Malta of Neoral (R) Novartis, still, this tender was published EU-wide and, as a result, distributors for this particular product in other EU states could have submitted a bid:*
- *having gone through the following administrative 'iter' to enable the Board to obtain an independent, international professional advice, namely:*
  - *Contacted a pharmacological expert based in Aberdeen Scotland – 14.05.2012*
  - *Expert placed this Board in touch with Dr. Rachel Knott from the Robert Gordon University-15.5.2012-who showed interest and requested further information*
  - *Received confirmation from Dr. Knott that Dr Yash Kumarasamy, a Clinical Pharmacology Senior Lecturer, at the Robert Gordon University was interested -22.06.2012.*
  - *Contract finalised for signature 20.07.2012*
  - *Prof Anne Humphrey from the Robert Gordon University informed the Board on the 23.07.2012 that Dr. Yash Kumarasamy passed away*
  - *Prof Cherry Wainwright, Robert Gordon University, informed the Board that it was not possible to assign anyone else from the University – 26.07.2012*

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- *Proof Susan Klein, Robert Gordon University, proposed Dr Peter Mullen who had been confirmed by Ms Hazel O'Mullen that he is a member of the British Pharmacological Society – 07.08.2012*
  - *Negotiations started with Peter W. Mullen, PhD, FCSFS, consultant Pharmacologist/Toxicologist, Kemic Bioresearch Laboratories Limited, Kentville, Nova Scotia, Canada and were concluded on the 15.09.2012*
  - *A report was submitted by Dr Peter Mullen on 3<sup>rd</sup> November 2012*
- *Having gone through Dr. Mullen's detailed report;*

*This Board concludes that "Deximune is bioequivalent to Neoral" as according to its appointed arbitrary professional consultant on subject matter, Peter W. Mullen, PhD, FCSFS, Consultant Pharmacologist/Toxicologist, Kemic Bioresearch Laboratories Limited, "Considering the bioequivalence testing results (especially) reviewed at length herein, the stated clinical experience of established clinicians involved in organ transplantation and the undisputed fact of its marketed status and apparently unblemished clinical reputation in the UK and elsewhere" he opines that there is sufficient evidence to conclude that Deximune is bioequivalent to Neoral.*

*As a result, this Board concluded that Deximune products can be used interchangeably and, as a result, does not concur with the contracting authority that there was enough reason for the latter to disqualify the appellant company's tender.*

*In view of the above, this Board finds in favour of the appellant company and, apart from recommending the reintegration of the appellant company's bid in the re-evaluation process, this Board also recommends that the deposit paid by the same company for the appeal to be lodged should be reimbursed."#*

Illi s-socjeta appellanti aggravata b'din id-decizjoni, kif ukoll bid-decizjoni *interim* tal-Bord datata 30 ta' Lulju 2012 fejn l-istess Bord ma laqax it-talbiet taghha li tinghata kopja tar-rapport tekniku u li teskuti lit-tekniku hekk imqabbad mill-Bord qabel tinghata decizjoni finali, ressqet l-appell taghha fit-termini tas-segwenti aggravvji:

1. Illi fil-proceduri quddiem l-Bord ta' Revizjoni dwar il-Kuntratti Pubblici gew vjolati gravament il-principji ta' smiegh xieraq in kwantu is-socjeta appellanti qatt ma giet moghtija kopja tar-rapport li kien sar kontra taghha qabel ma inghatat id-decizjoni finali u ma thallietx teskuti l-espert qabel ma il-Bord ghadda ghad-decizjoni finali tieghu. Inoltre is-socjeta appellanti qatt ma intallbet tipprezenta dokumentazzjoni teknika u espert

taghha in sostenn tal-posizzjoni taghha *qua* offerent tal-prodott specifikatament rikjest fis-sejha ghal-offerti. Dan wassal sabiex hija ma inghatatx l-opportunita li tissottometti l-kaz taghha lill-Bord.

2. Inoltre gie vjolat il-principju tal-*equality of arms*, imhaddan ukoll fid-dritt tas-smigh xieraq f' kwalunkwe process gudizzjarju u kwazi-gudizzjarju. Dan ghaliex l-espert imqabbad mill-Bord fil-konkluzjonijiet tieghu strah unikament fuq l-evidenza moghtija lil mill-*generic manufacturer*, Dexcel Pharma, minghajr ma inghatat, s-socjeta appellanti, l-opportunita li tressaq dokumentazzjoni u provi fir-rigward tal-punt tekniku (u cioe' jekk id-Deximune huwiex verament *bioequivalent* ghal Neoral). Fuq kollox il-Bord naqas milli jaghmel valutazzjoni tar-rapport imressaq mit-tekniku izda biss assuma dana r-rapport bhala konklussiv u naqas ghalhekk milli ighaddi ghall-process ta' decizjoni li kellu jsir minnu.

