ISSN 1178–2560
Decision Series
Project no. 11.04/14894

PUBLIC version

Determination

GlaxoSmithKline plc and Novartis AG [2014] NZCC 37

The Commission:	Dr Mark Berry Anna Rawlings Dr Jill Walker
Summary of application:	An application from GlaxoSmithKline plc (GSK) seeking clearance for Leo Constellation Ltd (a majority owned subsidiary of GSK to be renamed GlaxoSmithKline Consumer Healthcare Ltd) to acquire sole control of Novartis AG's consumer healthcare pharmaceuticals business.
Determination:	Under section 66(3)(a) of the Act, the Commerce Commission determines to give clearance for Leo Constellation Ltd to acquire sole control of Novartis AG's consumer healthcare pharmaceuticals business.
Date of determination:	27 November 2014

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

The proposal

1. On 23 September 2014, the Commerce Commission (the Commission) received an application from GlaxoSmithKline plc (GSK) seeking clearance for Leo Constellation Ltd (a majority owned subsidiary of GSK to be renamed GlaxoSmithKline Consumer Healthcare Ltd (GSKCH)) to acquire sole control of Novartis AG's (Novartis) consumer healthcare pharmaceuticals business.

The decision – clearance given

2. The Commission gives clearance to the proposed acquisition. 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 any market.

Our framework

3. Our approach to analysing the competition effects of the proposed acquisition is based on the principles set out in our Mergers and Acquisitions Guidelines.[1]

The substantial lessening of competition test

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

5. 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).[2]

6. 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'),[3] or reduce non-price factors such as quality or service below competitive levels.

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

8. 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.[4]

1 Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013.
2 *Commerce Commission v Woolworths Limited* (2008) 12 TCLR 194 (CA) at [63].
3 Or below competitive levels in a merger between buyers.
4 Section 3(1A). See also *Brambles v Commerce Commission* (2003) 10 TCLR 868 at [81].

When a lessening of competition is substantial

9. 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.[5] Some courts have used the word 'material' to describe a lessening of competition that is substantial.[6]

10. 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

11. 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.[7]

The clearance test

12. We must clear a merger if we are satisfied that the merger would not be likely to substantially lessen competition in any market.[8] If we are not satisfied – including if we are left in doubt – we must decline to clear the merger.

Key parties

GSK

13. GSK is an international healthcare company active in over 150 countries worldwide. GSK's principal areas of operation are the development, manufacture and sale of pharmaceuticals, vaccines, and consumer healthcare products. In New Zealand, GSK operates consumer healthcare and prescription pharmaceutical divisions. GSK has no manufacturing operation in New Zealand.

Novartis

14. Novartis is a global group of healthcare companies active in a range of areas including pharmaceuticals, eye care, animal health, vaccines and consumer health. In New Zealand, Novartis has a marketing, sales and distribution operation for its pharmaceutical and animal health products. Novartis' New Zealand consumer healthcare division is operated from Australia.

---

[5] *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [127].
[6] *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [129].
[7] Ibid at [111].
[8] Commerce Act 1986, s 66(1) of the Commerce Act 1986.

Other relevant parties

Retailers

Pharmacies

15. There are approximately 900 pharmacies in New Zealand which, in addition to supplying prescription medicines, typically retail a range of consumer healthcare products.

Supermarkets

16. The two main supermarket chains in New Zealand are Progressive Enterprises Limited (Progressive) and Foodstuffs New Zealand (Foodstuffs). Both supermarket chains retail a range of healthcare products including a number of house brand products.

Industry background

17. Medicines are generally divided into two categories, prescription and over-the-counter (OTC) medicines. As the name suggests, prescription medicines are only available from a pharmacy with a prescription from a doctor. OTC medicines can be sold directly to consumers without the need for a prescription.

18. OTC products fall into two categories. Pharmacist-only medicines, (also known as restricted medicines) are medicines that can only be sold under the direction of a pharmacist (but can be sold without a doctor's prescription). When selling these medicines, the pharmacist must fulfil special requirements designed to make sure the consumer is properly informed about the safe and correct use of the medicine.

19. All other OTC products can be sold in any retailer outlet. These products are typically referred to as 'open' or grocery products. As certain pharmacist-only products become more widely used and consumers become aware of the effects of the medicine, there is a tendency for these products to be reclassified as grocery products which means that they can be sold without a pharmacist's direction.

