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COMMERCE COMMISSION

Decision No. 398

Determination pursuant to the Commerce Act 1986 in the matter of an application for clearance of a business acquisition involving:

Glaxo Wellcome Plc

and

SmithKline Beecham Plc

The Commission:	M J Belgrave (Chair) M N Berry E C A Harrison
Summary of Proposed Acquisition:	Glaxo Wellcome and SmithKline Beecham to merge, by way of a scheme of arrangement between the companies.
Determination:	Pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance for the proposed acquisition, subject to written undertakings.
Date of Determination:	1 September 2000

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THE PROPOSAL

1. Pursuant to section 66(1) of the Commerce Act 1986 (the Act), Glaxo Wellcome Plc and SmithKline Beecham Plc ("the Applicants") gave notice to the Commission dated 5 July 2000 ("the Application"), seeking clearance to merge by means of a scheme of arrangement between the companies under section 425 of the United Kingdom Companies Act.

2. This Application is part of a decision to merge the global activities of the ultimate parent companies. In New Zealand, the scheme of arrangement between Glaxo Wellcome and SmithKline Beecham has been considered only to the extent that the proposal affects the relevant New Zealand markets.

UNDERTAKING

3. On 1 September 2000, the Applicants' lawyer provided to the Commission a Deed which contains an Undertaking pursuant to section 69A of the Act. Attached as Appendix A is a copy of the Deed.

4. Section 69A states:

> Commission may accept undertakings –
>
> (1) In giving a clearance or granting an authorisation under section 66 or section 67 of this Act, the Commission may accept a written undertaking given by or on behalf of the person who gave notice under section 66(1) or section 67(1) of this Act as the case may be, to dispose of assets or shares specified in the undertaking.
>
> (2) The Commission shall not accept an undertaking in relation to the giving of a clearance or the granting of an authorisation under section 66 or section 67 of the Act, other than an undertaking given under subsection (1) of this section.
>
> (3) An undertaking given to the Commission under subsection (1) of this section is deemed to form part of the clearance given or the authorisation granted in relation to the acquisition to which the undertaking relates.

5. The Commission is satisfied that the Undertaking in the Deed has been given on behalf of the Applicants, and that it relates to the disposal of assets or shares. Accordingly, the Commission is able to accept the undertaking in accordance with section 69A(1).

6. In terms of the Deed, the Applicants have undertaken that they will sell to [ ], all of their rights in New Zealand and globally, for *penciclovir*, a product manufactured by or for SmithKline Beecham for use in the treatment of cold sores, and marketed under the brand name "Vectavir". The Applicants have undertaken to execute the Undertaking within 12 months of the Commission granting a clearance for the proposed acquisition.

7. The parties advise that negotiations are currently proceeding with [ ] with a view to selling to that company on a global basis, two pharmaceutical products, one of which is *penciclovir*.

THE PROCEDURES

8. Section 66(3) of the Act requires the Commission either to clear, or to decline to clear, a notice given under section 66(1) within 10 working days, unless the Commission and the person who gave the notice agree to a longer period. By

agreement between the Commission and the Applicants, the date for the Commission's determination on the application has been extended on four occasions: to 4 August, 11 August, 18 August and 1 September 2000.

9. The Applicants sought confidentiality for certain information contained in the Application, and the Deed, and confidentiality orders have been made in respect of that information for a period of 20 working days from the Commission's determination of the Application. When the confidentiality orders expire, the provisions of the Official Information Act 1982 will apply to the information.

10. The Commission's determination is based on an investigation conducted by its staff. In the course of their investigation of the proposed acquisition, Commission staff have discussed the Application with a number of parties. These parties included pharmaceutical companies, PHARMAC, the Ministry of Health, the Researched Medicines Industry Association, the Pharmacy Guild of New Zealand (Inc), and retail chemists.

THE PARTIES

Glaxo Wellcome Plc

11. Glaxo Wellcome Plc is a pharmaceutical company principally engaged in the research, development, manufacture and marketing of pharmaceuticals. The company's products are sold world-wide.

12. Glaxo Wellcome operates in New Zealand through its New Zealand incorporated subsidiary, Glaxo Wellcome New Zealand Limited ("GWNZ"). GWNZ's activities relate to the importation and distribution of pharmaceutical products. GWNZ supplies pharmaceuticals to purchasers in the "ethical", "proprietary", "public hospital", and "private hospital" segments of the market (see paragraphs 38 and 39).

13. GWNZ does not manufacture pharmaceuticals. Since 1996, when the manufacturing facility at Palmerston North was closed, GWNZ imports nearly all its products, mainly from Australia and the United Kingdom.

SmithKline Beecham Plc

14. SmithKline Beecham Plc is principally involved in the research, development, manufacturing and marketing of pharmaceuticals, vaccines, over-the-counter ("OTC") medicines, and health-related consumer products. SmithKline Beecham is also involved in the provision of healthcare services (principally in the United States), including clinical laboratory testing and pharmaceutical benefit management.

15. SmithKline Beecham sells its products in most countries in the world. Its principal markets are the United States, the United Kingdom, Germany, France, Italy, Spain, Japan, Brazil and Canada.

