QORTI TAL-APPELL

IMHALLFIN

S.T.O. PRIM IMHALLEF JOSEPH AZZOPARDI
ONOR. IMHALLEF JOSEPH R. MICALLEF
ONOR. IMHALLEF TONIO MALLIA

Seduta ta' nhar il-Gimgha 28 ta' Frar 2020

Numru 16

Rikors numru 394/19

V.J. Salomone Pharma Limited (C 10268)

v.

Central Procurement and Supplies Unit tal-Ministeru tas-Sahha, Direttur Generali tad-Dipartiment tal-Kuntratti, u Charles de Giorgio Limited (C 340)

Il-Qorti:

Dan hu appell imressaq fid-9 ta' Dicembru, 2019, mis-socjeta` rikorrenti V.J. Salomone Pharma Limited wara decizjoni datata 21 ta' Novembru, 2019, moghtija mill-Bord ta' Revizjoni dwar il-Kuntratti Pubblici (minn hawn 'il quddiem imsejjah "il-bord") fil-kaz referenza CT 2276/2019 (kaz numru 1358).

Dan hu kaz marbut ma' sejha ghall-offerti li hareg il-Ministru tas-Sahha "*for the supply of interleukin 17A inhibitors*". Is-socjeta` rikorrenti ressqet talba ghal *pre-contractual remedy* ghall-quddiem il-Bord. Hi ssottomettiet illi s-sejha ghal proposti hija msejsa fuq zbalji u ambigwitajiet, li l-istess sejha hija msejsa fuq vjolazzjoni tal-ligi, u li s-sejha hija diskriminatorja. Il-Bord b'decizjoni tal-21 ta' Novembru. 2019, cahad l-ilment tas-socjeta` rikorrenti u kkonferma l-validita` tas-sejha. Id-decizjoni tal-Borg hija s-segwenti:

> "**This Board,**
>
> "**having noted this 'Call for Remedy Prior to the Closing Date for Call for Competition' filed by V J Salomone Pharma Ltd (herein after referred to as the Appellants) on 26th August 2019, refers to the claims made by the same Appellants with regard to the tender of reference CT 2276/2019 listed as case No. 1358 in the records of the Public Contracts Review Board.**
>
> "**Appearing for the Appellants: Dr Mario De Marco**
> **Dr Therese**
> "**Comodini Cachia**
> **Appearing for the Contracting Authority: Dr Marco Woods**
> **Appearing for the Department of Contracts: Dr Franco Agius**
>
> "**Whereby, the Appellants contend that:**
>
> **a) "Their main concern refers to the fact that the Contracting Authority in the present tender of Ref. CT 2276/2019, did not follow the Public Contracts Review Board's decision in Case No. 1279, wherein, it was decided that more than one product should be procured so long, as these were approved by the medical consultants. In this regard, Appellants maintain that the present tender is discriminatory against other drugs that can affect treatment to the benefit of the well-being of the patient.**
>
> **b) "Appellants also contend that the technical specifications as stipulated in the tender document were not approved by the medical consultants as duly directed in the Public Contracts Review Board's decision in case No. 1279.**

"**This Board also noted the Contracting Authority's 'Letter of Reply' dated 12 September 2019 and a 'Letter of Reply' dated 5 September 2019 from Charles de Giorgio Ltd an interested party, followed by submissions during the hearings held on 27 September and 25 October 2019, in that:**

a) "**The Authority maintains that it is the Contracting Authority's prerogative as to how the technical specifications of the tender are formulated. In this regard, the Authority insists that the Public Contracts Review Board's decision directed that Medical Boards were consulted, and such directions were duly applied.**

"**This same Board also noted the testimony of the witnesses namely:**

"**Dr Cecilia Mercieca, duly summoned by the Public Contracts Review Board**

"**Dr Denis Vella Baldacchino, duly summoned by the Public Contracts Review Board**

"**Ms Antonia Formosa, duly summoned by the Public Contracts Review Board**

1. "**This Board, after having examined the relevant documentation to this 'Call for Remedy' and heard submissions made by all the interested parties, including the testimony of the witnesses duly summoned during the hearings held on 27 September and 25 October 2019, opines that, the issue that merits consideration is the adherence by the Contracting Authority to the directions given by the Pubic Contracts Review Board's decision in case No. 1279, in the issuance of this tender of reference CT 2276/2019.**

2. "**In its decision, in case No. 1279, this Board recommended the availability of more than one product, always after consulting the medical consultants, as follows:**

> "*3. With regard to Appellants' suggestion that the Contracting Authority should consider procuring more than one equivalent product on a particular tender, this Board, although in agreement with such a recommendation, would respectfully leave such a decision to be approved by the Medical Consultants, taking into consideration the fact as to whether such an option is in the interest of the patient."*

