

SOUTH AFRICA / JUDGMENT

Pharmacare Ltd t/a Aspen Pharmacare v Eli Lilly (S.A.) (Pty) Ltd (LM086Sep23) [2023] ZACT 82 (1 December 2023)

[2023] ZACT 82

COURT

Competition Tribunal

BEFORE

Andreas Wessels, Geoff Budlender, Thando Vilakazi

CASE / FILE NUMBER

LM086Sep23

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COMPETITION TRIBUNAL
OF SOUTH AFRICA

Case No: LM086Sep23

In

the matter between:

Pharmacare
Ltd t/a Aspen Pharmacare
Acquiring
Firm
And
Eli
Lilly (S.A.) (Pty) Ltd
Target
Firm

Panel:

Andreas
Wessels (Presiding Member)
Geoff
Budlender (Tribunal Member)
Thando
Vilakazi (Tribunal Member)
Heard

on:

09
November 2023
Order

issued on:

10
November 2023
Reasons

issued on: 01
December 2023

REASONS FOR DECISION

Approval

- [1] On 10 November 2023, the Competition Tribunal (“Tribunal”) unconditionally approved the large merger wherein Pharmacare Ltd, trading as Aspen Pharmacare (“Aspen Pharmacare”) will acquire the promotion, sales and distribution rights relating to 23 pharmaceutical products supplied in South Africa (the “Lilly Portfolio”), by Eli Lilly (S.A.) (Pty) Ltd (“Lilly SA”). Upon implementation of the proposed transaction, Aspen Pharmacare will exclusively conduct the promotion, sales and distribution of the Lilly Portfolio in South Africa.

Parties to the transaction and their activities

Primary acquiring firm

- [2] The acquiring firm is Aspen Pharmacare, which is wholly owned by Aspen Pharmacare Holdings Limited (“Aspen Holdings”). Aspen Holdings is listed on the Johannesburg Stock Exchange and is not controlled by any firm. Aspen Holdings controls several firms which include Aspen SA Operations (Pty) Ltd, Brimpharm SA (Pty) Ltd, Alphamed Formulations (Pty) Ltd, Beta Health Internationals and Ethicare (Pty) Ltd, amongst others.
- [3] Aspen Pharmacare, all the firms it controls, all the firms controlling Aspen Pharmacare, and all the firms controlled by those, will be referred to as the “Acquiring Group”.
- [4] The Acquiring Group is a multinational pharmaceutical company which focuses on manufacturing, marketing and distribution of a broad range of generic as well as branded pharmaceuticals covering both hospital and consumer markets. Of relevance to this merger assessment are the Acquiring Group’s antidepressants, which fall under Anatomical Therapeutic Classification (“ATC”) level 3 category N06A. In that regard, the Acquiring Group supplies Cymgen, Lorien, Trepiline, Voxra, Wellbutrin, Cilift, Ethipramine, Aropax, Aspen Trazodone, Espadrep, Thaden, Camcolit and Paxil. These products are used to treat depressive disorders, anxiety, chronic pain and addiction.
- [5] In addition, the Acquiring Group supplies antimetabolites, which fall under ATC3 category L01B. Antimetabolites are commonly used to treat leukaemia and other various types of cancer such as cancer of the lung, breast, ovarian, testicles, bladder and the intestinal tract. In this regard, the Acquiring Group supplies Purinethol and Lanvis. These products are all distributed throughout South Africa.

Primary target firm

- [6] The primary target firm is the Lilly Portfolio. The Lilly Portfolio is ultimately owned and controlled by Eli Lilly and Company Inc., USA (“Lilly”), a public company listed on the New York Stock Exchange. Lilly is not controlled by any firm.
- [7] The Lilly Portfolio comprises the promotion, sales and distribution rights relating to the 23 pharmaceutical products set out in Table 1 below. Relevant to the proposed transaction are Lilly Portfolio’s offerings of antidepressants and antimetabolites.