16. SmithKline Beecham operates in New Zealand through its New Zealand incorporated subsidiary, SmithKline Beecham (NZ) Limited ("SBNZ"). SBNZ's activities in New Zealand relate to the importation and distribution of pharmaceutical products to purchasers in the ethical, proprietary, public hospital and private hospital segments of the market (see paragraphs 38 and 39).

17. SBNZ, through its consumer division, also supplies a range of consumer health products, including analgesics, fruit drinks and toothpastes.

18. SBNZ is not involved in the manufacture of pharmaceuticals.

Other Relevant Parties

[ ]

19. [

]

20. [

]

Pharmaceutical Management Agency Limited ("PHARMAC")

21. PHARMAC is a Crown Agency set up in 1993 as a limited liability not-for-profit company, owned by the Health Funding Authority (HFA), to manage New Zealand's Pharmaceutical Schedule. The Pharmaceutical Schedule is the list of almost 3,000 subsidised prescription drugs and related products available in New Zealand. The schedule records the price of each drug, the subsidy it receives from public funds, and the guidelines or conditions under which it may be prescribed.

Medsafe

22. Medsafe, a business unit of the Ministry of Health (MOH), is the authority responsible for the regulation of therapeutic products in New Zealand. Medsafe administers the Medicines Act 1981 and Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Regulations 1977.

23. Medsafe carries out its functions by applying a framework of controls designed to ensure that the therapeutic products available in New Zealand are those that can be expected to have greater benefits than risks if used appropriately.

Other Pharmaceutical Suppliers

24. There are a number of other pharmaceutical suppliers currently operating in New Zealand, including:

- Searle (a division of Monsanto (NZ) Ltd);
- Merck Sharp & Dohme (NZ) Ltd;
- Parke Davis (a division of Warner Lambert (NZ) Ltd);
- Douglas Pharmaceuticals Ltd;
- AFT Pharmaceuticals Ltd;
- Sigma;
- Pacific Pharmaceuticals Ltd; and
- Astra Zeneca.

INDUSTRY BACKGROUND

Global Developments in the Pharmaceutical Industry

25. Internationally, there is increasing concentration in the pharmaceutical industry. The European Community Commission (EC Commission) has identified three main forces driving this merger activity: research and development, a wider range of products, and extended geographical markets.

26. Research and development is essential for the future of pharmaceutical companies. Patent protection for pharmaceutical products is limited in time while the approval procedures for new products are becoming more stringent and time consuming. In addition the cost of research is escalating. It appears generally agreed by industry parties that only very large companies can now support the costs of research necessary to ensure a continued flow of products.

27. The second reason is related and concerns the desire for companies to provide a wider range of products and enables the merged company to become a more competitive supplier to wholesalers, hospitals and pharmacy chains. A wider product range also reduces the risk that the demise of a single product has a disproportionate effect on the company's future.

28. Finally, in Europe, the creation of a single market has encouraged pharmaceutical wholesalers to extend their operations, often across national boundaries.

Pharmaceuticals in New Zealand

The Public Health Sector

29. In New Zealand, the government, through the MOH, funds public health services. On their behalf the HFA purchases the required health services. These services are purchased from public and private health service providers, including Hospital and Health Services (HHSs), private hospitals, general practitioners, nurses, physiotherapists and pharmacists.

30. In terms of the New Zealand Public Health and Disability Bill, which was introduced into Parliament recently, the HFA and HHSs will be disestablished. The Bill also provides for the establishment of District Health Boards, which in time will carry out many of the functions performed currently by the HFA. The functions of the MOH will also be expanded.

Research and Development

31. Industry information shows that, in general, it takes up to 12 years and NZ$1.1 billion to develop a medicine. Medicines may be made up of a number of ingredients, centred on a basic compound. Compounds have a high failure rate, and it has been estimated that only one compound out of 10,000 reaches pharmacists' shelves.

32. Once a compound has been identified as a candidate for further development it is patented (to protect the company's investment in research), usually for a 20 year period. Generally speaking, the manufacturer has approximately eight years of intellectual property protection before generic manufacturers are allowed to copy and sell the medicine.

33. Neither GWNZ nor SBNZ are involved in research and development, or the manufacture of pharmaceuticals in New Zealand. Therefore, research and development and manufacturing will not be considered further in this decision.

Generic Products

34. Patents are registered over "innovator" medicines, in order to protect the investment in research and development of the product. When the patent expires, other pharmaceutical companies can make copies of the innovator medicine. These copies are termed "multi-source" or "generic" medicines. Generic medicines contain the same active ingredient, at the same strength, and in the same form as the innovator medicine.

Testing

35. Each candidate medicine undergoes pre-clinical and clinical testing. Upon completion of testing the manufacturer applies to the MOH (through Medsafe) for approval to market the medicine. The MOH receives specialist advice from the Medicines Assessment Advisory Committee.

The Pharmaceutical Schedule

36. Having received marketing approval, the manufacturer usually applies to PHARMAC to have a medicine included on the pharmaceutical schedule. Inclusion means patients can gain access to the medicine via a government subsidy towards the cost of the medicines. The level of patient subsidy is usually decided through a "reference pricing" system, where the subsidy for all medicines in the same therapeutic subgroup is set at the level of the lowest priced medicine in that subgroup. This is applied where PHARMAC considers the medicines have the same or similar therapeutic effects in treating the same or similar condition.