Illi fir-risposta tieghu ghall-appell, id-Direttur tal-Kuntratti jitlob il-liberazzjoni mill-osservanza tal-gudizzju stante illi huwa ma kienx l-awtorita kontraenti fil-kaz ta' dina is-sejha ghall-offerti pubblici ghall-provvista ta' *Cyclosporin 25mg capsules*, billi din kienet giet imhabbra u ippubblikata mill-awtorita kontraenti li f'dan il-kaz kien il-*Government Health Procurement* fi hdan dak iz-zmien il-Ministeru ghas-Sahha, l-Anzjani u Kura fil-Komunita. Dan ghaliex il-valur tal-kuntratt pubbliku kien stmat f'ammont ta' inqas minn €120,000 u allura skont ir-regolament 19 tat-Taqsima II tar-Regolamenti Dwar il-Kuntratti Pubblici il-kuntratt *de quo* kellu jigi regolat mill-awtorita kontraenti.

Illi id-Direttur appellat ghandu ragun billi jidher car kemm mir-regolament iccitat kif ukoll mill-atti probatorji, illi huwa ma kellux xejn x'jaqsam la mal-hrug tas-sejha ghall-offerti pubblici u wisq anqas ma'l-aggudikazzjoni sussegwenti, oltre il-fatt illi allura huwa ma kienx kompartecipi fil-proceduri

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quddiem il-Bord ta' Revizjoni dwar il-Kuntratti Pubblici.<sup>1</sup> Ghal dawn il-motivi dana il-pregudizzjali ser jigi milqugh u id-Direttur tal-Kuntratti qed jigi liberat mill-osservanza tal-gudizzju.

Illi lanqas ma huwa il-legittimu kuntradittur, il-Bord ta' Revizjoni dwar il-Kuntratti Pubblici f'dana l-appell mid-decizjoni mehuda proprju minnu. Il-Bord ma huwiex parti interessata kif trid il-ligi izda huwa bord stabbilit bil-ligi b'funzjonijiet kwazi-gudizzjarji.

Illi in succinct il-fattispecje tal-kaz tnisslu minn sejha ghall-offerti pubblici li saret fit-05 ta' Awwissu 2011 u dana ghall-provvista ta' *Cyclosporin 25mg capsules*. Wara din is-sejha kienu biss zewg operaturi li tefghu l-offerta taghhom wahda minnhom is-socjeta appellanti u l-ohra is-socjeta appellata Cherubino Limited. Illi permezz ta' ittra datata 08 ta' Mejju 2012, il-kuntratt pubbliku gie aggudikat favur is-socjeta appellanti. Illi s-socjeta appellata Cherubino Limited appellat minn din id-decizjoni quddiem il-Bord ta' Revizjoni dwar il-Kuntratti Pubblici billi sahqet illi hija kienet osservat l-ispecificazzjonijiet teknici tal-prodott meta offriet "*a generic product*" u mhux "*an originator product*" b'evidenza ta' "*bioequivalence*" kif rikjest. Illi il-perm tal-kwistjoni kollha ghalhekk kienet iddur madwar jekk il-prodott offert mis-socjeta appellata "*Deximune*" kienx "*bioequivalent*" ghal-"*Neoral*" u cioe l-*originator product* offert mis-socjeta appellanti, fejn allura il-*generic product* kellu prezz iktar baxx. Illi l-Bord ta' Revizjoni dwar il-Kuntratti Pubblici rinfaccjat b'kwistjoni ferm teknika u delikata ta' prodott medicinali li jigi moghti lill-pazjenti wara trapjant tal-organi u rinfaccjat b'opinjoni divergenti dwar dan il-prodott hass il-htiega li jahtar espert indipendenti barrani sabiex jassistieh fid-decizjoni tieghu. Wara li kiseb dan il-parir, l-Bord ghadda ghal

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<sup>1</sup> Ara sentenza App. Sup deciza 07/08/2013 fl-ismijiet Gatt Tarmac Limited vs Kunsill Lokali Victoria et.

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decizjoni favur is-socjeta appellata, fejn allura infetah mill-gdid il-konkors pubbliku ta' l-agjudikazzjoni. Illi qabel ma ghadha ghad-decizjoni tieghu, izda s-socjeta appellanti kienet ressqet talba sabiex tkun tista' tinghata kopja tar-rapport ta' dan l-espert indipendenti kif ukoll illi tkun tista taghmel eskussjoni tieghu jekk ikun il-kaz. Il-Bord izda cahad dina it-talba u ghadha ghad-decizjoni tieghu li fiha huwa strah unikament fuq il-konkluzzjonijiet raggunti minn dan l-espert imqabbad minnha u dan ghalhekk minghajr ma avza lill-partijiet u wisq anqas tahom l-opportunita iressqu is-sottomissjonijiet taghhom rigward l-istess.