Table 1: The Lilly Portfolio[1]

Item No. ATC3 Code Active Pharmaceutical Ingredient (API) Name of Product ATC3 category

N06A (Antidepressants) N06AX21 Duloxetine Cymbalta 2 N06AB03 Fluoxetine Prozac 3 N06AB03 Fluoxetine Lilly-fluoxetine ATC3 category L01B (Antimetabolites) 4 L01BC05 Gemcitabine Gemzar 5 L01BA04 Pemetrexed Alimta ATC3 category A10A (Insulin) 6 A10AE04 Insulin glargine Basaglar 7 A10AD04 Insulin lispro Humalog 8 A10AC01 Insulin (human) Humulin ATC3 category G04B (Urologicals) 9 G04BE08 Tadalafil Cialis 0 G04BE08 Tadalafil Ciavor ATC3 category L04A (Immunosuppressants) L04AC13 xekizumab Copellor 2 L04AA37 Baricitinib Unamity/olumiant ATC3 category G03X (Sex Hormones) 3 G03XC01 Raloxifene Evista ATC3 category L01F (Antineoplastics) 4 L01FG02 Ramucirumab Cyramza ATC3 category L01E (Antineoplastics) 5 L01EF03 Abemaciclib Yulareb/Verzenio ATC3 category H05A (Calcium) 6 H05AA02 Teriparatide Forteo ATC3 category H01A (Pituitary) 7 H01AC0 Somatropin Humatrope ATC3 category A01B (Diabetes) 8 A10BJ05 Dulaglutide Trulicity ATC3 category J5C (HIV Antivirals) 9 Not available in South Africa Mirikizumab Elemetra ATC3 category N2C (Anti-migraine preparations) 20 Not available in South Africa Galcanezumab Emagality/Pontevia 2 Not available in South Africa Lasmiditan Reyvow/Bimiere 22 Not available in South Africa Insulin lispro Lyumjev ATC3 category A10S GLP-1 agonist a-diabs 23 Not available in South Africa Tirzepatide Mounjaro/Yurpeak

Proposed transaction and rationale

Transaction

- [8] In terms of the proposed transaction, Aspen Pharmacare will acquire the promotion, sales and distribution rights relating to the Lilly Portfolio. Post-merger, Aspen Pharmacare will exclusively conduct the promotion, sales and distribution of the Lilly Portfolio in South Africa[2] and retain all the revenue derived from distributing the Lilly Portfolio in South Africa.[3]
- [9] Lilly will continue to own all the intellectual property related to the 23 pharmaceutical products comprising the Lilly Portfolio. In addition, Lilly will conduct all the manufacturing of all the pharmaceutical products comprising the Lilly Portfolio.

Rationale

[10] According to Aspen Pharmacare, the transaction presents an opportunity to expand into product categories where Aspen Pharmacare currently has little or no presence, such as its therapeutic product portfolio[4]. Aspen Pharmacare intends to utilise the complementary nature of the Lilly SA Products with Aspen Pharmacare's existing product range. The objective is that commercialising the Lilly SA Products will further diversify Aspen Pharmacare's South African business and therefore improve its resilience, while also supporting the continuity of supply of medication to South African patients.[5]

[11]

From Lilly's perspective, the rationale for the distribution and promotion arrangement is to increase market reach and patient access as a result of Aspen Pharmacare's significant commercial footprint and on the ground presence in South Africa. It is intended that this will enhance the growth prospects for the Lilly SA Products, enabling greater access to innovative and high-quality medicines for South African patients.[6]

Competition assessment

[12] In its assessment of product overlap, the Commission had regard to the ATC Classification System[7], which is used in local and foreign jurisprudence for the classification of active ingredients in medicines, according to the organ or system on which they act, and their respective therapeutic, pharmacological, and chemical properties. Medication is classified at five different levels. Relevant to the proposed merger is the third level, ATC3 which is referred to as the chemical,

pharmacological or therapeutic subgroup (in that it groups indications for their intended use).

[13] The merging parties' activities overlap horizontally as both the Acquiring Group and Lilly are involved in the provision of pharmaceutical products classified under ATC3 category N06A (Antidepressants). Further, there is an overlap between the merging parties' activities in the provision of pharmaceutical products classified under ATC3 category L01B (Antimetabolites).

[14] The proposed transaction does not present any vertical overlap, and Lilly will continue to manufacture the Lilly Portfolio, post-merger.

Product market

[15]

In assessing the relevant product market, the Commission had consideration[8] to Glaxo Austell[9] and the European Commission's Mylan N.V[10] merger, where ATC categorisation was used as a base in determining the relevant product market.

[16] However, what is considered truly substitutable, or clinically interchangeable at the dispensing level is a bioequivalent generic medication with the same active pharmaceutical ingredient ("API"), strength and dosage formulation.