Supply of Pharmaceutical Products

37. Pharmaceutical products are marketed and promoted to buyers through traditional means such as sales representatives, industry publications, trade fairs and television advertising.

38. The Applicants identified four market "segments" into which pharmaceutical products are supplied. These are the "ethical", "proprietary", "New Zealand Government hospital", and "private hospital" segments. Ethical pharmaceuticals are prescription-only pharmaceuticals. Most ethical products in New Zealand are subsidised.

39. Proprietary pharmaceuticals are those sold over the counter ("OTC"), without the need for a prescription. OTC medicines are sold in retail pharmacies, supermarkets and some consumer goods stores, directly to consumers. Some OTC medicines are classified as "pharmacy only" requiring them to be sold only by retailers holding the necessary pharmacists licence. Most OTC products in New Zealand are not subsidised.

40. Public and private hospitals are located throughout New Zealand. These organisations purchase both ethical and OTC products.

THE RELEVANT MARKETS

Introduction

41. The purpose of defining a market is to provide a framework within which the competition implications of a business acquisition can be analysed. The relevant markets are those in which competition may be affected by the acquisition being considered, and in which the application of section 47(1) of the Act can be examined.

42. Section 3(1A) of the Act provides that:

> ". . . the term 'market' is a reference to a market in New Zealand for goods and services as well as other goods and services that, as a matter of fact and commercial common sense, are substitutable for them."

43. Relevant principles relating to market definition are set out in *Telecom Corporation of New Zealand Ltd v Commerce Commission*,[1] and in the Commission's *Business Acquisition Guidelines* ("the Guidelines").[2] A brief outline of the principles follow.

44. Markets are defined in relation to three dimensions, namely product type, geographical extent, and functional level. A market encompasses products that are close substitutes in the eyes of buyers, and excludes all other products. The boundaries of the product and geographical markets are identified by considering the extent to which buyers are able to substitute other products, or across geographical regions, when they are given the incentive to do so by a change in the relative prices of the products concerned. A market is the smallest area of product and geographic space in which all such substitution possibilities are encompassed. It is in this space that a hypothetical, profit-maximising, monopoly supplier of the defined product could exert market power, because buyers, facing a rise in price, would have no close substitutes to which to turn.

45. A properly defined market includes products which are regarded by buyers or sellers as being not too different ('product' dimension), and not too far away ('geographical' dimension), and are therefore products over which the hypothetical monopolist would need to exercise control in order for it to be able to exert market power. A market defined in these terms is one within which a hypothetical monopolist would be in a position to impose, at the least, a "small yet significant and non-transitory increase in price" (the *"ssnip"* test), assuming that other terms of sale remain unchanged.

46. Markets are also defined by functional level. Typically, production, distribution, and sale occurs through a series of stages, with markets intervening between suppliers at one vertical stage and buyers at the next.

Product Market

47. Pharmaceutical products are used for the treatment of human illnesses and diseases. A central issue in analysing the proposal is the breadth of products that fall within the relevant market.

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[1] (1991) 4 TCLR 473.

[2] Commerce Commission, *Business Acquisition Guidelines*, 1999, pp. 11-16.

ATC Classification

48. In its decision on the Glaxo Wellcome / SmithKline Beecham merger proposal[3], the EC Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification (ATC). The ATC system was devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS).

49. The ATC is hierarchical and has 16 categories (A,B,C,D, etc) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, ie. their intended use, and can therefore be used as an operational market definition. These groups of products generally have the same therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

50. However, the EC Commission also notes that the third level of the ATC is not in all cases an appropriate basis for the definition of product markets and that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceutical specialities. This would be the case where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease.

51. On the other hand, the EC Commission notes that it may also be appropriate to apply a narrower market definition where the pharmaceutical specialities forming part of a certain ATC 3 class have clearly differing indications. In certain cases, pharmaceuticals may be further subdivided into various segments on the basis of a variety of criteria, and in particular demand-side criteria.

52. The Commission, through its enquiries, has found that the ATC classification affords an appropriate initial approach to defining product markets. The Commission also notes, however, that there may be instances where broader or narrower classifications are necessary, dependent upon the particular circumstances of the pharmaceuticals and the condition requiring treatment.

The Current Proposal

53. The Applicants submit that there are two ATC Level 3 product categories in which they both compete. These are Topical Anti-Virals (D6D) and Diuretics (C3A).

54. Topical anti-virals are principally used in the treatment of cold sores. The normal treatment for cold sores is self-medication with OTC products and only a very small proportion of outbreaks of cold sores are treated on prescription.

55. The active molecule in topical treatments for cold sores is "*aciclovir*". *Aciclovir* was protected by patent and used in the topical anti-viral treatment marketed as "Zovirax", by Glaxo Wellcome. When the patent for *aciclovir* expired, generic manufacturers copied the molecule and produced their own topical anti-viral products.

56. In addition to patented products, there may also exist "second generation" products. Second generation products are not generic forms of the patented molecule but rather new innovative products, which may offer superior treatment. SmithKline Beecham's

[3] *Glaxo Wellcome/SmithKline Beecham*, Case No COMP/M.1846, 8 May 2000.

product "Vectavir" is a second generation drug, based upon the active molecule "*penciclovir*". The *penciclovir* molecule is under patent in New Zealand to SmithKline Beecham and expires on 16 August 2004.