With and without scenarios

With the acquisition

20. With the acquisition GSK will acquire majority control of Novartis' consumer healthcare business. This will be gained through it obtaining a controlling stake in a new business (GSKCH). Both Novartis and GSK will contribute their existing consumer healthcare businesses to this new company with Novartis obtaining a minority stake.

21. The parties' other New Zealand operations (GSK NZ Pharmaceuticals and Novartis Pharma NZ) will be retained by the respective parties and continue to operate as separate companies.

Without the acquisition

22. The Commission considers that the most appropriate scenario against which to assess the competition aspects of the proposed acquisition is the status quo.

Ways in which the merger could substantially lessen competition

23. We have considered that the proposed merger could substantially lessen competition if the merged entity could profitably raise price[9] above the level that would prevail without the acquisition for:

    23.1 the wholesale supply of OTC systemic pain relief products;

    23.2 [ ]; and

    23.3 the wholesale supply of OTC cold sore treatment products.

24. Given the lack of aggregation, the Commission does not consider issues are likely to arise in relation to topical nasal preparations, anti-fungals (dermatological), or anti-viral products. In New Zealand, GSK does not supply any non-prescription anti-smoking products.

Market definition

Our approach to market definition

25. Market definition is a tool that provides a framework to help identify and assess the close competitive constraints the merged firm would likely face.[10] It encompasses actual and potential transactions between sellers and buyers, and seeks to capture the factors that directly shape and constrain rivalry between sellers.[11]

26. A market is defined in the Commerce Act as a market in New Zealand for goods and services as well as other goods and services that are substitutable for them as a matter of "fact and commercial common sense". In general, the more closely substitutable two products are, the closer the competition and the greater the competitive constraint between the products.

27. We define markets in a 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.

28. To help us establish whether customers would switch sufficient purchases to alternative products, we use the hypothetical monopolist test as a conceptual tool. This test asks whether a hypothetical sole supplier of a set of products (or locations) would profitably increase prices for at least one of the merging firms' products (or locations) by at least a small, but significant, amount.[12] This small, but significant, amount is often referred to as a SSNIP – a small, but significant, non-transitory increase in price.

---

9 Price in this document refers to all dimensions of competition, including quality, range, the level of innovation, service or any other element of competition valued by buyers.

10 *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].

11 *Commerce Commission v Air New Zealand Ltd et al* (2011) 9 NZBLC 103,318 (HC) at [124].

12 The test assumes that all other prices are held at current levels.

29. In general, the smallest set of products (or locations) in which the SSNIP can be profitably sustained is defined as the relevant product (geographic) market.

The applicant's view of the relevant markets

30. The applicant submits that the proposed transaction would primarily affect two broad product categories,[13] namely:

    30.1 OTC systemic pain relief products; and

    30.2 OTC topical cold sore management products.

31. The applicant also notes that the proposed acquisition creates potential overlap in four ATC code areas: topical nasal preparations, anti-smoking products, anti-fungals (dermatological), and anti-virals.[14]

The Commission's view of the relevant markets

32. The Commission considers that the appropriate markets in which to consider the competition effects of the proposed acquisition are:

    32.1 the national market for the wholesale supply of OTC systemic pain relief products;

    32.2 [ ]; and

    32.3 the national market for the wholesale supply of OTC cold sore treatment products, both topical and systemic.

Pain relief products

33. Within the OTC pain relief product category there are a wide range of products that contain different active ingredients, treat pain using different biological pathways, and may be better suited to different ailments. As a result the degree of substitutability of different OTC pain relief products varies considerably with some products being very closely substitutable and others not very substitutable at all. In other cases substitutability may run only one way between two products; that is, a consumer might use product A instead of product B, but would not use product B instead of product A. Additionally, it may be that for some ailments two or more OTC pain relief products are complements rather than substitutes.

34. The main types of pain relief products in New Zealand can be broadly grouped into the following four types.

    34.1 Paracetamol-based products – paracetamol is a general purpose non-narcotic analgesic which works by reducing pain signals in the brain. Paracetamol is

[13] Application at [1.4].

[14] ATC – Anatomical Therapeutic Chemical Classification System. This is a classification system used by the World Health Organisation to classify drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

off-patent and is used in a large number of products by generic manufacturers as well as GSK's Panadol.

