IN THE COURT OF APPEAL
OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In the matter of an Application for mandates in the nature of Writs of Certiorari, Mandamus and Prohibition in terms of Article 140 of the Constitution of the Democratic Socialist Republic of Sri Lanka

CA (Writ) Application No: 124/2019

Markss HLC (Pvt) Limited,
Nawala Road, Narahenpita,
Colombo 5.

PETITIONER

Vs.

1) State Pharmaceuticals Corporation,
No. 75, Sir Baron Jayathilake Mawatha,
Colombo 1.

2) Rajitha Senaratne,
Minister of Health, Nutrition and Indigenous Medicine,
385, Rev Baddegama Wimalawansa Mawatha, Colombo 10.

3) Wasantha Perera,
Secretary,
Ministry of Health, Nutrition and Indigenous Medicine,

385, Rev Baddegama Wimalawansa Mawatha, Colombo 10.

4) National Medicines Regulatory Authority, 120, Norris Canal Road, Colombo 10.

5) Pharmace (Pvt) Limited, 46, Galle Road, Dehiwela.

RESPONDENTS

Before: **Yasantha Kodagoda, P.C., J / President of the Court of Appeal**
Arjuna Obeyesekere, J

Counsel: Chandaka Jayasundera, P.C., with Pulasthi Rupasinha and Chinthaka Fernando for the Petitioner

Manohara Jayasinghe, Senior State Counsel for the 1st – 4th Respondents

Mangala Niyarepola with Kushini B. Guneratne for the 5th Respondent

Supported for interim relief on: 6th August 2019

Written Submissions: Tendered on behalf of the Petitioner on 24th September 2019

Tendered on behalf of the 5th Respondent on 22nd November 2019

Order delivered on: 17th December 2019

Arjuna Obeyesekere, J

The Petitioner states that it is a company incorporated under the Companies Act No. 7 of 2007 and is a diversified healthcare organization engaged in the importation and marketing of pharmaceuticals, surgical products etc.

The 4th Respondent, the National Medicines Regulatory Authority has been established in terms of Section 2 of the National Medicines Regulatory Authority Act No. 5 of 2015. The objects of the 4th Respondent, as set out in Section 3 of the Act *inter alia* is to ensure the availability of efficacious, safe and good quality medicines and to function as the central regulator for all matters connected with the registration, licensing etc. *inter alia* of all medicines. In terms of Section 14 of the Act, the 4th Respondent has the power to authorize, regulate and monitor the registration and licensing of medicines. Thus, the 4th Respondent is the central regulator of all medicines sold in Sri Lanka and the principal function of the 4th Respondent is to register medicines with a view of ensuring the availability of efficacious, safe and good quality medicines for the people of this country.

Pursuant to an application made by the Petitioner, the 4th Respondent has issued to the Petitioner, a 'Certificate of Registration' in respect of a medicine having the generic name of '*Bevacizumab*', manufactured under the brand name of '*Abevmy*' by Biocon Limited for Mylan Pharmaceuticals Private Limited.[1] It is not in dispute

[1] The 'Certificate of Registration' has been annexed to the petition marked 'P2'. It is a provisional registration granted for a period of one year from 27th September 2018.

that *Bevacizumab* is an injection that is used for the treatment of certain types of cancers and tumors.

'*Abevmy*' is a biosimilar of *Bevacizumab* which was first developed by Hoffman La-Roche, a Swiss based pharmaceutical manufacturing company under the trade name of '*Avastin*'. *Bevacizumab* is a biologic or a biological product which is a medicine made from living organisms through highly complex manufacturing processes. Biologics include a wide variety of products such as gene and cell therapies, therapeutic proteins, monoclonal antibodies, and vaccines. Biologics are used to prevent, treat or cure a variety of diseases including cancer, chronic kidney disease, diabetes, cystic fibrosis, and autoimmune disorders.

A biosimilar is exactly what its name implies — it is a biologic that is "similar" to another biologic medicine, known as the reference product. Biosimilars are highly similar to the reference product in terms of safety, purity and potency, but may have minor differences in clinically inactive components. In this instance, '*Avastin*' is the reference product while '*Abevmy*' is the biosimilar.