"**In this regard, Appellants are insisting that the above-mentioned recommendations were not adhered to by the Authority, since Medical Consultants were not consulted.**

3. "**This Board would refer to an extract from the testimony of Ms Antonia Formosa who confirmed that more than one product**

was taken onto consideration in the formulation of the technical specifications, as follows:

> "*Avukat : Ha nispjega ruhi ahjar. Mela il-GFLAC irrakkomanda pathways illi kienu jkopru iktar minn prodott wiehed ghax essenzjalment dawn il-prodotti mhux dejjem huma interchangeable jekk fhimtek sew*
>
> "*Xhud : Iva f'dan il-kaz mhumiex interchangeable*
>
> "*Avukat : Mela la darba mhux interchangeable, il-GFLAC hareg b'dan il-pathway. Il-pathway allura jitkellem dwar aktar minn prodott wiehed ghal pazjenti li qeghdin ibatu minn psoriasis jew psoriatric arthritis*
>
> "*Xhud : Yes"*

"**Furthermore, same witness re-affirmed the fact that this is an open tender where more than one product is being tendered for as duly testified. Viz:**

> "*Avukat : It-tender li nhareg issa li qeghdin fuqu hawn hekk illum mhux miftuh ghal aktar minn prodott wiehed ghax filwaqt li kif inhu miktub, filwaqt li iva iktar minn prodott wiehed jistghu jittenderjaw, pero l-ghazla ser tkun limitata ghal prodott wiehed li huwa l-irhas. F'dan il-kaz tender li huwa essenzjalment ser jintghazel one product based on x'inhu l-irhas, qieghed jirrifletti l-pathway rakkomandata mill- GFLAC?*
>
> "*Xhud : Dawk l-open specs ta' dan it-tender kienu qeghdin immirati biex niffolowjaw il-PCRB decision li kienet ittiehdet qabel din fejn ahna gejna gwidati wkoll mill-procurement illi ma stajniex nohorgu tender illi kien jismu Secukinumab imma kellu jkun an open spec."*

"**Through the credible testimony of Ms Formosa, this Board establishes that the tender specifications conformed with the recommendation of the Public Contracts Review Board's decision in that, more than one equivalent product should be considered in formulating the specifications of the new tender.**

4. "With regard to Appellants' contention that the Medical Consultants and the relative Authorities were not involved in the recommendations given by this Board in its decision in case No 1279, same Board would again refer to an extract from the testimony of Ms Formosa, who stated specifically that:

> "*Dan gie diskuss bejn kulhadd, bejn il-konsulenti u c-CMO, kulhadd kien involut fiha din id-decizjoni u d-direzzjoni li nghatajt jiena minghand is-CMO kienet illi ghal dawk il- kazijiet generali fejn pazjent jista jgawdi minn medicina jew ohra, jigifieri pazjent gdid qed nghidu, a new patient, jista jibbenefika kemm minn medicina u kemm minn ohra, ghal dawk kien hemm din l-ispec. Ghal pazjenti ohra li ma jaqghux within the spec, ser ikollu jkun hemm spec ohra*
>
> "*Avukat : Tista tkun iktar cara?*

"*Xhud : Nista naghti ezempji. Jekk inharsu lejn l-ewwel table il-kbira fejn hemm hafna pazjenti fuqha, dawn huma l-pazjenti, ovjament bdiltilhom l-initials u nehhejt l-informazzjoni kollha li hija relatata mal-pazjent u hallejt biss l-informazzjoni li tista twassal ghal decizjoni. Jekk inharsu lejn patient AB, dawn huma decizjonijiet li ttiehdu mill-exceptional committee. Patient AB perezempju ibati minn psoriasis u ghal dak id-decizjoni ttiehdet li dak jaqa fil-kategorija ta' IL 17A inhibitor li huwa l-open spec u therefore it-tender jghodd ghal dan il-grupp ta' pazjenti. Jekk immorru lejn patient QP li jbati minn rheumatoid arthritis, l-istess, IL17A inhibitor gie approvat u ghaliex ukoll il-psoriasis u r- rheumatoid arthritis jaqghu taht din l-ispec. Fejn ghandna pazjenti bl-spondylo arthritis, dawn mhux iz-zewg medicini in question huma licenzjati ghalihom u sa issa ghadu licenzjat biss is- Secukinumab u f'dan il-kaz id-decizjoni li ttiehdet mill-kumitat kienet li jridu jivverifikaw ezattament il-licensing status u nimxu minn hemm. Jigifieri f'dan il-kaz huma ma rawx illi is-17A inhibitors huma adattati ghalihom pero se imorru ghal medicina partikolari"*

