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Statement of Preliminary Issues

Mylan N.V. / Upjohn Inc.

14 January 2020

Introduction

1. On 18 December 2019, the Commerce Commission registered an application (the Application) from Mylan N.V. (Mylan) and Upjohn Inc. (Upjohn) seeking clearance to merge (the Proposed Merger). Upjohn is a subsidiary of Pfizer Inc. (Pfizer).[1]

2. The Commission will give clearance if it is satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

3. This statement of preliminary issues sets out the issues we currently consider to be important in deciding whether or not to grant clearance.[2]

4. We invite interested parties to provide comments on the likely competitive effects of the Proposed Merger. We request that parties who wish to make a submission do so by **28 January 2020**.

The parties

5. Mylan is a US-based global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic, and specialty pharmaceuticals. Globally, Mylan manufactures and markets more than 1,400 different medicines to retail, wholesale, government and institutional customers.[3]

6. Mylan is active in New Zealand through its wholly owned subsidiary, Mylan NZ Limited. Its product portfolio in New Zealand specialises in generic medicines.

7. Pfizer is a global pharmaceutical company involved in the research, development, manufacturing and supply of medicines. Upjohn is the subsidiary of Pfizer which operates Pfizer's off-patent branded, and generic established medicines business

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1 A public version of the Application is available on our website at: http://www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/.

2 The issues set out in this statement are based on the information available when it was published and may change as our investigation progresses. The issues in this statement are not binding on us.

3 Application at [2.1]-[2.2].

and is headquartered in China. Upjohn has a portfolio of 21 off-patent medicines across several different therapeutic areas.[4]

8. In New Zealand, Upjohn supplies a number of prescription and over-the-counter pharmaceutical products through its subsidiary Pfizer New Zealand Limited.

Our framework

9. Our approach to analysing the competition effects of the Proposed Merger is based on the principles set out in our Mergers and Acquisitions Guidelines.[5] As required by the Commerce Act 1986, we assess mergers and acquisitions using the substantial lessening of competition test.

10. We determine whether an acquisition is likely to substantially lessen competition in a market by comparing the likely state of competition if the acquisition proceeds (the scenario with the acquisition, often referred to as the factual), with the likely state of competition if the acquisition does not proceed (the scenario without the acquisition, often referred to as the counterfactual).[6] This allows us to assess the degree by which the Proposed Merger might lessen competition.

11. If the lessening of competition as a result of the Proposed Merger is likely to be substantial, we will not give clearance. When making that assessment, we consider, among other matters:

    11.1 constraint from existing competitors – the extent to which current competitors compete and the degree to which they would expand their sales if prices increased;

    11.2 constraint from potential new entry – the extent to which new competitors would enter the market and compete if prices increased; and

    11.3 the countervailing market power of buyers – the potential constraint on a business from the purchaser's ability to exert substantial influence on negotiations.

Market definition

12. We define markets in the way that we consider best isolates the key competition issues that arise from the Proposed Merger. In many cases this may not require us to precisely define the boundaries of a market. A relevant market is ultimately determined, in the words of the Commerce Act, as a matter of fact and commercial common sense.[7]

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4 Application at [3.1]-[3.2].

5 Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2019. Available on our website at www.comcom.govt.nz

6 *Commerce Commission v Woolworths Limited* (2008) 12 TCLR 194 (CA) at [63].

7 Section 3(1A). See also *Brambles v Commerce Commission* (2003) 10 TCLR 868 at [81].

13. The Proposed Merger relates to the supply of off-patent and generic medicines, most of which are sold on prescription.

14. In New Zealand, the Pharmaceutical Management Agency (PHARMAC) decides whether prescription medicines are publicly funded. PHARMAC typically decides which medicines are publicly funded through a tender process and the winning medicine in a tender is usually awarded exclusive sole-supply status for a fixed period (often three years).

15. Medicines can only be supplied in New Zealand if they are approved by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

16. In the Application, Mylan and Upjohn (the Parties) submitted the Proposed Merger will not raise competition concerns in any New Zealand market, irrespective of whether the relevant markets are defined broadly (eg, markets for all medicines that treat a given condition) or narrowly (eg, markets for specific medicines that have the same active ingredient).

17. In the Application, the Parties identify the following products where the Parties compete to supply medicines with the same active ingredient (with the relevant therapeutic use in brackets):[8]

    17.1 Atorvastatin (cholesterol and triglyceride regulators);

    17.2 Celecoxib (non-steroidal anti-rheumatics);

    17.3 Gabapentin (anti-epileptics);

    17.4 Venlafaxine (antidepressants and mood stabilisers); and

    17.5 Sildenafil (erectile dysfunction products).

18. The Parties also provided information in the Application on the following overlaps at the therapeutic use level:

    18.1 anti-epileptics;

    18.2 diuretics, and in particular, potassium sparing diuretics;

    18.3 calcium antagonists;

    18.4 antidepressants and mood stabilisers (in particular, medicines classified as selective serotonin reuptake inhibitors); and

    18.5 miotics and anti-glaucoma medications.

19. In testing the Parties' views, we will consider the extent to which medicines with different active ingredients but that have the same therapeutic use are substitutes

[8] Application at [1.13]-[1.30].

for each other. We will also consider whether there are separate markets for medicines that have the same active ingredients but are supplied in different dosages and forms (eg, tablet, capsule, injection). In addition, we will assess whether there may be different customer markets for sales that are made to PHARMAC as opposed to sales that are made to retailers such as pharmacies because of the difference in the way sales are made to these customers.