- [17] Therefore, whilst the ATC3 category identifies possible therapeutic equivalents, these may not be direct substitutes at a dispensing level since they may fall within the same broad drug category but have a different API or have a different clinical use.
- [18] Considering this, the Commission found that the following offerings by the merging parties under ATC3 category N06A (antidepressants), are substitutable at a clinical level:
- a) the Acquiring Group's Cymgen is substitutable for Lilly Portfolio's Cymbalta[11]; and
 - b) the Acquiring Group's Lorien is substitutable for the Lilly Portfolio's Prozac and Lilly Fluoxetine.[12]
- [19] As regards the ATC3 category L01B (Antimetabolites), the Commission found that whilst the merging parties have offerings in this category, neither of the Acquiring Group's offerings, Purinethol and Lanvis, are substitutable for the Lilly Portfolio's Alimta and Gemzar. That is because the Acquiring Group's offerings are used for the treatment of leukaemia, whilst the Lilly Portfolio's offerings are used for the treatment of various types of cancer, namely breast, lung, testicular, bladder and ovarian cancers.
- [20] Without taking a definite view the Commission assessed the impact of the merger on the provision of pharmaceutical products under ATC3 category N06A (antidepressants) and L01B (antimetabolites).

Geographic market

- [21] The Commission had regard to Glaxo[13] and Austell[14] where a national geographic market was assumed as the merging parties, including their competitors, supply pharmaceutical products throughout the country.
- [22] In addition, the customers of the merging parties such as Dis-Chem, Alpha Pharma, and Universal Pharmaceutical Distributors have a presence throughout South Africa. In this instant transaction, the Commission found no evidence to deviate from previous matters in which the relevant geographic market was defined as national.
- [23] The Commission therefore assessed the proposed merger in:
- a) The national market for the provision of pharmaceutical products classified under ATC3 category N06A (antidepressants).
 - b) The national market for the provision of pharmaceutical products classified under ATC3 category L01B (antimetabolites).

Assessment

ATC3 category N06A (Antidepressants)

- [24] The Commission found that the Acquiring Group has a market share of approximately [...] % (by value) and the Lilly Portfolio has a market share of approximately [...] % in ATC3 category N06A.[15] The merging parties combined market share post-merger in ATC3 category N06A will therefore be approximately [...] %.
- [25] Market participants[16] indicated that there remain numerous alternatives post-merger and that the merger does not raise any concerns under ATC3 category N06A.
- [26] Furthermore, within ATC3 category N06A, there are substantial unit price differences between the merging parties' competing offerings since Lilly Portfolio's products are non-generics and Aspen's products are generics—
- a) Lilly Portfolio's Cymbalta costs approximately 300% more than Aspen's Cymgen.
 - b) Lilly Portfolio's Prozac costs approximately 400% more than Aspen's Lorient.
 - c) Lilly Portfolio's Lilly Fluoxetine costs approximately 300% more than Aspen's Lorient.
- [27] Accordingly, whilst the merging parties' ATC3 category N06A offerings are clinically substitutable, the price differential between Lilly Portfolio antidepressants and Aspen's antidepressants is more than the 5-10% (utilised to determine the extent to which products are substitutable under the SSNIP Test).

ATC3 category L01B (Antimetabolites)

- [28] As mentioned, the Commission found that whilst the merging parties have offerings in this category, neither of the Acquiring Group's offerings, Purinethol and Lanvis, are substitutable for the Lilly Portfolio's Alimta and Gemzar.
- [29] Nonetheless, the Commission estimated market shares under the broad ATC3 category L01B and found that the combined market shares will be approximately [...] % (by value) with a market share accretion of less than [...] %.

Pipeline products

- [30] The Commission also considered whether there are any potential overlaps between the merging parties' pipeline products (i.e., pharmaceutical products under development). In this regard, the Commission found an overlap between the merging parties' pharmaceutical products classified under ATC3 category N2C (Anti-migraine Preparations) and ATC3 category J5C (HIV Antivirals).
- [31] However, whilst the Acquiring Group has offerings under the ATC3 category N2C and ATC3 category J5C, none of these products have the same API as Lilly Portfolio's products (awaiting registration).