5. "**This Board will not enter into the merits which have already been treated in the first hearing, however, it must be noted that the motive of the Board's decison in case No. 1279, was to ensure that there will be available more than one type of drug, so as to provide treatment for already existing patients with such a condition and also a choice of treatment for new patients. This Board opines that the Medical consultants should have the opportunity to choose the proper treatment for the particular patient.**

"**In conclusion, this Board opines that:**

a) "**The technical specifications of the new tender take into consideration this Board's recommendation with regard to an open tender where more than one type of drug should be tendered for.**

b) "**The technical specifiations were discussed with the Medical Specialists as directed in this Board's decision in case No. 1279.**

c) "**It cannot identify any justifiable reason as to why the technical specifications as stipulated in the tender, should be regarded as ambiguous or discrminatory.**

"**In view of the above, this Board,**

i."**does not uphold Appellants concerns,**

ii."**directs that the tendering process be resumed,**

iii."**directs that the closing date of the tender be 20 December 2019 at 12.00 noon**".

Is-socjeta` V.J. Salomone Pharma Limited issa qed tappella mid-decizjonji li ta l-Bord ghal quddiem din il-Qorti u ressqet essenzjalment tlett aggravji: (i) illi l-Bord ha decizjoni kontradittorja ghad-decizjoni precedenti tieghu numru 1249; (ii) illi l-Bord naqas li jaghmel konsultazzjoni effettiva mal-konsulenti medici kif kien fid-dover tieghu li jaghmel, u (iii) illi l-Bord naqas li jikkonsidra xi aggravvji li tressqu minnha.

Wara li semghet 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:

Fil-kuntest tal-ewwel ilment, jinghad mis-socjeta` rikorrenti li filwaqt illi l-Bord tenna d-decizjonijiet tieghu li ghandu jkun hemm aktar minn medicina wahda ghad-dispozizzjoni tal-konsulenti medici f'din il-klassi ta' medicina, imbaghad ghadda sabiex approva sejha ghal tender li twassal biss ghal medicina wahda. Jigi osservat li wara d-decizjoni precedenti li ha l-Bord f'Marzu tal-2019, l-awtorita` konvenuta kellha tohrog sejha fejn ma jkunx hemm riferenza diretta ghall-"*brand name*", izda li s-sejha tkun b'*open specifications*. B'hekk harget sejha ghas-supply of *Interleukin 17A Inhibitors*, b'mod li s-sejha kienet miftuha ghal diversi medicini. Dan sar anke biex tithares konkorrenza hielsa. Din is-sejha tippermetti li jigu

offruti aktar minn medicina wahda, u tippermetti lis-Central Procurement and Supplies Unit li tixtri l-irhas prodott u li ser ikun il-*first line treatment*. Dan ma jfissirx li l-*Unit* appellata ser tkun limitata biex tixtri dan il-prodott biss, u kif xehedu c-*Chief Medical Officer* u d-direttur, *Department of Pharmaceutical Affairs*, dejjem hemm lok li jekk pazjent ma jaqbilx mieghu l-*first line treatment*, jinqaleb fuq medicina ohra akkwistata permezz ta' metodi ohra ta' akkwist pubbliku. Is-sejha, fi kliem iehor, hija miftuha ghall-konkorrenza u miftuha sabiex aktar minn prodott wiehed ikun jista' jippartecipa. Fl-istess waqt l-appellati huma fil-liberta` kollha bis-sejha u b'mezzi ohra, inkluz in-*negotiated procedure*, biex jixtru aktar minn prodott wiehed fejn hemm il-bzonn u n-necessita` fl-interess tal-pazjent.

Iz-zewg prodotti tas-socjeta` appellanti u tas-socjeta` intimata, il-*Consentyx* u t-*Taltz*, jinghad li mhux identici u *mhux interchangeable* peress illi l-*active ingredient* u l-molekula tal-prodotti huma differenti. Pero`, minn lenti terapewtika, it-tnejn jistghu jigu preskritti ghall-indikazzjonijiet terapewtici indikati li jaqghu fil-klassi ta' *interleukin 17A inhibitors*. Fil-fatt, id-direttur tad-dipartiment tal-affarijiet farmacewtici., irrikonoxxiet li pazjent gdid seta' jinghata kemm wahda u kemm l-ohra mill-imsemmija prodotti, li juri li z-zewg prodotti jaqdu, sa certu sens, l-istess funzjoni.

