



Dr Franco Agius, Legal Representative of the Director of Contracts, said that the Director does not agree to the extension, and the letter of reply to the objection from the CPSU should be ignored.

Dr Alison Anastasi (398380M) testified on oath that in June 2017 certain Humira patents had expired, and therefore the CPSU decided to issue this tender. The European Medicines Agency has approved three 'bio similar' products, and once they were approved manufacturers start research to establish prices. It is therefore possible to compete before the expiry date of the patent. Witness explained that Humira is the brand name and Adalimumab is the name of the molecule (active ingredient). There are several types of patents and the CPSU is not aware of any prohibition on the distribution of bio similar products – by July 2018 there were three recognised bio similar products issued.

Dr Franco Agius (496577M) testified on oath that he was the Assistant Director of Post Contracts at the Directorate of Contracts. He verified that up to the morning of the 18<sup>th</sup> October there had been four offers received by the 11<sup>th</sup> September on this tender. He could provide no further details as the offers were still encrypted.

Dr Axiak said that according to the Google world-wise news the patent on Adalimumab expired on the 16<sup>th</sup> October, and it stands to reason that one cannot compete on this tender before the expiry of the patent; otherwise the patent laws would be held to ridicule.

Dr Agius tabled a document detailing the Humira patents which had expired in Europe in June 2017, and a list of related products which had been available before the 16<sup>th</sup> October.

Dr Anastasi re-iterated that the 16<sup>th</sup> October patent on this product was not a holistic one and the total patency will not expire till 2022. This does not mean that there will not be marketing of this product as manufacturers can produce the active ingredients under another name.

The Chairman emphasised the point that the letter of reply from the CPSU is to be ignored as it has been overridden by the Director of Contracts. He thanked the parties for their submissions and declared the hearing closed.

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**This Board,**

**having noted this Call for Remedies which was filed by Cherubino Limited, (hereinafter referred to as the Appellants) prior to the Closing Date for Competition on 11 September 2018 refers to the contentions made by the same with regards to the Tender of Reference CT 2116/2018 issued by the**

**Central Procurement and Supplies Unit and listed as Case No 1221 in the records of the Public Contracts Review Board.**

**Appearing for the Appellants: Dr Victor Axiak**

**Appearing for the Contracting Authority: Dr Marco Woods**

**Appearing for the Department of Contracts: Dr Franco Agius**

**Whereby the Appellants:**

- a) contend that their main concern is that the closing date of this Tender was 11 September 2018, yet, at the same time, the Appellants' product patent rights expires on the 16 October 2018. In this regard, the Appellants contend that the closing date of the Tender had to be a date beyond 16 October 2018, to enable the latter to participate in this tender. In fact, the Contracting Authority, in its "*Letter of Reply*" dated 20 September 2018 indicated their agreement to this modification.

**This Board has also noted the Contracting Authority's "*Reasoned Letter of Reply*" dated 20 September 2018 and its verbal submissions during the Public Hearing held on 18 October 2018, in that**

- a) The Department of Contracts maintains that since the European Medicines Agency has approved three "*Bio Similar*" products, it is possible for the Appellants to compete before the expiry date of the patent of their product. At the same instance, the same Department of

**Contracts contends that the Central Procurement and Supplies Unit's "Reasoned Letter of Reply" dated 20 September 2018 should be ignored.**

**This same Board has also noted the testimony of the witness, namely Dr Alison Anastasi who was duly summoned by the Department of Contracts.**

**This Board, after having examined the relevant documentation to this "Call for Remedies" and heard submissions made by the technical witness, took into consideration the opening statement made by the Legal Representative of the Department of Contracts, in that the Central Procurement and Supplies Unit's "Reasoned Letter of Reply" dated 20 September 2018, should be ignored. At the same instance, this Board, in arriving at its deliberations, considered substantially the credible explanations given by the technical witness, namely Dr Alison Anastasi.**

**With regards to the Appellants' contentions, this Board was made aware that their product, namely "Adalimumab" represents the name of the molecule, (active ingredient), of "Humira" which is the brand name. In this regard, it was established that the expiry date of the patent refers to "Humira" and this Board was also informed that the European Medicines Agency has approved three "bio similar" products. In this respect, there are sufficient similar products on the market to sustain an open and free competition among prospective Bidders and in fact, the Department of Contracts confirmed that up to 11 September 2018, there were already four offers. In this regard, this**

**Board opines that Cherubino Limited can still participate before the expiry date of the patent. This Board was also informed that the Contracting Authority is not aware of any prohibition on the distribution of bio similar products.**

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

- i) does not find any justifiable reason why there should be an extension to the closing date of the Tender;**
  
- ii) does not consider the technical specifications of the Tender to limit competition;**
  
- iii) orders that the Tendering Procedure is to be continued**

Dr Anthony Cassar  
Chairman

Mr Carmel Esposito  
Member

Mr Lawrence Ancilleri  
Member

*25<sup>th</sup> October 2018*