57. The Commission understands that both Zovirax and Vectavir are used in the treatment of cold sores. The Applicants advised that the active molecule in Vectavir (*penciclovir*) makes it more effective for treating cold sores which have reached a more advanced stage. Zovirax has been marketed for many years as the treatment to apply when consumers feel the early symptoms of a cold sore. In contrast, while Vectavir will also treat a cold sore in the early stages, it is more effective as a treatment of advanced cold sores.

58. The Commission does not consider that, in this instance, first generation drugs and second generation drugs should constitute separate product markets. While there may be small differences (such as frequency of administration of the drug), the first and second generation compounds are substitutable. Both first and second generation products are manufactured for the treatment of cold sores. No industry party spoken to by Commission staff supported a market definition placing first and second generation drugs in separate markets. Therefore, for the purposes of this proposal, first and second anti-viral compounds are considered to constitute one product market.

59. Industry parties did not generally agree with the inclusion of the products "Condyline" and "Aldara" in this product category. Condyline is registered to Yamanouchi and Aldara is registered to 3M Pharmaceuticals. While both these products fall within the ATC Level 3 category, they are principally used to treat genital warts. Both products are also available by prescription only.

60. Taking a demand-side perspective, it is unlikely that consumers wishing to "self treat" a cold sore would substitute a product designed for the treatment of genital warts, and available on prescription only. All parties contacted by the Commission during its investigation support this view. Given this, the Commission considers that the products "Condyline" and "Aldara" do not appropriately fall within the scope of products to be considered as part of this proposal.

61. On the balance of information provided, the Commission considers that one appropriate product definition for consideration of this proposal is topical anti-viral products for the treatment of cold sores.

62. A diuretic drug increases the amount of water in the urine, removing excess water from the body. Diuretic products are used for the treatment of hypertension and oedema. The Commission was not referred to any other use for diuretic products, nor was the classification of these products questioned by any party. In these circumstances it appears appropriate to define this market as being that for diuretic products.

63. Accordingly, the Commission considers that the appropriate product markets in this instance are those for topical anti-viral products for the treatment of cold sores, and diuretic products.

Function Market

64. The Applicants are engaged in the importation and wholesale distribution of pharmaceutical products. The products are distributed to customers, including

pharmaceutical wholesalers, retail chemists, doctors, public and private hospitals, and rest homes.

65. Distributors in New Zealand hold the supply rights under contract with the manufacturer of pharmaceutical products. In most cases the contract will be for exclusive distribution, but in other cases a manufacturer may supply through more than one distributor.

66. Parallel importation of pharmaceutical products is prohibited by the Medicines Act 1981. The Medicines Act requires a party to hold registered specifications for every imported product. These specifications are registered with the MOH. The party holding the licence to distribute a particular product will also register the specifications, thereby prohibiting any other party from parallel importing that product.

67. Pharmaceutical companies in New Zealand import products and distribute them to pharmaceutical wholesalers, or direct to major consumers such as hospitals, or retail buying groups (for example, the Unichem Pharmacy chain).

68. The appropriate functional level of the market is that for wholesale distribution.

Geographic Market

69. The wholesale distribution of pharmaceutical products is managed nationally by a number of pharmaceutical companies and wholesalers. A national market appears appropriate.

Conclusion on Market Definition

70. The Commission considers that the following national markets are relevant for the consideration of the present proposal:

- the market for the wholesale distribution of topical anti-viral products for the treatment of cold sores ("the topical anti-viral market"); and
- the market for the wholesale distribution of diuretic products ("the diuretic market").

COMPETITION ANALYSIS

Introduction

71. Section 47(1) of the Commerce Act prohibits certain business acquisitions:

> "No person shall acquire assets of a business or shares if, as a result of the acquisition, -
>
> (a) That person or another person would be, or would be likely to be, in a dominant position in a market; or
>
> (b) That person's or another person's dominant position in a market would be, or would be likely to be, strengthened."

72. Section 3(9) of the Commerce Act states:

> "For the purposes of sections 47 and 48 of this Act, a person has … a dominant position in a market if that person as a supplier … of goods and services, is or are in a position to exercise a dominant influence over the production, acquisition, supply, or price of goods or services in that market and for the purposes of determining whether a person is … in a

> position to exercise a dominant influence over the production, acquisition, supply, or price of goods or services in a market regard shall be had to-
>
> (a) The share of the market, the technical knowledge, the access to materials or capital of that person or those persons:
>
> (b) The extent to which that person is … constrained by the conduct of competitors or potential competitors in that market:
>
> (c) The extent to which that person is … constrained by the conduct of suppliers or acquirers of goods or services in that market."

73. The test for dominance has been considered by the High Court. McGechan J stated:[4]

> "The test for 'dominance' is not a matter of prevailing economic theory, to be identified outside the statute."
>
> …
>
> "Dominance includes a qualitative assessment of market power. It involves more than 'high' market power; more than mere ability to behave 'largely' independently of competitors; and more than power to effect 'appreciable' changes in terms of trading. It involves a *high degree of market control*."