Ghalhekk, mhux kaz li s-sejha hi immirata biss ghal medicina wahda, u ma hemm xejn kuntradittorju fis-sentenzi li ta l-Bord, u bhala fatt is-sejba hija miftuha ghal aktar minn prodott wiehed kif ordna l-Bord. Il-unit appellata imxiet ma' rakkomandazzjoni tal-Bord fid-decizjoni numru 1279 u dan billi harget sejha bhala *open specifications* sabiex kull operatur ekonomiku li ghandu medicina li hija konformi mas-specifikazzjonijiet teknici jkun jista' jissottometti offerta.

Ghalhekk, kif intqal qabel, minkejja li kull offerent huwa hieles li joffri kwalunkwe medicina tal-*interleukin 17A inhibitors*, l-awtorita` kontraenti appellata xorta tista' tixtri medicina differenti minn dik li tintaghzel permezz tas-sejha, u dan per ezempju f'kazijiet fejn ikun hemm parir mediku jew meta l-medicina ma tkunx taqbel mal-pazjent, u ghalhekk tinhtieg li tinxtara medicina differenti b'metodu iehor. Din is-sejha mhux sejra tillimita d-diskrezzjoni tat-tobba li jaghzlu l-medicina adatta.

Fil-kuntest tat-tieni aggravju, ghandu jinghad li c-*Chief Medical Officer* ikkonferma fix-xhieda tieghu li l-konsultazzjoni saret u r-rakomandazzjoni kienet li l-prodotti inkwistjoni, cioe`, *Consentyx* u *Taltz*, kienu tajbin u ugwalment effikaci ghat-trattament mehtieg. Anke d-direttur fuq imsemmi qalet li s-sejha inkwistjoni "*dan gie diskuss bejn kulhadd, bejn il-konsulenti u s-CMO, kulhadd kien involut fiha din id-decizjoni*". Kwindi, ma jistax jinghad li ma kinitx saret konsultazzjoni mal-konsulenti medici.

Fir-rigward tat-tielet aggravju, ghandu jinghad li r-riferenzi li ghamlet is-socjeta` appellanti ghal xi lanjanzi taghha li, skont hi, gew injorati mill-Bord, fil-fatt gew meqjusa mill-Bord jew fid-decizjoni appellata jew, kif osservat mill-Bord, fid-decizjoni precedenti. Il-kwistjoni dwar jekk iz-zewg medicini offruti humiex *interchangeable* kienet giet deciza fid-decizjoni numru 1279, u l-Bord stess irrimarka li ma kienx se jidhol fi kwistjonijiet li kienu decizi precedentement.

Dwar l-allegat limitazzjoni fl-ezercizzju ta' xoghol it-tobba, gia intwera illi mill-provi hareg li fl-eventwalita` li l-medicina li tinxtara permezz ta' din is-sejha ma taqbilx ma' certi pazjenti, dawn il-pazjenti mhux ser jithallew minghajr medicina, u l-konsulenti mhux ser ikunu kostretti jaghtu l-medicina li tintrabat permezz tas-sejha meta din ma taqbilx mal-pazjent. Lanqas ghall-istess ragunijiet ma jista' jinghad li s-sejha hi diskriminatorja peress li l-htigijiet differenti tal-pazjenti gew meqjusa. Pazjenti li huma fuq prodott partikolari u, forsi, ma jistghux jaqilbu fuq prodott iehor skont opinjoni medika, jigu moqdija billi jinxtara dak l-ewwel prodott wara procedura ohra – dejjem jekk hekk ikun hemm bzonn ghax il-kuntratt ghadu ma nghatax. Ovvjament, l-operaturi ekonomici ma jistghux igieghelu lid-dipartiment jixtru dak li jridu huma. Id-dipartiment jitlob li jixtri li jidhirlu opportun, dejjem skont il-htigijiet tal-pazjent u tal-mument.

Kwindi, kull argument marbut ma' x'messu jixtri l-intimat f'dan il-kaz, ma hux floku.

Fid-dawl tal-premess, hu car li d-diversi lanjanzi tas-socjeta` appellanti ma jistghux jintlaqghu ghax mhux validi u lanqas konformi mal-principji li jirregolaw il-materja.

Ghaldaqstant, ghar-ragunijiet premessi, tiddisponi mill-appell ta' V.J. Salomone Pharma Limited billi tichad l-istess u tikkonferma s-sentenza li ta l-Bord ta' Revizjoni dwar il-Kuntratti Pubblici fil-21 ta' Novembru 2019, b'dan li tiffissa terminu gdid li jaghlaq fl-24 ta' April, 2020.

L-ispejjez marbuta ma' dan l-appell ghandhom jithallsu mis-socjeta` rikorrenti appellanti V.J. Salomone Pharma Limited.

Joseph Azzopardi Prim Imhallef	Joseph R. Micallef Imhallef	Tonio Mallia Imhallef

Deputat Registratur
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