How a biosimilar product is developed has been described in the 'World Health Organisation Guidelines on evaluation of similar biotherapeutic products' in the following manner:

> *"Biotherapeutic products (biotherapeutics) have a **successful record** in treating many life threatening and chronic diseases. However, their cost has often been high, thereby limiting their access to patients, particularly in*

developing countries. Recently, the expiration of patents and/or data protection for the first major group of originator's biotherapeutics has ushered in an era of products that are designed to be 'similar' to a licensed originator product. These products rely, in part, for their licensing on prior information regarding safety and efficacy obtained with the originator products. The clinical experience and established safety profile of the originator products should contribute to the development of similar biotherapeutic products (SBPs). A variety of terms, such as 'biosimilar products', 'follow-on protein products' and 'subsequent-entry biologics' have been coined by different jurisdictions to describe these products.[2]

The Petitioner states that in the middle of 2018, the 1st Respondent, the State Pharmaceutical Corporation had called for tenders on five occasions for the supply of *Bevacizumab*, and that even though the Petitioner submitted a bid in respect of each of the said five tenders, and even though the Petitioner had submitted the lowest bid in terms of price, its bid had been rejected.

The 1st Respondent had published two further Notices on its website in October 2018, calling for tenders for the supply of 1848 vials and 2127 vials of *Bevacizumab*. The Petitioner states that it decided to submit a tender and responded to each of the said invitations, quoting a price of Rs. 28,500 per vial, while the 5th Respondent, M/s Pharmace (Pvt) Limited, who was the only other tenderer, quoted a sum of Rs. 35,000 per vial. The Petitioner states that although

[2] 'World Health Organisation Guidelines on evaluation of similar biotherapeutic products' found at https://www.who.int/biologicals/publications/trs/areas/biological_therapeutics/TRS_977_Annex_2.pdf?ua=1.

its bid was Rs.6,500 cheaper per vial than the 5th Respondent, the tender for the supply of 1848 vials of *Bevacizumab* was awarded to the 5th Respondent. Being dissatisfied with the said decision, the Petitioner invoked the jurisdiction conferred on this Court by Article 140 of the Constitution by filing Application No. CA (Writ) 400/2018.

The Petitioner states that subsequent to the filing of that application, it was verbally informed by officials of the 1st Respondent that a decision had been taken in early December 2018 that 25% of the tender for the supply of 2127 vials would be awarded to the Petitioner. Thus, it appears that the 1st Respondent has varied its original decision by permitting the Petitioner to supply 25% of the requirement.

The Petitioner states that by a letter dated 18th February 2019, annexed to the petition marked '**P7(a)**' it was informed by the 1st Respondent that its 'Procurement Committee' had decided to test samples of the Petitioner's product at a laboratory in Australia by the name of TGA – Australia at the Petitioner's cost and requested that samples of three vials be made available, on a date to be notified. The Petitioner had duly complied with the payment for the said testing and had informed the 1st Respondent that it will supply the samples when requested. On 21st February 2019, the Petitioner had informed the 1st Respondent that testing was not a condition in the terms and conditions of the Tender, but that it will nonetheless comply with the additional requirement.[3] The 1st Respondent does not appear to have responded to the said letter, with the result

[3] Vide letter annexed to the petition marked 'P7(b)'.

that the Petitioner, although awarded 25% of the requirement in the second tender, has been prevented from complying with the award.

The Petitioner filed this application on 22nd March 2019, seeking *inter alia* the following relief:

a) A Writ of Certiorari to quash the decision of the 1st Respondent to award the tender for the supply of 2127 vials of *Bevacizumab* to the 5th Respondent;

b) A Writ of Certiorari to quash the decision of the 1st Respondent that the product supplied by the Petitioner should obtain a certificate from TGA Australia;

c) A Writ of Prohibition preventing the 1st Respondent from directing the Petitioner to submit a certificate from TGA Australia;

d) A Writ of Mandamus compelling the 1st Respondent to permit the Petitioner to supply '*Abevmy*' in accordance with the tender conditions.

