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Determination

Mylan and Abbott Laboratories' Established Pharmaceuticals Division [2014] NZCC 40

The Commission:	Dr Mark Berry Anna Rawlings Dr Jill Walker
Summary of application:	An application from Mylan Inc. seeking clearance to acquire the Established Pharmaceuticals Division of Abbott Laboratories, Inc.
Determination:	Under s 66(3)(a) of the Commerce Act 1986, the Commerce Commission determines to give clearance to the proposed acquisition.
Date of determination:	11 December 2014

Confidential material in this report has been removed. Its location in the document is denoted by [ ].

CONTENTS

The proposed acquisition

1. On 9 October 2014, the Commerce Commission received an application from Mylan Inc. (Mylan) seeking to acquire from Abbott Laboratories, Inc. (Abbott) its Established Pharmaceuticals Division (Abbott EPD) in certain countries outside of the United States. Clearance was sought for the acquisition only to the extent it would affect a market in New Zealand.[1]

2. The proposed acquisition would result in the aggregation of Mylan's and Abbott EPD's operations in New Zealand.

The decision – clearance granted

3. The Commission gives clearance to the proposed merger as it is satisfied that it will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

Our framework

4. Our approach to analysing the competition effects of the proposed acquisition is based on the principles set out in our Mergers and Acquisitions Guidelines.[2]

The substantial lessening of competition test

5. As required by the Commerce Act 1986, we assess mergers using the substantial lessening of competition test.

6. We determine whether a merger is likely to substantially lessen competition in a market by comparing the likely state of competition if the merger proceeds (the scenario with the merger, often referred to as the factual), with the likely state of competition if the merger does not proceed (the scenario without the merger, often referred to as the counterfactual).[3]

7. A lessening of competition is generally the same as an increase in market power. Market power is the ability to raise price above the price that would exist in a competitive market (the 'competitive price'),[4] or reduce non-price factors such as quality or service below competitive levels.

8. Determining the scope of the relevant market or markets can be an important tool in determining whether a substantial lessening of competition is likely.

9. We define markets in the way that we consider best isolates the key competition issues that arise from the 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 Act, as a matter of fact and commercial common sense.[5]

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1 Merger filings have been or will be made in Canada, Japan, United States, Brazil, India, Australia and the European Union.

2 Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013.

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

4 Or below competitive levels in a merger between buyers.

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

When a lessening of competition is substantial

10. Only a lessening of competition that is substantial is prohibited. A lessening of competition will be substantial if it is real, of substance, or more than nominal.[6] Some courts have used the word 'material' to describe a lessening of competition that is substantial.[7]

11. Consequently, there is no bright line that separates a lessening of competition that is substantial from one that is not. What is substantial is a matter of judgement and depends on the facts of each case. Ultimately, we assess whether competition will be substantially lessened by asking whether consumers in the relevant market(s) are likely to be adversely affected in a material way.

When a substantial lessening of competition is likely

12. A substantial lessening of competition is 'likely' if there is a real and substantial risk, or a real chance, that it will occur. This requires that a substantial lessening of competition is more than a possibility, but does not mean that the effect needs to be more likely than not to occur.[8]

The clearance test

13. We must clear a merger if we are satisfied that the merger would not be likely to substantially lessen competition in any market.[9] If we are not satisfied – including if we are left in doubt – we must decline to clear the merger.[10]

Key parties

Mylan

14. Mylan is a global pharmaceutical company that manufactures and distributes a range of generic and specialty pharmaceutical products.

15. In New Zealand, Mylan operates through its wholly owned subsidiary, Mylan NZ Limited (Mylan NZ). Mylan NZ imports and distributes a range of off-patent pharmaceutical products including both prescription and over-the-counter (OTC) medicines.

Abbott and Abbott EPD

16. Abbott is a global healthcare company that manufactures and distributes a range of pharmaceutical products and other healthcare products. Abbott's range of pharmaceutical products is supplied through Abbott EPD and includes both prescription and OTC medicines. In addition, Abbott also supplies diagnostic products, nutritional products and vascular products.

17. At present, Abbott operates in New Zealand through its wholly owned subsidiary, Abbott Laboratories NZ Limited (Abbott NZ). Abbott NZ imports and distributes Abbott's range of

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6 *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [127].

