ISBN 978-1-869454-54-8

Statement of Preliminary Issues

Pfizer, Inc / Hospira, Inc

19 May 2015

Introduction

1. Pfizer, Inc (Pfizer) is proposing to acquire all outstanding shares of Hospira, Inc (Hospira). The acquisition is a global merger. On 28 April 2015, the Commerce Commission received an application from Pfizer seeking clearance for the New Zealand aspects of the acquisition.[1]

2. The Commission will grant clearance if it is satisfied that there is not likely to be a substantial lessening of competition in a relevant market in New Zealand.

3. This Statement of Preliminary Issues outlines the key competition 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 acquisition. We request that parties who wish to make a submission do so by **29 May 2015**.

The parties

5. Pfizer is a global, research-based biomedical and pharmaceutical company active in discovering, developing, manufacturing, marketing and selling innovative medicines for humans.

6. Hospira is a global provider of injectable pharmaceutical drugs and infusion technologies that it develops, manufactures and distributes worldwide. Hospira focuses predominantly on generic and biosimilar products, rather than innovator pharmaceuticals. Hospira has a particular focus on speciality injectable pharmaceuticals.

7. Neither Hospira nor Pfizer have manufacturing operations in New Zealand.

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1 The public version of the application is available on our website at: http://www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/detail/859

2 The issues highlighted in this statement are based on the information available at the time of publication and may change as our assessment of the application for clearance progresses. Therefore, the issues highlighted in this statement are not binding on us.

Potential overlap in New Zealand

8. The proposed merger relates to the parties' activities in the wholesale manufacture and supply of a range of predominantly off-patent prescription medicines. Pfizer has submitted that the proposed acquisition may result in actual or potential overlap in the supply of ten molecules, specifically:

    8.1 Cytarabine (used to treat luekaemia);

    8.2 Doxorubicin and Epirubicin (forms of antineoplastic antibiotics used in Chemotherapy treatment);

    8.3 Methotrexate (used as a chemotherapy agent, and to treat sever psoriasis and rheumatoid arthritis);

    8.4 Methlyprednisolone (used to treat a broad range of inflammatory conditions);

    8.5 Piperacillin/Tazobactam (a combination antibiotic used to treat infections);

    8.6 Gentamicin (an antibiotic used to treat serious infections);

    8.7 Heparin (an anticoagulant used to treat and prevent blood clots);

    8.8 Morphine (a narcotic used to relieve pain); and

    8.9 Phenytoin (an anti-epileptic medicine).

9. Within these molecules, the merging parties and other market participants supply a range of strengths and forms (eg tablet or injectable) which have different suitability for different conditions. This means that different dosages or forms of a medicine might not be substitutable for each other.

10. The Commission will consider whether the relevant markets can be distinguished by condition, molecule, strength and/or presentation.

Our framework

11. As required by the Commerce Act 1986, the Commission assesses whether an acquisition of shares is likely to result in a substantial lessening of competition. How we assess this is set out in our Mergers and Acquisitions Guidelines.[3]

12. We ask 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

[3] Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013. Available on our website at www.comcom.govt.nz

competition if the acquisition does not proceed (the scenario without the acquisition, often referred to as the counterfactual).[4]

13. A tool often used to assess competitive effects is market definition. Market definition provides a framework to help identify and assess the close competitive constraints the merged firm would likely face.[5] A market is defined in the Commerce Act as a market in New Zealand for goods or services as well as other goods or services that are substitutable for them as a matter of "fact and commercial common sense".[6]

14. We define markets in the way that we consider best isolates the key competitive constraints on the merging parties. In many cases this may not require us to precisely define the boundaries of a market.

15. We compare the extent of competition in each relevant market both with and without the acquisition. This allows us to assess the degree by which the proposed acquisition might lessen competition. If the lessening is likely to be substantial, we will not give clearance to the proposed acquisition. When making that assessment, we consider, among other matters:

    15.1 Existing competition – the degree to which existing competitors compete.

    15.2 Potential competition – the extent to which existing competitors would expand their sales or new competitors would enter the market and compete effectively if prices were increased.

    15.3 The countervailing market power of buyers – the potential for a business to be sufficiently constrained by purchaser's ability to exert substantial influence on negotiations.

Preliminary issues

16. In this investigation, we will assess whether the proposed acquisition is likely to substantially lessen competition in the relevant market(s) by focusing on the unilateral and conglomerate effects that might result from this acquisition. In particular, we will consider:

    16.1 the extent to which the relevant medicines are themselves substitutable on both the demand and supply side;

    16.2 the closeness of the competition between the merging parties and other suppliers in each of the relevant markets;

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

5 *Commerce Commission v New Zealand Bus Limited* (2006) 11 TCLR 679 (HC), at [123]. *Brambles New Zealand Ltd v Commerce Commission* (2003) TCLR 868 (HC) at [137].

6 Similarly, the courts have said that "[t]he boundaries of the market are defined by substitution between one product and another and between one source of supply and another, in response to changing prices". See *Commerce Commission v New Zealand Bus Limited* (HC), above n 5 at [123] citing *Re Queensland Co-operative Milling Association Ltd* (1976) ATPR 40-012 at 17,247.