74. Both McGechan J and the Court of Appeal, which approved this test,[5] stated that a lower standard than "a high degree of market control" was unacceptable.[6] The Commission has acknowledged this test:[7]

> "A person is in a dominant position in a market when it is in a position to exercise a high degree of market control. A person in a dominant position will be able to set prices or conditions without significant constraint by competitor or customer reaction."

75. The Commission's *Business Acquisitions Guidelines* state:

> "A person is in a dominant position in a market when it is in a position to exercise a high degree of market control. A person in a dominant position will be able to set prices or conditions without significant constraint by competitor {or} customer reaction."
>
> …
>
> "A person in a dominant position will be able to initiate and maintain an appreciable increase in price or reduction in supply, quality or degree of innovation, without suffering an adverse impact on profitability in the short term or long term. The Commission notes that it is not necessary to believe that a person will act in such a manner to establish that it is in a dominant position, it is sufficient for it to have that ability." (p21)

76. The role of the Commission in respect of an application for clearance of a business acquisition is prescribed by the Commerce Act. Where the Commission is satisfied that the proposed acquisition would not result, or would not be likely to result, in an acquisition or strengthening of a dominant position in a market, the Commission must give a clearance. Where the Commission is not satisfied, clearance is declined.

77. In cases where there is existing dominance, the Commission must also have regard to whether such dominance would be, or would be likely to be, strengthened. A strengthening must be more than merely *de minimis.*

78. In *NZ Co-op Dairy Co Limited v Commerce Commission*[8], the High Court (Wylie J. and R. G. Blunt) stated:

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[4] *Commerce Commission v Port Nelson Ltd* (1995) 5 NZBLC 103,762 103,787 (HC)
[5] *Commerce Commission v Port Nelson Ltd* (1996) 5 NZBLC 104,142 104,161 (CA)
[6] *Commerce Commission v Port Nelson Ltd* (1995) 5 NZBLC 103,762 103,787 (HC) and *Commerce Commission v Port Nelson Ltd* (1996) 5 NZBLC 104,142 104,161 (CA)
[7] *Business Acquisition Guidelines*, Section 7

> "…there is no definition of `strengthening' in the Act and its meaning in the present context has not previously been considered by the Court in New Zealand. The expression had, however, been considered in several decisions of the Commission where different shades of meaning seem to have been attributed to it. Phrases have been used such as `an appreciable difference', `a change more than de minimis', (de minimis in that context being described as `so small that it would not have observable effects' or `of such a hypothetical nature that it could not be taken into account'). In other cases phrases such as `a significant change of market power' or a `significant anti-competitive effect (ie one which is not de minimis)' have been used. Counsel submitted that the true test should be that of `significant added anti-competitive effect', or `significant strengthening of market power'. Notwithstanding counsel's careful argument we think all of this is an exercise in semantics in an endeavour to put a gloss on the plain words of the statute. If by de minimis is meant a change so slight and insignificant as not to justify the intervention of the law we agree with the concept. But if by `significant' there is sought to be introduced the concept of something of greater substance than is necessary merely to take the change out of the de minimis category then we do not think that is an appropriate test. It would seek to add something to the statute which is not there. In our opinion such epithets are best avoided. As an ordinary word in common use `strengthening' does not need elaboration. The degree of strengthening of dominance, once there is a strengthening worthy of the Commission's (or the Court's) attention, will be reflected in the extent of the detriment, if any, which will, or will be likely to, result therefrom:

79. This statement on the principle of strengthening of dominance was endorsed by the High Court in *Telecom Corp of NZ v Commerce Commission (*1991) 4 TCLR 473, 510-511; 3 NZBLC 102, 360, 102,369-102,370, and was also specifically adopted in *Broadcast Communications Ltd v Commerce Commission*[9].

80. In *Broadcast Communications Ltd v Commerce Commission,* Greig J. stated that:

> "Increase to or strengthening of that dominance is also proscribed and in terms in which the commission deciding the question had to be satisfied only that that increase "would be likely". I do not think that that does mean "probable" or " more than a 50 percent chance". It means more than a possibility or a speculation but it "would be likely" if it could well happen if it is less than an even chance less than probable but is more than a possibility."

81. Adapting these judicial pronouncements to the current test set out in sections 66(3) and 47(1), the Commission must give clearance to a proposal involving a person with a dominant position in a market where it is satisfied that the acquisition will not result, or be likely to result in any strengthening of that dominant position. The test of strengthening involves a very low threshold, and is distinct from the dominance threshold contained in section 47(1). It is not, for example, a question of whether the acquisition will be likely to remove an effective competitive constraint. Such an issue is more likely to be determinative of the dominance rather than the strengthening of the dominance limb of section 47(1). For the Commission to be satisfied that a strengthening of dominance will not result, or be likely to result, it must be satisfied that the overall effect, or likely effect, on the market will be no more than *de minimis*. Any further elaboration of principle on what effects may, or may not be *de minimis,* is problematic. Each case will turn on its own facts.

82. The Commission applies the dominance test, and that for finding any strengthening of dominance, in the following competition analysis.

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[8] [1992] 1 NZLR 601.

[9] *Broadcast Communications Ltd v Commerce Commission* (1991) 4 TCLR 537.

The Topical Anti-Viral Market

Market Concentration

83. An examination of concentration in a market often provides a useful first indication of whether a merged firm may or may not be constrained by others participating in the market, and thus the extent to which it may be able to exercise market power.