Mill-kontenut ta' l-ewwel aggravju jirrizulta li s-socjeta` appellanti qed tinvoka l-ksur tal-principju fundamentali ta' gustizzja naturali "*audi alteram partem* u ghalhekk tilmenta illi hija giet imcahhda mill-jedd ghal smigh xieraq u dana f'process kwazi gudizzjarju fejn hija kellha interess issemma lehinha stante li l-ezitu tad-decizjoni setghet twassalha biex issofri pregudizzju irrimedjabbli. Dan ghaliex tilmenta illi l-Bord ingustament cahad it-talba taghha sabiex tigi notifikata bir-rapport tal-espert imqabbad minnu u li teskuti lill-istess espert meta il-Bord iddecieda:

*"Dawn it-teknici qeghdin jigu mqabbda sabiex iservu ta' arbitru u jassistu lil dan il-Bord jasal ghal konkluzjoni hu u mhux sabiex isiru parti mill-process huma stess. Dan il-Bord ma ghandu l-ebda obbligu li jikkonsulta ma'l-ebda parti dwar it-teknici li jaghzel hu u dan minhabba l-fatt li kieku kellu jaghmel hekk jispicca jintilef l-iskop ta' arbitrarjeta tieghu."*

Illi bir-rispett lejn il-membri tal-Bord tali affermazzjoni ma issib l-ebda konfort la fil-ligi specjali li tirregola l-ghoti ta' kuntratti pubblici u wisq anqas fir-regoli bazilari ta' harsien tal-jeddijiet fundamentali ta' smigh xieraq li huma l-qafas ta' kull procediment gudizzjarju jew kwazi gudizzjarju.

Ibda biex kull process ta' *public procurement* ghandu bhala il-bazi tieghu il-kuncett bazilari tat-trasparenza li ifisser illi l-partecipanti kollha tas-sejha ghandhom jigu trattati bl-istess mod. Naturalment biex ikun hemm dan it-trattament ugwali l-konkorrenti kollha tas-sejha jridu ikunu mqieghda fil-kundizzjoni li ikunu jistghu jitolqu mill-istess punt ta' tluq. Dan jista' jimmatterjalizza ruhu biss jekk l-offerenti ikun moghtija l-istess informazzjoni u l-istess mezzi biex jippartecipaw fis-sejha pubblika illi issir. Illi dan il-kuncett ta' trasparenza u ugwaljanza fil-process ta' l-aggudikazzjoni huwa imfisser sahsitra fid-Direttiva 2004/18/EC tal-Unjoni Ewropeja trasportata fil-legislazzjoni taghna li ghandha bhala l-qafas taghha dawn il-principji balizari meta jinghad:

**“The award of contracts concluded in the Member States on behalf of the State, regional or local authorities and other bodies governed by public law entities, is subject to the respect of the principles of the Treaty and in particular to the principle of freedom of movement of goods, the principle of freedom of establishment and the principle of freedom to provide services and to the principles deriving therefrom, such as the principle of equal treatment, the principle of non-discrimination, the principle of mutual recognition, the principle of proportionality and the principle of transparency”<sup>2</sup>.**

*Multo magis* dawn il-principji ghandhom ikunu applikabbli b'iktar forza meta l-aggudikazzjoni tkun qed tigi ikkontestata ghal xi raguni jew ohra. Fil-fatt ir-regolamenti dwar il-Kuntratti Pubblici ihaddnu dawn il-jeddijiet fundamentali ta' trattament ugwali u ta' trasparenza meta fir-Regolament 85(7)(j) tar-Regolamenti dwar il-Kuntratti Pubblici, li jitkellem dwar il-procedura li ghandha tkun adottata mill-Bord ta' Revizjoni dwar il-Kuntratti Pubblici jinghad:

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<sup>2</sup> Recital 2 to the Council Directive



Is-sessjonijiet tal-Bord ta' Revizjoni li matulhom jigi ttrattat l-ilment ghandhom isiru bil-miftuh u kemm min ikun qed jaghmel l-ilment kemm il-parti li jkollha interess ikollhom jedd jattendu u jkollhom isehibhom lil kull persuna, professjonali jew xort'ohra, li huma jqisu li jkun adatt biex jiddefendi l-interessi taghhom. (sottolinjar tal-Qorti).