The Petitioner's complaint to this Court is that obtaining a TGA - Australia certificate was not a condition of the tender issued by the 1st Respondent, and that in any event, the medicine that is to be supplied by the Petitioner has been issued with the Certificate of Registration by the NMRA only after the NMRA was satisfied with the safety and efficacy of the said medicine. The Petitioner states further that this condition has not been imposed on the 5th Respondent, and that

it *'verily believes that the purported requirement to conduct additional testing imposed upon the Petitioner is a mere contrivance designed to disrupt the Petitioner's supply of its product and for the unlawful and mala fide purpose of facilitating the 5th Respondent to continue an unabated supply'.*

The above allegation that the 1st Respondent is acting in collusion with the 5th Respondent is based on the fact that all tenders for the supply of *Bevacizumab* in the year 2018 have been awarded by the 1st Respondent to the 5th Respondent, at a price which is approximately 23% higher than the Petitioner.

By way of an affidavit tendered to this Court on 6th May 2019, the Petitioner brought to the attention of this Court that its bid to supply a quantity of 11,250 vials of *Bevacizumab* had been rejected as being non-responsive to the tender requirements. Being dissatisfied by the said decision, the Petitioner had filed an appeal with the Procurement Appeal Board (PAB). The PAB, having heard the Petitioner as well as the 1st and 5th Respondents, by its report marked '**P20**' had *inter alia* held that it *'does not agree with the recommendation of the Standing Cabinet Appointed Procurement Committee to award this tender to M/s Pharmace (Private) Limited at a cost of Rs. 389,475,000.00 and recommends the award of this tender to Ms/ Markss HLC (Private) Limited at a total cost of Rs. 247,251,250.00, considering the vast price difference between the two bidders ... .'*

This Court, having heard the learned President's Counsel for the Petitioner, the learned Senior State Counsel for the 1st – 4th Respondents and the learned Counsel for the 5th Respondent, issued formal Notice of this application on all

Respondents, on 3rd June 2019. Even though this Court directed the parties to complete the pleadings on or before 30th August 2019 and fixed this matter for argument on 25th September 2019, the Objections of the 1st – 4th Respondents are yet to be filed.

By way of a further petition dated 2nd July 2019, the Petitioner brought to the attention of this Court that the 1st Respondent is delaying the completion of the TGA – Australia certification, thereby preventing it from supplying the quantity awarded to it (25%), and prayed for the following 'interim relief':

a) An interim order suspending the decision contained in '**P7a**';

b) An interim order preventing the 1st – 4th Respondents from requiring the Petitioner to obtain the TGA – Australia certificate.

In support of his argument that the imposition of an additional condition is illegal, irrational and arbitrary, the learned President's Counsel for the Petitioner has brought to the attention of this Court, three documents which demonstrate the position of the 2nd – 4th Respondents on the issue of pre-shipment samples.

The first document is a letter dated 4th June 2019 sent by the 3rd Respondent - Secretary, Ministry of Health, Nutrition and Indigenous Medicine, annexed to the further petition marked '**P21**', by which the 1st Respondent was informed as follows:

"Decisions to award tenders for purchasing of pharmaceuticals subject to condition of testing pre-shipment samples for quality

This refers to .... procurement of Trastazumab and ***Bevacizumab*** *Injections on the above subject.*

The NMRA has informed that the registration for any pharmaceutical product is granted following a detailed evaluation for safety, efficacy and quality which conforms its compliances to the required criteria.

I observe that imposing additional conditions at the time of contract award has created long delays in the supplies, which leads to out of stocks situations of critical and lifesaving drugs.

In view of the above SPC and other Procuring Entities (PE) that involve in the procurement of pharmaceuticals are requested for adhering to following instructions strictly.