34.2 Opioids – these include codeine, tramadol, morphine and similar active ingredients. Opioids affect the nervous system and gastrointestinal tract. Only weak opioids like codeine are available in OTC products, such as GSK's Panadeine.

34.3 Non-steroidal anti-inflammatory (NSAIDS) – these include diclofenac, ibuprofen, aspirin and other similar substances. NSAIDS work by treating inflammation that causes pain. Many of these are off patent, including diclofenac, used in Novartis' Voltaren, and ibuprofen, used in Reckitt Benckiser's Nurofen.

34.4 Combinations of two or more of the above ingredients – for example, GSK's Panafen Plus which contains codeine (an opioid) and ibuprofen (a NSAID).

35. As in Decision 567,[15] the Commission remains of the view that it is appropriate to consider pain relief products containing different active ingredients as part of the same market as they are all used in the treatment of pain, with the type and severity of pain dictating which product is chosen.

36. The Commission, however, considers it appropriate in this case to consider [ ] pain relief products.

37. Consumers view these two categories of products differently. [ ]. Consequently, these two categories of products are promoted differently by manufacturers and retailers, including being positioned in different locations on shop displays and shelves.

38. We also consider that defining the pain relief markets in this way best isolates the potential competition concerns [ ].

39. Within [ ].

40. In New Zealand, GSK offers systemic pain relief products which are marketed under the Panadol banner and have paracetamol as their primary active ingredient.

---

15 Reckitt Benckiser plc and Boots Healthcare International Limited (Commerce Commission Decision 567, 30 November 2005).

Novartis supplies systemic pain relief products under the Voltaren brand which contain diclofenac as the active ingredient. Novartis also supplies a topical pain relief product under the Voltaren brand.

Cold sore treatment products

41. Cold sores are caused by a variation of the Herpes virus called Herpes Labialis. Cold sores are commonly treated by topical or systemic applications of anti-viral medications. These medications act by inhibiting the virus' ability to replicate itself.

42. In Decision 398,[16] the Commission proposed a topical anti-viral market when considering the merger of two competing OTC suppliers of anti-viral cream. At that time, no systemic OTC anti-viral products were available so the Commission did not consider whether topical and systemic anti-viral treatments should be considered as part of the same market.

43. Topical cold sore treatments are available for self-selection by the consumer whereas the systemic treatment is a pharmacist only medicine. Systemic treatments also have a different side effect profile, cost 30% more, and are designed for frequent or severe sufferers. The majority of systemic products are also prescription only.

44. Notwithstanding that we do not consider systemic cold sore treatments to be a close substitute for topical treatments, the Commission considers that it is appropriate to apply a conservative approach and consider systemic and topical cold sore treatments as being in the same broader product market. Applying a broad market definition that includes both topical and systemic products increases the overlapping products of the merging parties and highlights the potential competition concerns raised by the removal of Novartis' Famvir Once product as an independent competitor.

45. In addition to the anti-viral products, a number of cold sore treatments which have no active ingredient (' non-medicated treatments') are available and are viewed by the parties as competing with medicated treatments. Unlike non-medicated pain relief products, non-medicated cold sore treatments act to speed up the healing process by keeping the lesion clean and covered.

46. Nevertheless, the Commission considers it appropriate to consider non-medicated cold sore products as being in a separate market because defining the market in this way highlights the overlap between the merging parties.

Competition analysis – unilateral effects

47. The Commission considers it unlikely that the proposed acquisition would lead to a substantial lessening of competition in any of the relevant markets.

[16] Glaxo Wellcome plc and SmithKline Beecham plc (Commerce Commission Decision 398, 1 September 2000).

48. The Commission does not consider that GSK and Novartis are close competitors in OTC systemic pain relief, [ ], or OTC cold sore treatment products. The merged entity will continue to face strong competition from a number of alternative competitors.