84. The *Business Acquisitions Guidelines* specify certain "safe harbours" which can be used to assess the likely impact of a merger in terms of s 47 of the Act -

> "In the Commission's view, a dominant position in a market is generally unlikely to be created or strengthened where, after the proposed acquisition, either of the following situations exist:
>
> - the merged entity (including any interconnected or associated persons) has less than in the order of a 40% share of the relevant market;
> - the merged entity (including any interconnected or associated persons) has less than in the order of a 60% share of the relevant market and faces competition from at least one other market participant having no less than in the order of a 15% market share." (p 17)

85. These safe harbours recognise that both absolute levels of market share, and the distribution of market shares between the merged firm and its rivals, is relevant in considering the extent to which the rivals are able to provide a constraint over the merged firm. The Commission went on to state (at page 17) that:

> "Except in unusual circumstances, the Commission will not seek to intervene in business acquisitions which, given appropriate delineation of the relevant market and measurement of shares, fall within these safe harbours."

86. Although, in general, the higher the market share held by the merged firm, the greater the probability that dominance will be acquired or strengthened (as proscribed by section 47 of the Act), market share alone is not sufficient to establish a dominant position in a market. Other factors intrinsic to the market structure, such as the extent of rivalry within the market and constraints provided through market entry, also typically need to be considered and assessed.

87. The Applicants submitted market share data obtained from IMS Health (NZ) Limited ("IMS Health"). Among other services, IMS Health tracks sales of pharmaceutical manufacturers' products to retail pharmacies, doctors, hospitals, nursing homes, and other purchasers.

88. On the basis of the IMS Health information provided, the Commission has determined the respective market shares of suppliers in the topical anti-viral market. The market shares are recorded in Table 1 below.

Table 1
Market Shares in the Topical Anti-Viral Market*

Supplier (Product)	Unit Sales (year ended May 2000)	Revenue (year ended May 2000)	Market Share
GWNZ (Zovirax)	[ ]	[ ]	[ ]%
SBNZ (Vectavir)	[ ]	[ ]	[ ]%
Combined entity	**[ ]**	**[ ]**	**[ ]%**
Douglas (Lovir)	[ ]	[ ]	[ ]%
AFT (Viraban)	[ ]	[ ]	[ ]%
Total	**[ ]**	**[ ]**	**100%**

*The Sigma product "Zolaten" is not included as it was introduced two months ago, and the figures are reported sales to May 2000.

89. On the basis of the above figures, the combined entity's market share of the topical anti-viral market is [ ]%.

90. From this data, the combined entity's market share falls well outside the Commission's "safe harbours" (refer paragraph 84). However, as stated earlier, the fact that a proposed acquisition may lead to a market share falling outside these "safe harbours" does not necessarily mean that it will be likely to result in the acquisition or strengthening of a dominant position in a market. Additional factors must also be considered before a conclusion on dominance is reached. These other factors are discussed below.

Existing Competition

91. The Applicants submit that the combined entity would continue to be constrained by the conduct of other pharmaceutical companies. The Applicants note that many of these pharmaceutical companies form part of larger international organisations, which invest in research and development of new products for distribution throughout the world, including New Zealand.

92. The Commission notes that three other OTC products are currently available. Douglas Pharmaceuticals Ltd (Douglas) supplies "Lovir", AFT Pharmaceuticals Ltd (AFT) supplies "Viraban", and Sigma supplies "Zolaten".

93. Douglas introduced Lovir approximately 12 months ago. Lovir has attained a market share of [ ]%, with little advertising or promotion. Douglas advised that it had a target of [ ]% within two years, and was planning on [ ]. Douglas did not consider that there would be a change in the market dynamics, as a result of the proposed merger.

94. AFT introduced Viraban in August 1999. It has attained a market share of [ ]% to date. Viraban is advertised in health-related magazines such as "Family Health". [ ]

95. AFT did not consider that Vectavir was an effective competitor to Zovirax, noting that there is "very little" promotion of Vectavir, and that Vectavir is priced more expensively than Zovirax, and other OTC cold sore treatments. AFT did not consider that there was likely to be any change in this market as a result of the merger.

96. Sigma introduced Zolaten to New Zealand approximately two months ago. Zolaten has been available in Australia for approximately 12 months. Sigma advised that it [

].

97. The Commission notes that the patent protection for Zovirax expired in 1997. Entry was then not effected by any party until mid-1999. While generic products such as Lovir and Viraban have achieved a small market share, industry parties were divided on the competitive effect of their entry. Some parties submitted that the performance of these products provided an effective constraint upon the behaviour of Zovirax, notwithstanding a relatively low market share. Other parties did not consider that these products provide a "real" constraint upon Zovirax, and did not expect generic products to attain a market share of higher than 10%.

98. The Commission received comments from retail pharmacists that Zovirax is a very strong, established brand in the market. It is promoted through television and print advertising, as well as point-of-sale advertising in retail pharmacies. In contrast, the competing generic products are not as widely advertised. A number of retail pharmacists commented that consumers will actually ask for Zovirax by name, rather than seek a recommendation from the pharmacist. Further, when it is pointed out to the consumer that the generic products are cheaper, consumers still prefer to purchase Zovirax because they believe it to be an effective treatment, and it is trusted by the consumer. Pharmacists advised that when a consumer feels comfortable with a particular product, they are hesitant to change to another product.