7 Ibid at [129].

8 Ibid at [111].

9 Commerce Act 1986, s 66(1) of the Commerce Act 1986.

10 In *Commerce Commission v Woolworths Limited* (CA), above n 2 at [98], the Court held that "the existence of a 'doubt' corresponds to a failure to exclude a real chance of a substantial lessening of competition". However, the Court also indicated at [97] that we should make factual assessments using the balance of probabilities.

patented and generic pharmaceutical products. Abbott has no manufacturing operation in New Zealand.

Other relevant parties

18. In addition to Mylan and Abbott NZ, there are a number of other suppliers of generic pharmaceutical products in New Zealand. These suppliers include:

    18.1 Apotex NZ Limited (Apotex);

    18.2 Actavis New Zealand Limited (Actavis);

    18.3 Douglas Pharmaceutical Limited (Douglas); and

    18.4 Aft Pharmaceuticals Limited.

Industry background

19. Pharmaceutical products are generally divided into two categories, prescription and OTC medicines. Prescription medicines are only available with a prescription from a doctor, and are dispensed from a pharmacy. OTC medicines can be sold directly to consumers without the need for a prescription.

20. Before any medicine can be supplied in New Zealand, it must be approved by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Medsafe's role is to ensure that medicines and medical devices supplied in New Zealand have acceptable efficacy, quality and safety.

21. Once a prescription medicine has been approved by Medsafe, the supply and funding of the vast majority of these medicines are controlled by the Pharmaceutical Management Agency (Pharmac).[11]

22. Pharmac decides, on behalf of District Health Boards, which medicines and related products are subsidised for use in community and public hospitals. Once Pharmac has decided to subsidise a medicine, it will typically select its preferred supplier for that medicine through a tender process. Winning bidders get the right to be the sole supplier of that medicine for a fixed term (usually three years).

23. Pharmac can also accept alternative commercial proposals from suppliers if it considers it is able to negotiate a better deal with a supplier outside of the tender process (for example, when it is considering entering into agreements for the supply of multiple products from a single supplier).

Previous decisions

24. In previous decisions involving pharmaceutical products, the Commission has noted that there can be instances where it is necessary to take either a broad or a narrow approach to market definition. The approach will depend on the particular characteristics of the

[11] See CDC Pharmaceuticals Limited and Pharmacy Wholesales (Central) Limited [2014] NZCC 21 for further information on how Pharmac funds medicines in New Zealand.

relevant pharmaceutical products and the conditions that the pharmaceuticals are used to treat.[12]

25. For example, the Commission has assessed markets based on therapeutic classes according to the Anatomical Therapeutic Classification (the ATC).[13] The ATC was devised by the European Pharmaceutical Marketing Research Association and has been referenced by a number of other jurisdictions when they have considered the competition implications of mergers in the pharmaceuticals industry. Within each therapeutic class there can be a wide variety of products that contain different active ingredients which can be used to treat similar conditions and, therefore, be considered to be substitutes for one another.

26. However, there can be instances where certain active ingredients are used to treat different conditions. In these instances, the Commission has found it can be appropriate to take a narrower approach and define separate product markets within each therapeutic class.[14]

With and without scenarios

With the acquisition

27. With the acquisition, Mylan would acquire Abbott EPD while Abbott would continue to supply its other products independently of Mylan.

Without the acquisition

28. Without the acquisition, Mylan and Abbott EPD would continue to operate independently from one another, with Abbott EPD remaining a business unit within Abbott.

The relationship between Mylan and Abbott

29. In exchange for selling Abbott EPD to Mylan, Abbott would acquire a 22% shareholding in the merged entity. Further, Abbott and the merged entity intend to enter into toll manufacturing arrangements for certain products because post acquisition Abbott would retain the ownership of its Established Pharmaceuticals Division in certain countries.[15]

30. Post acquisition, if Mylan and Abbott continued to be close competitors the shareholding and toll manufacturing arrangements could change each party's incentive to compete with one another. However, in New Zealand this does not appear to be the case. Abbott advised that its existing range of diagnostic, nutritional and vascular products do not compete with any of the products that Mylan currently supplies and this would continue to be the case post acquisition.

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12 For example, see Novartis AG and Alcon, Inc (Commerce Commission, Decision 692, 6 May 2010) and more recently GlaxoSmithKline Plc and Novartis AG [2014] NZCC 37.

13 For example, see Schering Plough Corporation and Organon Biosciences NV (Commerce Commission, Decision 621, 4 October 2007).

14 For example, see Novartis AG and Alcon, Inc (Commerce Commission, Decision 692, 6 May 2010).

15 As above, the proposed transaction is limited to certain countries outside of the United States.

How the acquisition could substantially lessen competition

31. The proposed transaction could substantially lessen competition if the merged entity could profitably raises prices[16] above the level that would prevail without the acquisition.