Third party concern

- [32] A medical aid scheme raised a concern that whilst it did not object to the proposed transaction, it was concerned about the prices of the products within the Lilly Portfolio which it considered to be high, given Lilly's practice of "global price benchmarking".
- [33] In response, the merging parties indicated that Lilly Portfolio products are subject to the Single Exit Pricing regulatory regime[17]. In this regard, the Minister of Health restricts any annual price increases to levels that typically reflect inflation and currency fluctuations. The same pricing regime therefore continues irrespective of whether the products are distributed by Lilly or Aspen.
- [34] The Commission found that no intervention is required to address the concern raised since the merger does not result in high market shares in the overlapping ATC3 categories.
- [35] Competitors and customers of the merging parties raised no concerns.
- [36] Having regard to the above and the Commission's thorough assessment, we find no evidence to suggest that the proposed transaction will result in a substantial prevention or lessening of competition in any relevant market.

Public interest

Employment

- [37] The merging parties submitted that there will be no retrenchments or job losses as a result of the proposed transaction.
- [38] The merging parties submitted that Lilly SA currently employs [...] employees in South Africa, [...] of which will transfer to Aspen Pharmacare as part of the Lilly Portfolio, in terms of section 197 of the Labour Relations Act, 66 of 1995. The remaining [...] employees will remain in the full-time employment of Lilly SA.
- [39] The Commission contacted the employee representative of Lilly SA and the South African Chemical Workers Union ("SACWU") and the Chemical, Energy, Paper Printing, Wood and Allied Workers Union ("CEPPWAWU") who represent employees of Aspen Pharmacare. No concerns were raised.

Spread of ownership

- [40] Aspen Pharmacare has 44.66% ownership held by historically disadvantaged persons ("HDPs"). Lilly SA does not have any ownership by HDPs or workers.
- [41] The Commission found that the proposed transaction will result in the level of (indirect) ownership by HDPs over Lilly Portfolio increasing by 44.6%.
- [42] No further public interest concerns arise through the transaction and we are satisfied that the transaction is not likely to raise any concerns from a public interest perspective.

Conclusion

[43] Considering the above, we unconditionally approved the proposed merger.

Signed by: Thando Vilakazi

Signed at: 2023-12-01 13:06:20 +02:00

Reason: Witnessing Thando Vilakazi

1 December 2023

Prof Thando Vilakazi

Date

Concurring: Adv Geoff Budlender SC and Mr Andreas Wessels

Tribunal case manager: Leila Raffee For the merging parties: Neil MacKenzie, Veronica Cadman, and Palesa Mpe of Fasken For the Commission: Nhlakanipho Mbhense and Wiri Gumbie

- [1] Source: Commission's compilation based on submissions by the merging parties' and [...].
- [2] Aspen Pharmacare will be responsible for selling, distributing, and promoting Lilly's current and future pipeline products in various therapeutic areas in South Africa and certain sub-Saharan countries. Aspen will promote, sell and distribute Lilly Portfolio and pipeline products in the Southern African Development Community ("SADC") and the following key sub-Saharan countries: Kenya, Nigeria, and French West Africa.
- [3] The Acquiring Group will retain all the sales revenue it generates from the Lilly Portfolio.
- [4] Commission's Merger Report, para 14.
- [5] Merging parties' Joint Competitiveness Report, para 28.
- [6] Merging parties' Joint Competitiveness Report, para 27.
- [7] The ATC classification was developed and maintained by the World Health Organization Collaborating Centre for Drug Statistics Methodology. See <https://www.who.int/tools/atc-ddd-toolkit/atc-classification>
- [8] Glaxo Wellcome plc/SmithKline Beecham plc
Case No. 58/AM/May00 and National Association of Pharmaceutical Wholesalers and Others/
Glaxo Wellcome (Pty) Ltd and Others
Case No. 68/IR/Jun00.
- [9] Austell Pharmaceuticals (Pty)Ltd and Dezzo Trading 392(Pty) Ltd Commission Case No. 2020Oct0034.
- [10] Mylan N.V and Meda AB, EC Case No. M.7975.

[11] These products have the same API, (Duloxetine).

[12] These products have the same API (Fluoxetine).

[13] Glaxo Wellcome plc/SmithKline Beecham plc

Case No. 58/AM/May00 and National Association of Pharmaceutical Wholesalers and Others/
Glaxo Wellcome (Pty) Ltd and Others

Case No. 68/IR/Jun00.

[14] Austell Pharmaceuticals (Pty)Ltd and Dezzo Trading 392(Pty) Ltd Commission Case No.
2020Oct0034.

[15] The Commission calculated market shares using IQVIA data, which measures the sale of
pharmaceutical products from various outlets for the period of July 2022 - June 2023.

[16] Medical aid schemes and pharmaceutical distributors.

[17] Letter dated 11 October 2023 (Record, p513-514).

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