1. *The recommendations and decisions to Award of Contract* ***should not include any new conditions****, such as testing of pre-shipment samples which are related to safety, efficacy and quality of a particular item.*

2. *The PEs* ***should not amend, modify or introduce new conditions*** *to the specifications of the formulary approved items with regard to safety, efficacy and quality.*

3. *SPC, MSD and Heads of all other PEs should take necessary actions to inform their Officers, members of all TECs and Procurement Committees and implement the above (1) and (2) Instructions."*

The second document is a letter dated 24th July 2019 sent by the 4th Respondent to the 3rd Respondent, annexed to the Counter Affidavit of the Petitioner, marked '**PX3(a)**', which reads as follows:

*"Pre-shipment sample testing of Trastuzumab and **Bevacizumab** bio similar products registered by the NMRA*

Reference letter of 29.05.2019 sent by Additional Secretary (Procurement), Ministry of Health .... I write at the direction of the Board of the Authority to provide our observations and clarifications based on guidance received from Medicines Pre-Qualification experts in the South East Asia office and Head Quarters of the WHO regarding pre-shipment sample testing of referenced biosimilars registered by the NMRA.

General

1) *Trastuzumab and Bevacizumab biosimilars, produced by Biocon Limited and Mylan Pharmaceuticals, India, have received market authorization in Sri Lanka by the NMRA **after rigorous scrutiny of all available***

evidence. *In addition, these trastuzumab biosimilars are also registered in many other countries including USA, Canada and Australia.*

2) *The manufacturing and release testing facility (Biocon Limited, Bangalore, India) of these trastuzumab and bevacizumab biosimilars has obtained current Good Manufacturing practice Regulations (cGMP) clearance and compliance certification from many stringent Regulatory Authorities (SPA) such as European Medicines Agency (EMA), TGA Australia, Health Canada and US FDA.*

<u>*Specific*</u>

1) *Biosimilars are large molecules with batch-to-batch variations.* ***Pre-shipment testing of biosimilars, that have obtained market authorization by the NMRA, does not add value for various reasons.*** *The regulatory review of these products for market authorization by the NMRA included extensive assessment of batch to batch variability on physicochemical characteristics across many batches (i.e. the physicochemical characteristics of the biosimilars have been found to be no more variable than the reference/originator product). This is particularly applicable for biosimilars, products that have also received market authorization by Stringent Regulatory Authorities.* ***Therefore, pre-shipment testing of the above-mentioned biosimilar products does not provide additional assurance.*** *Furthermore, such testing cannot*

serve as a surrogate in case of inadequate characterization and view at the time of registration.

2) *Many of the release tests performed by the manufacturer (in particular biological activity, ADCC, CDC, antigen binding and others), in this case at a SRA-approved facility, are all tests developed in-house using in-house reference standards. It would be extremely difficult for an external quality control lab to reproduce the release testing without product-specific training and material from the manufacturer.*

3) *Other countries that have granted market authorization to these biosimilar products have not requested pre-shipment sample testing as a procurement condition.*

4) *Unlike vaccines, biosimilars do not require batch release testing. The NMRA, depending on local requirements for import clearance, can crosscheck the Certificate of Analysis (CoA) issued by the manufacturer against the approved specifications, and if needed, share the outcome of such comparison with the procuring entity.*

Therefore, taking into consideration internationally-accepted scientific and regulatory principles ***we are of the opinion (that) pre-shipment sample testing of*** *trastuzumab and* ***bevacizumab biosimilars that have received market authorization by the NMRA is unnecessary, does not add value*** *and*

will be extremely difficult to be carried out at an external quality control laboratory." (emphasis added)

The third document that was referred to by the learned President's Counsel for the Petitioner is a Cabinet Memorandum submitted by the 2nd Respondent, Minister of Health, Nutrition and Indigenous Medicine, which was brought to the attention of this Court by the learned Senior State Counsel, and a copy of which has been filed by the 5th Respondent. The said Memorandum dated 30th August 2019 relates to the issue of pre-shipment samples relating to the supply of *Trastuzumab*. Having referred to the above letter of the NMRA, which dealt with *Trastuzumab* as well as *Bevacizumab*, the 2nd Respondent has sought and obtained the approval of the Cabinet of Ministers to dispense with the requirement for pre-shipment samples for a particular tender of 3750 vials of *Trastuzumab*, as well as to amend the Procurement Guidelines to permit the supply of biosimilars that have received registration of the NMRA without any pre-shipment sample testing. This Court must observe that even though the said decision does not specifically relate to *Bevacizumab*, the letter of the 4th Respondent deals with *Bevacizumab* as well, and the principle that was sought to be established with regard to pre-shipment samples in respect of biosimilars, would apply to the issue before this Court.