32. Both Mylan and Abbott EPD import and supply a range of prescription and OTC pharmaceuticals. As a result of the transaction, Mylan would effectively acquire Abbott's pharmaceutical operations in New Zealand. The vast majority of the prescription pharmaceuticals supplied by the two parties are purchased by Pharmac.[17] As a result of the transaction, Mylan and Abbott EPD would no longer compete for various different tenders held by Pharmac.

33. For the merger to result in a substantial lessening of competition, the necessary requirements are:[18]

    33.1 one or both of the merger parties being a significant competitor in the market; and

    33.2 the merger giving the merged entity the ability to raise prices above pre-merger levels. This means that existing competition, potential competition, buyer power and other potential constraints would not be sufficient to make such a price rise unprofitable.

Market definition

Introduction

34. Market definition is a tool that helps identify and assess the close competitive constraints the merged firm would face. Determining the relevant market requires us to judge whether, for example, two products are sufficiently close substitutes as a matter of fact and commercial common sense to fall within the same market.

35. We define markets in the way that best isolates the key competition issues that arise from the merger. In many cases this may not require us to precisely define the boundaries of a market. We consider all relevant competitive constraints, and the extent of those constraints. For that reason, we also consider products which fall outside the market but which still impose some degree of competitive constraint on the merged firm.

Applicant's view of the markets

36. The applicant submitted that Mylan and Abbott EPD have largely complementary businesses so the overlap between the two parties is limited.

37. The applicant submitted that the relevant product markets should be based on each pharmaceutical product's therapeutic purpose so as to include the relevant treatment profile of the medicine, the mechanism of action (such as the active ingredient of the medicine) as well as a range of other factors.

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16 Price in this document refers to all dimension of competition including quality, the level of service, or any other element of competition valued by buyers.

17 As discussed below, there is limited overlap between the OTC products that the two parties supply and so we have not considered these products any further.

18 See *Merger Assessment Guidelines* at 3.62.

38. For pharmaceutical products requiring a prescription, the applicant submitted that there are four categories of products[19] where there are overlaps[20] between Mylan and Abbott EPD.

    38.1 Antiarrhythmics are drugs which are used to suppress abnormal rhythms of the heart and include all products recommended for use in arrhythmia, disorders of cardiac rhythm, and tachycardia.

    38.2 Macrolides are a class of antibiotics which are used in the treatment of a range of infections.

    38.3 Non-steroidal anti-rheumatic drugs are anti-inflammatory drugs used primarily for the treatment of a range of arthritis.

    38.4 Antihypertensives are drugs used to treat high blood pressure and the complications of such an indication, including stroke and myocardial infarction.

39. As both Mylan and Abbott supply all these products on a national basis, Mylan submitted that the relevant geographic dimension is national.

The Commission's view of the relevant markets

40. In general, the more closely substitutable two products are, the closer the competition and the greater the competitive constraint between the products.

41. For a number of the categories of products listed above by the applicant, Mylan and Abbott EPD do not appear to be close competitors.

42. For the supply of antiarrhythmics, macrolides, and non-steroidal anti-rheumatic medicines, taking either a wide or a narrow approach, there is limited overlap between Mylan and Abbott EPB as the two parties supply products that contain different active ingredients. In addition, there are a number of alternative suppliers of these products.

43. Accordingly, the Commission does not intend to consider antiarrhythmics, macrolides or non-steroidal anti-rheumatic medicines any further.

Antihypertensives

44. Mylan and Abbott EPD both supply a range of antihypertensive products. Antihypertensives are used to treat high blood pressure. There are a range of different products, such as Angiotensin Converting Enzyme inhibitors (ACE inhibitors), calcium channel blockers and beta blockers.

45. The applicant noted that, within the range of antihypertensive treatments, some of the medicines differ in their mechanisms of action (or active ingredient) as well as in side

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19 The application noted that there is overlap in laxatives supplied without a prescription. These OTC laxatives are widely available from various different retail outlets and are supplied from a range of different producers and so we have not considered these products any further.

20 The applicant noted overlap relates to [

effects, profile and cost. Despite the differences in approach, the applicant considers that there is high demand side substitutability between different hypertension treatments.

46. Listed below are antihypertensive medicines that the two parties currently supply in New Zealand (with the relevant active ingredient noted in brackets).