The wholesale supply of systemic pain relief products

49. Table 1 below outlines the market shares for the firms supplying systemic pain relief products in New Zealand.

Table 1: Market share estimates for systemic pain relief products 2013

Company	Brand Name(s)	Revenue ($)	Revenue share (%)
GSK	Panadol, Panadeine, Panafen Ib Plus	[ ]	[ ]%
Novartis	Voltaren	[ ]	[ ]%
Combined entity		[ ]	[ ]%
Reckitt Benckiser	Nurofen, Nuromol, Disprin	[ ]	[ ]%
Foodstuffs	Pams	[ ]	[ ]%
Progressive	Signature Range, Homebrand	[ ]	[ ]%
Aspen	Pamol	[ ]	[ ]%
Multichem	Ethics, I-Profen, Sonaflam, Pacimol	[ ]	[ ]%
Pfizer	Advil, Ponstan, Act 3	[ ]	[ ]%
AFT	Maxigesic	[ ]	[ ]%
Bayer	Aspro, Naprogesic, Aspro Clear	[ ]	[ ]%
Sanofi	Mersyndol	[ ]	[ ]%
API	Paracare, Medco	[ ]	[ ]%
GreenCross	Your Pharmacy	[ ]	[ ]%
Arrow	Arrow Pharmace, Ibucode Plus	[ ]	[ ]%
Other		[ ]	[ ]%
Total		[ ]	100%

Source: Grocery and pharmacy data provided by GSK

50. Table 1 shows that with the acquisition, GSK would increase its market share by [ ]% to [ ]%. The next largest competitor would be Reckitt Benckiser with its Nurofen, Nuromol, and Disprin products with [ ]% market share.

Closeness of competition between GSK and Novartis

51. GSK's main systemic pain relief product is Panadol, which has paracetamol as its main active ingredient. Paracetamol relieves pain by interrupting the electrical signals sent from the nerves to the brain.

52. Novartis’ main pain relief product is Voltaren, a NSAID which has Diclofenac as its active ingredient. Diclofenac relieves pain by reducing inflammation in the body.

53. In its application, GSK submitted that it does not view Novartis’ Voltaren product as a close competitor to its Panadol range of products and considers that [ ] to be the main competitive threats.

54. In its marketing materials, GSK notes:

- [
-
-
- [17]]

55. All of the parties we spoke to during the investigation considered that Voltaren and Panadol were not close competitors, as they have different mechanisms of action, and target different types of pain. In some instances these products may be complementary, for instance after an acute injury. In this case paracetamol products may be more appropriate in the 24 to 48 hours immediately after an injury when the body’s inflammatory response may assist with healing. After this initial period an anti-inflammatory (NSAID) treatment may be more appropriate.

56. The channel of purchase is also somewhat different, with Voltaren Rapid 25s being a pharmacist-only medicine and therefore not available outside of pharmacies. Generally Voltaren is marketed more specifically at localised sports-related injuries and inflammation-related ailments, ie, at “weekend warriors”. In contrast, Panadol products are typically marketed to a broader group of potential users for less specific types of pain or headaches.

57. The Commission also notes that anti-inflammatory and general pain relievers are often viewed as complimentary products and taken in conjunction with each other, (for example paracetamol taken with ibuprofen).

58. Both GSK and Novartis submitted that [ ].

59. Reckitt Benckiser considered that its [ ].

[17] [ ]

60. The Commission considers that GSK's Panadol range and Novartis' Voltaren range are not close competitors and that with the acquisition, the merged entity would continue to face strong competition from the Nurofen range of products, and a growing range of generic pain relievers.

[

61.

62.

63.].

[ ]

Company	Brand	Sales value ($000)	Sales share
[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	[ ]	[ ]
[ ]	[ ]	[ ]	[ ]
[ ]		[ ]	[ ]
Total		**[ ]**	**100%**

Source: [ ]

64. [

65.

]

The wholesale supply of cold sore products

66. Table 3 below outlines the market shares for the firms supplying OTC cold sore treatment products in New Zealand.

Table 3: Market share estimates for OTC cold sore products 2013

Company	Brand name	Revenue ($)	Revenue Share (%)
GSK	Zovirax	[ ]	[ ]
Novartis	Vectavir,	[ ]	[ ]
	Famvir Once	[ ]	[ ]
Combined entity		[ ]]	[ ]
Multichem	Viratac	[ ]	[ ]
Valeant	Virasolve	[ ]	[ ]
AFT	Viraban	[ ]	[ ]
Sanofi	Betadine cold sore	[ ]	[ ]
Roncor	Herstat	[ ]	[ ]
Total		[ ]	100%

Source: Grocery and pharmacy data provided by GSK

67. Table 3 shows that with the acquisition, GSK would increase its market share by [ ] to [ ].

Competition between Zovirax and Vectavir

68. The Commission considers that currently, Novartis' Vectavir cold sore product does not exert a significant amount of competitive constraint on GSK's Zovirax product.