Even though the position of the 2nd – 4th Respondents on this issue is that the imposition of the requirement in '**P7(a)**' is not correct, and the above documents have all been issued after this application was filed, the 1st Respondent, who is the procurement entity, is insisting on pre-shipment samples, in spite of the fact

that the medicine proposed to be supplied by the Petitioner has been approved by TGA - Australia. As observed earlier, the 1st Respondent is yet to file its Objections and this Court is yet to be apprised of the reasons as to why the 1st Respondent is continuing to insist on pre-shipment samples.

It is in the above circumstances that this Court has to consider the interim relief sought by the Petitioner. In doing so, this Court would bear in mind the following observation by Chief Justice Neville Samarakoon in **Billimoria v. Minister of Lands and Land Development & Mahaweli Development and two others:**[4]

> *"It would not be correct to judge such orders in the same strict manner as a final order. Interim orders by their very nature must depend a great deal on a Judge's opinion as to the necessity for interim action."*

In **Duwearachchi and another vs Vincent Perera and others**[5] this Court considered the application for an interim order in the light of three essential considerations:

a) Will the final order be rendered nugatory if the petitioner is successful?

b) Where does the balance of convenience lie?

c) Will irreparable and irremediable mischief or injury be caused to either party?

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[4] (1978-79-80) 1 Sri LR (SC) 10 at page 15.
[5] (1984) 2 Sri LR 94.

The decision in **Duwearachchi** has been consistently followed by this Court in several cases including in **Ceylon Tobacco Company PLC vs Hon. Maithripala Sirisena, Minister of Health and others**[6], **Tokyo Super Cement Company Lanka (Private) Limited vs Sri Lanka Ports Authority and others**,[7] **NatWealth Securities Lanka (Private) Limited vs The Monetary Board of the Central Bank and others**[8], **F Hoffmann La-Roche Ltd and another vs National Medicines Regulatory Authority and others**[9], **Wadugodage Wijeratne vs Faiszer Mustapha, Minister of Provincial Councils and Local Government and another**[10]and **Major General Nirmal Dharmaratne vs Lieutenant General Mahesh Senanayake and others.**[11]

It is clear from the material that has been placed before this Court that the medicine proposed to be supplied by the Petitioner has been registered with the 4th Respondent, only after the 4th Respondent was satisfied with its efficacy and safety. The 1st Respondent has called for tenders for the supply of over 20,000 vials of *Bevacizumab* during the period of September 2018 and March 2019. The Petitioner has submitted its bid to supply one vial at the rate of Rs. 28,500, which is the cheapest price at the moment, and a decision has been taken to permit the Petitioner to supply 25% of 2127 vials. However, having done so, the 1st Respondent has placed an obstruction in the way of the Petitioner supplying the said medicine, and has not changed its position in spite of strong

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[6] CA (Writ) Application No. 336/2012; CA Minutes of 22nd February 2013.
[7] CA (Writ) Application No. 258/2013; CA Minutes of 30th August 2013.
[8] CA (Writ) Application No. 335/2015; CA Minutes of 29th March 2016.
[9] CA (Writ) Application No. 98/2016; CA Minutes of 22nd June 2016.
[10] CA (Writ Application) No. 373/2017; CA Minutes of 22nd November 2017.
[11] CA (Writ) Application No. 375/2018; CA Minutes of 30th April 2019.