Isegwi ir-Regolament 85(7)(k) fl-istess vena:

(i) Ic-Chairman ikun jista' jistabbilixxi l-procedura ghas-smigh tal-ilmenti kollha li jsiru lill-Bord ta' Revizjoni u ghandu jizgura li matul is-smigh li jsir bil-miftuh kull parti li jkollha interess tinghata l-opportunita li tressaq il-kaz taghha. (sottolinjar tal-Qorti).

Illi l-opportunita li kull parti interessata tinghata jedd ghal smigh xieraq isib iktar forza fid-dawl tal-provvedimenti tar-regolament 85(8)(b) li jaghti forza ezekuttiva lid-decizjonijiet tal-Bord:

**“Id-decizjoni tal-Bord tikkostitwixxi titolu ezekuttiv u tista' tkun infurzata skond l-artikolu 273 tal-Kodici ta' Organizzazzjoni u Procedura Civili.”**

Dawn id-decizjonijiet jorbtu mhux biss lid-Direttur tal-Kuntratti jew l-Awtorita Kontraenti skont il-kaz, izda lill-offerenti kollha.

Premess dan ghalhekk ma ghandux ikun dubitat illi ghalkemm il-Bord kellu kull jedd jikseb parir minn ghand espert indipendenti imqabba minnu sabiex ighinu fl-investigazzjonijiet tieghu, u dana bis-setgha moghtija lill-fir-regolament 85(7)(i), madanakollu dan ghandu isir b'osservanza tal-jedd tas-smigh xieraq lill-partijiet kollha involuti fil-procediment pendenti quddiemu. Din il-Qorti ghalhekk ma tistax taqbel mal-fehma addotata mill-Bord illi jichad il-jedd lis-

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socjeta appellanti milli tispezzjona ir-rapport ta' l-espert imqabbad minnha qabel ma tittiehed id-decizjoni finali, u li dan l-offerent jithalla jaghmel is-sottomissjonijiet tieghu in konnessjoni ma' l-istess, iktar u iktar fid-dawl tal-fatt illi d-decizjoni ta' l-istess Bord kien ser ikollha effett eżekuttiv u kienet ser torbot lis-socjeta appellanti li favur taghha kien gie aggudikat il-kuntratt pubbliku fl-aggudikazzjoni ikkontestata. Mhux biss, izda f'kwistjoni ta' natura delikata bhal ma hi l-oggett ta' dan il-kuntratt pubbliku u cioe' il-provvista ta' medicinali lill-pazjenti li ikunu ghaddew minn operazzjoni serja bhalma hi dik ta' trapjant ta' organi, il-Bord messu mexa b'iktar kawtela u dana meta kellu quddiemu opinjoni medika ohra li kienet qed issostni il-kontra ta' dak konkluz mill-espert imqabbad minnha u mhux taqbad u taddotta dina l-konkluzjoni minghajr ma tisma' is-sottomissjonijiet tal-partijiet kollha involuti in konnessjoni ma' l-istess.

Illi b'analogija il-Qorti tigbed bhala eżempju l-procedura segwieta quddiem diversi bordijiet, bhal Bord li jirregola l-Kera kif ukoll it-Tribunal ghar-Revizjoni Amministrattiva fejn il-bord/tribunal ikun assistit minn membri teknici bhala arbitri fil-kaz. Illi kull rapport sottomess mill-membri teknici huwa disponibbli lill-partijiet li jinghataw il-jedd iressqu is-sottomissjonijiet dwaru qabel ma tinghata s-sentenza finali. Illi ghalhekk il-Bord ma kellux ragun illi icahhad lis-socjeta appellanti mill-jedd illi tigi notifikata bir-rapport ta' l-espert imqabbad minnu u li tressaq dawk il-provi u sottomissjonijiet li jidhrilha xieraq.

Ghaldaqtsant il-Qorti qed tilqa' l-ewwel aggravju u ghalhekk ma tarax illi ghandha tinoltra ruhha fl-aggravju l-iehor imressqa mis-socjeta appellanti.

Ghal dawn il-motivi l-appell qed jigi milqugh, id-decizjonijiet tal-Bord dwar ir-Revizjoni tal-Kuntratti Pubblici tat-30 ta' Lulju 2012 u tal-14 ta' Novembru 2012 qed jigu revokati. Tirrimetti l-atti lura quddiem il-Bord sabiex wara li

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jisma' s-sottomissjonijiet, u jekk ikun il-kaz anke provi, mill-partijiet kollha interessati u dana fid-dawl tar-rapport sottomess mill-espert Peter W. Mullen, ighaddi ghad-decizjoni tieghu skont il-ligi.

Fid-dawl tac-cirkostanzi partikolari ta' dan il-kaz, l-ispejjez ta' din il-procedura ghandhom jibqghu bla taxxa bejn il-partijiet.

**< Sentenza Finali >**

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