99. The Commission sought wholesale pricing information relating to the sale of topical anti-viral products. This information showed that the price of Zovirax and Vectavir has remained unchanged since December 1998, and October 1997 respectively. The price has not changed notwithstanding the introduction of three cheaper products within the last 12 months. This suggests that Zovirax has been able to maintain market share without being effectively constrained by the pricing of rival products.

100. Taken overall, the information available shows that since the expiry of the patent in 1997, generic competition to Zovirax has not been very successful. Zovirax has maintained a high market share and, while entry has occurred, the market share of the generic products remains small.

Conclusion on Existing Competition

101. GWNZ already has a market share of [ ], and when combined with SBNZ's market share of [ ], would place the merged entity outside the Commission's "safe harbours". GWNZ's market position is reinforced by the strong brand recognition and wide consumer acceptance of Zovirax. GWNZ also faces limited effective constraint from any of its existing competitors, including SBNZ, and the suppliers of various brands of generic topical anti-viral products. This is reflected in the fact that GWNZ has not adjusted its price since the introduction of generic products within the last 12 months, and has substantially maintained its market share throughout this period. In

light of these factors, the Commission considers that GWNZ is not sufficiently constrained by existing competition.

Potential Competition

102. In the Commission's view, a business acquisition is unlikely to result in a dominant position in a market if the threat of new entrants acts as a significant constraint on behaviour in that market. An assessment of the nature and extent of that constraint represents a key element of the Commission's assessment of competition and market dominance. Evaluation of the weight to be given to the possibility of new entry requires assessing the conditions of entry, and identifying any barriers to entry. If these barriers are high in aggregate, the likelihood of new entry is diminished.

103. The Applicants submit that individual product categories are contestable by pharmaceutical companies, notwithstanding that they may not sell a product within a particular category at any given time. These pharmaceutical companies base their businesses on the research and development of new products, and are therefore well placed, the Applicants submit, to enter the market if given the appropriate economic incentive to do so.

104. The Applicants submit further that product categories are quickly contested by new entrants with generic products, and that the protection provided by a patent is only transitory. The Applicants also claim that barriers to entry are low, comprising regulatory approval, and the cost of establishing a distribution network.

105. The Commission has reviewed the relevant entry conditions below.

Regulatory Approval

106. A company wishing to market a medicine that has not previously been marketed in New Zealand must obtain the consent of the Minister of Health (or his/her delegate). The company submits an application to the MOH, containing information about the safety, quality and efficacy of the medicine for assessment by MOH evaluators.

107. If the application is accepted, the MOH approves the medicine. Notification of the consent is published in the New Zealand Gazette, and the medicine can then be marketed.

108. The Commission has been told by the MOH that the timeframe for registration for new medicines can take up to 18 months from the date of lodging the application. However, for generic products the timeframe is usually shorter (up to 12 months), as the generic products do not have new active substances or novel dose forms (to be assessed). The cost of registration is $7,800.

Distribution Network

109. Distribution may be effected either through the establishment of a new distribution network, or by contracting distribution through an established pharmaceutical wholesaler, or appropriate distribution agent.

Cost of Establishing Brand Loyalty and Reputation

110. As noted above, Zovirax enjoys a strong branding and reputation in this market. It is the preferred brand of cold sore cream for the large majority of consumers, and is often requested directly. It has enjoyed a high profile in the market for many years.

111. While generic products are identical copies of the "branded" products, there has not been a strong showing by the generic entrants in recent times. This suggests, and information received from industry sources supports this, that many consumers continue to purchase Zovirax due to their "trust" in its qualities and effectiveness. The Commission understands that the generic products are not heavily promoted by distributors and retailers as being an alternative treatment to Zovirax.

112. In order to obtain some market exposure, the Commission understands that entrants would be required to undertake a marketing campaign, including back-up technical support. Such a campaign is likely to include television advertising, coupled with magazine advertising and point-of-sale promotional material. One pharmaceutical company suggested that the cost of such a campaign could be between $50,000 and $150,000. Pacific Pharmaceuticals advised that a marketing campaign aimed at attaining up to a 30% market share was likely to cost between [ ].

Assessment of the Constraint by Potential Competition

113. In order for the threat of market entry to be a sufficient constraint on the exercise of market power, the Commission's approach is based on the "*lets*" test. Under this test, to constitute a sufficient constraint, entry must satisfy all four of the following criteria: it must be *l*ikely, sufficient in *e*xtent, *t*imely and *s*ustainable.[10] Each of these criteria are assessed below.

Likelihood and Sustainability of Entry

114. In order to be an effective constraint on incumbent market operators, entry must be likely in commercial terms. That is, there has to be a "reasonable prospect of achieving a satisfactory return on … investment".[11] In addition, entry is likely only if there is likely to be a lasting economic incentive to enter the market.

115. While the Applicants claim that the market is competitive, and entry barriers are low, the question arises as to why successful entry has not occurred. The only examples of entry into this market are those of Douglas, AFT, and Sigma. Of these, Douglas has a market share of [ ]% and AFT [ ]%.