16.3 the ability of new suppliers to enter, or for existing suppliers to expand in a relevant market, including by extending the range of generic, biosimilar or innovative medicines; and

16.4 the ability and/or incentive of the merged entity to foreclose competition by, for example, bundling or tying the supply of certain medicines.

Market definition

17. We will consider the extent to which the relevant medicines supplied by the merging parties are substitutable and this will inform the most appropriate way to define the relevant markets.

18. Pfizer considers that the market definitions should be based on the key molecule active in the medicine (for example Heparin). However, Pfizer submits that in the case of some medicines a more narrow approach is appropriate, such as galenic form.[7]

19. On that basis, Pfizer submitted that the medicines the parties each produce largely fall into separate markets, due to a lack of clinical substitutability.

20. On the demand side, we will be focusing particularly on the factors which may impact clinical substitutability, including:

20.1 clinical indication;[8]

20.2 molecule;

20.3 dosage;

20.4 pharmaceutical form (capsules, tablets, oral liquids/solutions, creams, injections and gels);

20.5 route of administration (self-administered or hospital-administered); and

20.6 other relevant safety considerations (patient specific requirements, etc).

21. On the supply side, we will be focusing particularly on the factors which may impact manufacturing substitutability, including:

21.1 required ingredients;

21.2 machinery and other manufacturing requirements;

21.3 staff expertise;

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7 Galenic form is defined by Pfizer to be "a combination of features including dosage, pharmaceutical form, and route of administration, which may limit substitutability as between products comprised of the same Active Pharmaceutical Ingredients (APIs)."

8 A clinical indication is the condition the medicine is used to treat.

21.4 regulatory processes and requirements; and

21.5 required distribution networks.

Existing competition

22. Our investigation will consider the closeness of competition between the merging parties and the closeness of competition between the merging parties and other suppliers, for each of the relevant medicines noted above.

23. Pfizer submitted that the merged entity would face competition from a number of large, sophisticated and well-resourced international pharmaceutical companies in the supply of prescription pharmaceuticals.

24. We will consider whether this competition would effectively constrain the merged entity from raising prices above the competitive level.

Potential competition

25. For each of the relevant markets, we will assess whether entry by new competitors or expansion by existing competitors is likely, of sufficient extent, and would occur in a timely enough fashion to prevent a substantial lessening of competition.

26. Pharmaceutical markets are often characterised by large expenditures on research and development with long development processes. In addition, not all products are marketed in all countries. We will consider whether or not the merging parties have relevant products either in development, or for sale in other countries that could be expected to come to market within the short to medium term and the competition that exists for those products.[9]

27. Pfizer submitted that the barriers to entry and expansion for generic prescription pharmaceuticals are low. In addition, Pfizer considers that the absence of New Zealand manufacturing facilities is no obstacle to efficient and timely entry, due to the ability to use New Zealand based distributors.

Countervailing power

28. PHARMAC is the New Zealand government agency with the responsibility of deciding, on behalf of District Health Boards, which medicines, medical devices and related products are subsidised. Given this, PHARMAC negotiates the price and terms of a large number of medicines from suppliers.

29. Pfizer submitted that this negotiating position gives PHARMAC significant countervailing power.

30. We will consider whether PHARMAC will have the ability to constrain the merged entity from profitably increasing prices, including for instance by sponsoring entry

[9] In general, we consider entry and expansion within two years is sufficiently timely. However, this timeframe may vary depending on the facts of the case. For example, in *Commerce Commission v New Zealand Bus Ltd* (2006) 11 TCLR 679 (HC) at [155] the court adopted a three year timeframe.

and/or expansion by other suppliers, or by punishing a price increase in other markets where the merged entity operates.

31. The ability for PHARMAC to exercise countervailing power depends, among other things, on the number of legitimate competitive alternatives to the merged entity in the relevant markets, as well as the ability of PHARMAC to leverage the bargaining power it has in other, more competitive, product areas to constrain price rises in the relevant markets where competition may be lessened.

Conglomerate effects

32. We will also investigate whether the merger could result in conglomerate effects. Conglomerate effects can result where two firms, producing complementary goods, are able to bundle or tie those goods in order to foreclose competitors.

33. We will consider whether or not the merged entity would have the ability and incentive to bundle or tie different types of medicines or product areas, potentially foreclosing competitors.

Next steps in our investigation

34. The Commission is currently aiming to make a final decision on whether or not to grant clearance to the merger by **19 June 2015.** However, this date may change as our investigation progresses.[10]

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

Making a submission

36. If you wish to make a submission, please send it to us at registrar@comcom.govt.nz with the reference Pfizer / Hospira 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 **29 May 2015**.

37. Please clearly identify any confidential information contained in the submission. All information we receive is subject to the principle of availability under the Official Information Act 1982. However, we recognise that preserving the confidentiality of commercially sensitive information and providing protection against disclosure is necessary.

[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.