Without the acquisition

20. We will consider what the parties would do if the Proposed Merger does not go ahead. We will consider the evidence on whether the without-the-Proposed Merger scenario is best characterised by the status quo, or whether the Parties would seek alternative options, for example, finding different partners with which to merge.

Preliminary issues

21. The Parties appear to compete directly in the supply of a range of medicines. Therefore, our primary focus will be on investigating whether the Proposed Merger would be likely to substantially lessen competition in any of the relevant markets by assessing the unilateral effects of the Proposed Merger.

22. A key question that we will be focusing on is whether the loss of competition between the Parties would enable the merged entity to profitably raise prices or reduce quality or innovation by itself.[9]

23. We will also consider whether the Proposed Merger would increase the potential for:

    23.1 conglomerate effects, for example by allowing the merged entity to bundle or tie its products and foreclose competing suppliers; and

    23.2 coordinated effects, where, for example, the Proposed Merger would change the conditions in the relevant markets so that coordination is more likely, more complete or more sustainable.

Unilateral effects: would the merged entity be able to profitably raise prices by itself?

24. Unilateral effects arise when a firm merges with a competitor that would otherwise provide a significant competitive constraint (particularly relative to remaining competitors) such that the merged firm can profitably increase price above the level that would prevail without the merger and without the profitability of that increase being thwarted by rival firms' competitive responses.

25. The Parties overlap in the supply of the active ingredients and medicines with the same therapeutic use listed above.

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[9] For ease of reference, we only refer to the ability of the merged entity to "raise prices" from this point on. This should be taken to include the possibility that the merged entity could reduce quality or innovation, or worsen an element of service or any other element of competition, i.e. it could increase quality-adjusted prices.

26. In the Application, the Parties submitted that the Proposed Merger would not be likely to substantially lessen competition in any New Zealand market because:

    26.1 a number of competitors have products with the same active ingredients that have received approval from Medsafe and are therefore permitted to supply equivalent medicines in New Zealand and so would be able to compete with the merged entity at the next PHARMAC tender for that active ingredient;

    26.2 a number of large pharmaceutical companies supply many of the particular active ingredients at a global level and would easily be able to enter the market in New Zealand; and

    26.3 PHARMAC is a sophisticated procurer and has strong countervailing power. PHARMAC can drive a competitive outcome with two competitors in a tendering scenario, and also has the means to intervene if the merged entity were to attempt to increase the price of a particular product.

27. We will consider:

    27.1 closeness of competition: the degree of competitive constraint that Mylan and Upjohn impose upon one another. To the extent that any constraint is material, we will assess whether the lost competition between the merging parties could be replaced by rival competitors;

    27.2 remaining competitive constraints: the degree of constraint that existing competitors would impose on the merged entity;

    27.3 entry and expansion: how easily rivals could enter and/or expand; and

    27.4 countervailing power: whether customers (PHARMAC and acquirers such as pharmacies) have special characteristics that would enable them to resist a price increase by the merged entity.

Conglomerate effects: would the merged entity be able to foreclose rivals?

28. A conglomerate merger is a merger between firms that supply products that may relate to each other (eg, complementary products). Conglomerate mergers can substantially lessen competition if they increase a merged entity's ability or incentive to foreclose its competitors.

29. We will consider whether the Proposed Merger would increase the merged entity's ability or incentive to foreclose competitors, for example, the merged firm may provide bundled discounts where customers buy products together rather than separately, or may refuse to sell one product to customers unless they also buy a second product from it (tying).

Coordinated effects: would the proposed acquisition make coordination more likely?

30. A merger can substantially lessen competition if it increases the potential for the merged entity and all or some of its remaining competitors to coordinate their

behaviour and collectively exercise market power or divide up the market such that output reduces and/or prices increase.

31. We will assess whether the Proposed Merger would change the conditions in the relevant markets so that coordination is more likely, more complete or more sustainable.

Next steps in our investigation

32. The Commission is currently scheduled to make a decision on whether or not to give clearance to the Proposed Merger by **6 March 2020**. However, this date may change as our investigation progresses.[10] In particular, if we need to test and consider the issues identified above further, the decision date is likely to extend.

33. As part of our investigation, we will be identifying and contacting parties that we consider will be able to help us assess the preliminary issues identified above.

Making a submission

34. If you wish to make a submission, please send it to us at registrar@comcom.govt.nz with the reference "Mylan / Upjohn" in the subject line of your email, or by mail to The Registrar, PO Box 2351, Wellington 6140. Please do so by close of business on **28 January 2020**.

35. Please clearly identify any confidential information contained in your submission and provide both a confidential and a public version. We will be publishing the public versions of all submissions on the Commission's website.

36. All information we receive is subject to the Official Information Act 1982 (OIA), under which there is a principle of availability. We recognise, however, that there may be good reason to withhold certain information contained in a submission under the OIA, for example in circumstances where disclosure would unreasonably prejudice the supplier or subject of the information.

[10] The Commission maintains a clearance register on our website at http://www.comcom.govt.nz/clearances-register/ where we update any changes to our deadlines and provide relevant documents.