    46.1 Mylan: Prodopa (methyldopa), Felo (felodipine), Adefin (nifedipine), Verpamil (verapamil), Zapril (cilazapril), Acetec (enalapril), Candestar (candesartan cilexetil), Lostaar (losartan).

    46.2 Abbott EPD: Gopten (trandolapril) and Isoptin (verapamil).

47. For almost all of these products, there is limited overlap between the Mylan and Abbott EPB as the two parties supply products that contain different active ingredients and there are a number of alternative suppliers of these products. However, at present, Mylan and Abbott EPD are the only two suppliers with existing consents in New Zealand to supply products that contain the active ingredient verapamil.

48. Verapamil is a calcium antagonist that inhibits influx of calcium into cells. In New Zealand, verapamil is indicated for the treatment of supra-ventricular tachycardia, angina and hypertension.[21]

49. Mylan submitted that hypertension and angina (as well as various arrhythmias) can be treated with a range of different medicines such as calcium channel blockers and ACE inhibitors and these products are all prescribed and used interchangeably.

50. Pharmac noted that while verapamil is a calcium channel blocker, most calcium channel blockers are derived from the dihydropyridine molecule. However, verapamil is a non-dihydropyridine medication which can result in different side effects compared with dihydropyridines and treats a different range of patient clinical needs. At present, there is one other common non-dihydropyridine medication which is diltiazem. [22]

51. Mylan stated that demand for verapamil products is very low and verapamil accounts for approximately [ ] of all calcium channel blockers supplied in New Zealand.[23]

52. We understand that the use of verapamil in New Zealand has been in decline for some time as other, newer calcium channel blockers have been prescribed instead.

53. Further, some patients who are currently prescribed with a verapamil-based product could be treated with a different calcium channel blocker without any negative side effects or any reduction in the efficacy of the patient's treatment plan. This would suggest a product market that is wider than just verapamil-based products.

54. For example, for many patients with hypertension and angina, there are a number of hypertensive products, with diltiazem and other calcium channel blockers being the closest alternatives to verapamil.[24]

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21 Letter from Pharmac 25 November 2014.

22 Letter from Pharmac 25 November 2014.

23 Letter from Mylan 21 November 2014. Mylan noted that verapamil accounted for sales of [ ].

55. In most instances, verapamil is not the first choice or the preferred option for prescribing to a patient with hypertension or angina. A common side effect of verapamil is constipation and so many cardiologists prefer to prescribe patients with either diltiazem or amlodipine instead of verapamil.[25]

56. While verapamil may not be a preferred medicine for some patients, various cardiologists advised that there are certain patients for which verapamil is the most effective treatment option.[26] For example, we understand that verapamil is more effective than diltiazem (the closest non-dihydropyrindine to verapamil) in preventing particular cardiac rhythms problem. While industry estimates of the proportion of patients that could switch to another medicine varied,[27] the Commission understands that there are some patients who do not currently have an alternative to verapamil (primarily due to their intolerance of the other drugs).

57. Accordingly, the Commission considers it appropriate to focus its analysis on a product market for verapamil-based products on the basis that if there are no competition concerns on this narrow approach, there are unlikely to be any concerns on a wider market.

58. Mylan and Abbott EPD supply verapamil products, as well as all their other pharmaceutical products, on a national basis and so the Commission considers a national market to be appropriate in this instance.

Conclusion of market definition

59. As a starting point for its analysis, the Commission considers the relevant market to be the national market for the manufacturer/import and wholesale supply of verapamil-based products (the verapamil market).

Competition analysis – the verapamil market

60. Unlike in most markets, where transactions occur on an ongoing basis, in this instance competition most commonly occurs only when market participants bid to win three year, sole supply contracts with Pharmac.

61. We have assessed how the recent competition for Pharmac tenders for verapamil has occurred and the closeness of competition between the participants. Next we compare that scenario to what we consider the competitive constraints will be like when competition occurs at the next tender round if the proposed acquisition proceeds.

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[24] For example, see responses from [ ].

[25] For example, see interview with [ ].

[26] For example, see responses from cardiologists including [ ].

[27] The proportions ranged from between 20-90%. For example, see responses from cardiologists including [ ].

The recent state of competition

62. In New Zealand, Mylan supplies the two most prescribed verapamil products while Abbott EPD also supplies several other verapamil products.

63. Pharmac advised that in 2000 it decided to select Mylan as the sole subsidised supplier of verapamil. Pharmac advised that it could have selected more than one supplier of verapamil if it wanted to. However, because the demand for verapamil is relatively low, it considered that it would likely obtain a better price if it could guarantee that the entire demand went to one particular supplier.