recommendations from the regulator itself and the Cabinet of Ministers. What is significant is that the condition that the 1st Respondent is insisting upon was introduced only after tenders had been closed. In fact, the Supreme Court in **Pamkayu (M) SND BHD and another v. P. Liyanaarachchi, Secretary, Ministry of Transport and Highways and others**[12] has held that, *"the award of a tender must be based on compliance with the terms and conditions of the tender documents on the date and at the time specified for the closing of the tender."*

This Court has examined the documents marked '**PX2(c)**' – '**PX2(i)**' and observes that the Petitioner has submitted the following bids, after being verbally informed that 25% out of the tender for the supply of 2127 vials would be offered to the Petitioner:

Document	Closing Date for tenders	Number of Vials	Price offered
PX2(c)	02.01.2019	2645	31,500
PX2(d)	27.02.2019	2532	29,000
PX2(e)	08.03.2019	2591	29,000
PX2(f)	03.05.2019	2692	29,000
PX2(g)	31.05.2019	2276	29,500
PX2(h)	18.06.2019	2663	29,500
PX2(i)	19.08.2019	2602	28,900

[12] (2001) 1 Sri LR 118 at 125; per Amerasinghe, J.

As demonstrated by the above table, the 1st Respondent is continuing to call for fresh tenders each month for the supply of *Bevacizumab* and it is the view of this Court that the said obstruction effectively prevents the Petitioner from participating in any further tenders for the supply of *Bevacizumab*. Thus, even if this Court grants the Petitioner the relief it has sought at the end of the application, such an Order would be nugatory as during the interim period, the Petitioner has been shut out from supplying the said medicine.

Useful guidance on how to determine where the balance of convenience lies is found in **Felix Dias Bandaranaike vs State Film Corporation and another**[13] where it was held as follows:

> *"This is tested out by weighing the injury which the defendant will suffer if the injunction is granted and he should ultimately turn out to be the victor against the injury which the plaintiff will sustain if the injunction were refused and he should ultimately turn out to be the victor. The main factor here is the extent of the uncompensatable disadvantage or irreparable damage to either party. As the object of issuing an interim injunction is to preserve the property in dispute in status quo, the injunction should not be refused if it will result in the plaintiff being cheated of his lawful rights or practically decide the case in the defendant's favour and thus make the plaintiff's eventual success in the suit if he achieves it a barren and worthless victory— see Bannerjee (ibid) pp. 578, 579."*

[13] (1981) 2 Sri LR 287.

In this application, the responsibility for the efficacy and safety of the medicine supplied by the Petitioner has been taken by the 4th Respondent, by issuing the registration for the said medicine in terms of the Act. By '**PX3(a)**', the 4th Respondent has confirmed that the manufacturing and release testing facility of the said product has obtained current Good Manufacturing practice Regulations (cGMP) clearance and compliance certification from many stringent Regulatory Authorities (SPA) such as European Medicines Agency (EMA), **TGA Australia**, Health Canada and US FDA, and that the said medicine received market authorization only after rigorous scrutiny of all available evidence. Thus, if the interim relief is issued, that would not cause any damage to the 1st Respondent, as there does not appear to be any issues with the safety and efficacy of the product of the Petitioner. It would, in fact, be to the advantage not only to the 1st Respondent but to the entire country as one vial of *Bevacizumab* could be obtained for approximately Rs. 6000 less per vial. On the other hand, if this Court were to refuse the interim relief but the Petitioner was to succeed at the end of the application, it would suffer uncompensatable disadvantage and irreparable damage as it has been deprived of supplying the said medicine during the interim period. For these reasons, this Court is of the view that the balance of convenience lies in favour of the Petitioner and that irreparable loss will be caused, not only to the Petitioner but to the country at large.

In the above circumstances, it is the view of this Court that the interests of justice would be best served by issuing the interim orders as prayed for in paragraphs (a) and (b) of the prayer to the further petition dated 2nd July 2019, until the final determination of this application.

This Court, while directing all parties to complete the filing of their pleadings as early as possible and in any event no later than 31st January 2020, would endeavour to give priority to conclude this case at its earliest.

Judge of the Court of Appeal

Yasantha Kodagoda, P.C., J/

President of the Court of Appeal

I agree

President of the Court of Appeal