69. While the active ingredient, method of application and efficacy of the Vectavir product is very similar to Zovirax, it has [ ].

70. Novartis informed the Commission [ ].

71. CDC Pharmaceuticals (a large pharmaceutical, OTC, and veterinary wholesaler) stated that [ ]CDC is one of three large pharmacy wholesalers and accounts for approximately [ ]and [ ] of Novartis' and GSK's sales respectively.

72. GSK submitted that generic cold sore creams [ ]Zovirax product. The Commission notes that Viratac's share of the market has [ ]over the last year.

73. GSK also submitted that Compeed, a non-medicated cold sore patch supplied by Johnson & Johnson is a serious competitive threat to its Zovirax product.[18] The Commission notes that the Compeed product does not contain an active ingredient to treat cold sores but instead is designed to quicken the healing process by covering the lesion and keeping it clean.

74. The Commission notes that Compeed, which had sales of [ ]in 2013 claims to heal cold sores at a comparable speed to topical cold sore creams such as Zovirax. [ ].

75. We consider that with the acquisition, the addition of the Vectavir topical cold sore treatment to GSK will result in [ ] of market share. Furthermore, GSK will continue to face strong competitive constraint from generic medicated cold sore treatment products. We also consider that non-medicated products such as Compeed will continue to provide constraint on the merged entity from outside of the market.

Competition between Zovirax and Famvir Once

76. Novartis introduced a systemic cold sore medication called Famvir Once into the OTC market in 2010 when it was reclassified from a prescription only medicine into a pharmacist only medicine.

77. Famvir Once contains a similar active ingredient to topical creams but in a much higher dosage (1500mg of Aciclovir taken in the form of 3 tablets). Famvir Once must be taken within the first 48 hours of the onset of cold sore symptoms in order to be effective and acts by inhibiting the replication of the cold sore virus within the body. Famvir Once also acts to prevent secondary lesions occurring.

78. A once only treatment of Famvir Once costs approximately $30.00 - $35.00 and a topical cold sore cream costs between $18.00 - $24.00 for a multiple use tube.

79. Novartis stated that [ ]Famvir Once is designed to treat severe and recurrent episodes of cold sores whereas the topical creams are designed for less severe cold sore outbreaks.

80. GSK stated that since the introduction of the Famvir Once product into the OTC category [ ], and does not consider it to be a close competitor to Zovirax. GSK stated that Famvir Once is aimed at those consumers with severe cold sore episodes.

81. In response to the entry by Famvir Once, [ ].

82. GSK also submitted that Famvir Once, as a pharmacist-only product, is not able to be self-selected by the consumer and that a consumer's decision to use Famvir Once will be taken in consultation with a pharmacist or physician.

[18] Application at [7.29].

83. Johnson & Johnson
[ ].

84. The Commission considers that the proposed acquisition by GSK of Novartis' Famvir Once would remove a competitor from the cold sore treatment market. However, the Commission also considers that Famvir Once is not a close competitor to Zovirax and does not exert a significant level of competitive constraint.

85. The Commission also notes that Apotex NZ, a manufacturer of generic pharmaceuticals, sells a single dose systemic cold sore tablet (containing the same active ingredient as Famvir Once) in Australia. In July 2013 Apotex obtained preliminary approval for its sale as a pharmacist-only product in New Zealand.

86. We consider that generic cold sore products such as Viraban, Virasolve and Viratac, are the closest competitors to Zovirax.

87. The Commission considers that the proposed acquisition is likely to lead to a lessening of competition in the market for cold sore treatment. However, due to the lack of material aggregation between the Vectavir and Zovirax products, the lack of close competitive tension between Zovirax and Famvir Once, and the ease of potential entry by at least one rival supplier, we do not consider that this lessening of competition is likely to be substantial.

Determination on notice of clearance

89. We are 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.

90. Under section 66(3)(a) of the Act, the Commerce Commission determines to give clearance for Leo Constellation Ltd (a majority owned subsidiary of GSK to be renamed GlaxoSmithKline Consumer Healthcare Ltd) to acquire sole control of Novartis AG's consumer healthcare pharmaceuticals business.

Dated this 27th day of November 2014

Dr Mark Berry
Chairman