64. In 2008, Mylan advised Pharmac that it was experiencing problems producing two verapamil products. Pharmac then entered into an arrangement with Abbott EPD for supply of these two particular products.[28]

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66. Table 1 outlines the recent sales of verapamil-based products in New Zealand. Both Mylan and Abbott EPD advised that the demand for verapamil in New Zealand is relatively low.

Table 1: Sales of verapamil products in New Zealand (NZ$)

Parties	2011	2012	2013
Mylan	[		
Abbott EPD			
Total			]

Source: Pharmac

67. Table 2 lists the five verapamil-based products that Pharmac has decided to subsidise and the number of patients that each product was prescribed to last year. Mylan supplies the two products with the highest demand and, as noted above, two of the products that Abbott EPD supplies are the result of Mylan's inability to supply these particular products.

[28] In addition, since 1994 Abbott EPD has supplied an injection form of verapamil although the use of this product is very limited and it was not included in the terms of the sole supply agreement listed above.

Table 2: The supply of verapamil-based products in New Zealand for 2013

Supplier	Product	Subsidy	Units dispensed	Prescriptions	Patients	Approximate Value (NZ$)
Abbott EPD	Inj 2.5mg/ml/ 2ml	$7.54 per 5	[			
Abbott EPD	Tab 40mg	$7.01 per 100				
Abbott EPD	Tab 80mg	$11.74 per 100				
Mylan	Tab LA 120mg	$15.20 per 250				]
Mylan	Tab LA 240mg	$25.00 per 250				

Source: Pharmac

Competition at the next tender round

68. The proposed acquisition would remove Abbott EPD as the most likely alternative bidder to Mylan in future tenders held by Pharmac for the sole supply of verapamil in New Zealand. However, there is a real chance that the merged entity would face competition for the supply of verapamil at future tenders held by Pharmac.

69. The closing date for the next Pharmac tender in relation to verapamil is 18 December 2014. Following that, the next tender will not be for another three years.[29]

70. Mylan stated that the cost of registering a new product in New Zealand is relatively low, approximately $43,000, especially if that product is already registered and supplied in another jurisdiction. Further, the sole supply contract offered by Pharmac, worth approximately $900,000 over three years, is of sufficient scale to encourage entry.

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[29] If unsatisfactory, Pharmac could run the tender earlier.

[30] [ ]

72. Other parties interviewed consider that it is unlikely that a new entrant would consider supplying verapamil in New Zealand, given the limited demand.

72.1 Douglas previously supplied verapamil products in New Zealand. [

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72.2 Apotex currently manufacturers verapamil products in Canada. [

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72.3 Aspen Pharmacare Australia (Aspen) distributes two verapamil products in Australia. [

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Countervailing power

73. If faced with a price increase by the merged entity, it is likely that Pharmac would have some degree of countervailing power. The Commission considers that Pharmac, as the sole funder of verapamil, would have scope to use its ability to manage the patient demand for verapamil in order to constrain a potential price increase post acquisition.

74. Under all current contracts with Pharmac, suppliers have to give Pharmac reasonable notice of a price change. [

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80. While the proposed acquisition would remove a supply option for Pharmac, overall, the Commission considers that Pharmac, as the sole funder of verapamil in New Zealand, would have an ability to manage patient demand in order to constrain a potential price increase, post acquisition.

Overall conclusion

81. The proposed acquisition would result in aggregation in the national market for the wholesale supply of verapamil. Verapamil is a prescription medicine that is used in the treatment of hypertension and angina.

82. At present, Mylan and Abbott are the only two suppliers of verapamil. In the without scenario, the two parties would continue to operate independently from one another in New Zealand.

83. The supply of verapamil in New Zealand is currently fully subsidised by Pharmac. There is a real chance that the merged entity would face competition for the supply of verapamil at future tenders held by Pharmac. Further, if faced with a price increase, Pharmac, as the sole funder of verapamil, would likely have a degree of countervailing power.

84. Accordingly, the Commission gives clearance to the proposed acquisition as it is satisfied the acquisition will not, or would not be likely to, substantially lessen competition in a market in New Zealand.

Determination on notice of clearance

85. The Commission is satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

86. Under s 66(3)(a) of the Commerce Act 1986, the Commission gives clearance to Mylan Inc. to acquire the Established Pharmaceuticals Division of Abbott Laboratories, Inc. insofar as the acquisition would affect a market in New Zealand.

Dated this 11th day of December 2014

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Dr Mark Berry
Chairman