116. The Applicants submit that the market share of patented products quickly erodes following expiry of the patent. With regard to topical anti-virals, the Commission did not find that to be the case through its investigation. Many consumers continue to purchase Zovirax, notwithstanding the presence of cheaper generic products. Whilst generic products have a marked impact upon the price of scheduled drugs, this is not necessarily the case for OTC products. In the case of topical anti-virals, entry by generic products has had little effect on the market share of Zovirax.

117. Of those parties that have entered, [

[10] *Ibid*, pp. 19-20.
[11] *Ibid*, p. 19.

]. In the case of both AFT and Sigma, it appears that the introduction of their generic products is an attempt to broaden their product range, in order that it may be more attractive to purchasers. This is in contrast to introducing a product that will compete effectively against Zovirax.

118. Notwithstanding the lack of successful new entry, the Commission considers that the entry over the past 12 months by three suppliers of generic topical anti-viral products, indicates that entry is feasible, at least on a small scale. Further, although the history of entry is limited, and the future dynamics of the market are hard to predict, the available information suggests that entry is likely to be sustainable over the long term.

119. On the basis of the information received, the Commission has concluded that entry is both likely and sustainable.

Extent of Entry

120. If entry is to constrain an otherwise dominant firm, then entry must potentially be at a scale and spread of operations as to impact significantly on its behaviour.

121. Given the history and brand strength of Zovirax, industry sources did not consider that entry was likely on a sufficiently large scale to effectively constrain the merged party. For example, and as described previously, Pacific Pharmaceuticals has told the Commission that it would require an investment of between [ ]in an advertising campaign to acquire a 30% market share. [

]. The limited size of the topical anti-viral market in New Zealand, and the relatively poor uptake of generic products, were also cited by some sources as factors which are likely to restrict entry into this market on a significant scale.

122. Given the costs of introducing a new product on a large scale, the existing market strength of Zovirax, and the relatively small size of the topical anti-viral market in New Zealand, the Commission considers that new entrants are unlikely to enter on a scale sufficient to provide an effective constraint on the combined entity. Accordingly, it is the Commission's view that the "extent" criterion is not likely to be satisfied.

Timeliness of Entry

123. To constrain effectively the exercise of market power to the extent necessary to alleviate concerns about market dominance, entry must be likely to occur before consumers in the relevant market are detrimentally affected to a significant extent.[12] The Commission has said that the relevant time frame has to be considered on a case-by-case basis, but that 'for most markets, entry which cannot be achieved within two years from initial planning is unlikely to be sufficiently timely to alleviate concerns about market dominance".

124. Industry sources advised that entry could be effected within 12 months. This period refers to the time necessary to organise registration, distribution networks, and the purchase of stock. It does not include the likely timeframe within which an entrant is expected to attain a certain degree of market share. Once entry has been effected, the entrant can start competing. Therefore, notwithstanding that entry to date has been on

[12] *Ibid.* p.19.

a limited basis, the Commission considers that if a firm were to enter the market, entry could be achieved within 12 months.

Conclusion on Constraints from Potential Competitors

125. The Commission considers that entry into the relevant market would satisfy the "likely", "timely" and "sustainable" criteria, but not the "extent" criterion.

126. Accordingly, the Commission concludes that the threat of potential competition from new entry would not be sufficient to effectively constrain the combined entity.

Conclusion on Dominance

127. Having regard to the above factors, the Commission considers that GWNZ is not significantly constrained by existing or potential competition and, therefore, is already in a dominant position in the relevant market. The Commission must then consider whether or not implementation of the acquisition would result, or would be likely to result, in any strengthening of existing dominance.

Strengthening of Dominance

128. The Applicants submit that the merged entity will account for a share "only fractionally greater than that already attributed to GWNZ". When considered along with the constraints identified in the notice, the Applicants submit further that the merger will not result in "any meaningful increase in market power". In a further submission, the Applicants contend that, if it is assumed that Zovirax already holds a dominant position, the merger will not result in a strengthening of that position through the acquisition of Vectavir. In other words, the merged entity will not have any greater ability to influence the price or supply of products in the market than that currently able to be exercised by Glaxo Wellcome.

129. Industry sources agreed that the overall effect of the merger in this market is likely to be minimal.

130. The Commission notes that the acquisition will have a limited immediate impact on the topical anti-viral market. Also, the Commission recognises that Vectavir is currently providing only a limited competitive constraint on Zovirax.

131. However, as earlier noted (paragraph 81), the strengthening test involves a very low threshold. The Commission considers that some actual and potential effects result from this proposal which are, or are likely to be, more than *de minimis.*

132. First, there would be an aggregation in market share, which is indicative of a strengthening of dominance, which is more than *de minimis.* SBNZ's market share of [ ]%, when combined with GWNZ's share of [ ]%, would take the merged entity to [ ]%.

133. Secondly, the merged entity would move from having a single, middle range product to having two products, one of which, Vectavir, may be perceived by some parties to be superior to products such as Zovirax. Vectavir is a second generation product, and unlike Zovirax, it remains under patent. It has not been strongly promoted, and is currently priced considerably higher than Zovirax. The product's patent expires in New Zealand in August 2004. Different incentives are likely to apply to the future marketing of this product depending upon whether this proposal proceeds. If Vectavir continues to be distributed through independent channels, then its distributor has the

potential incentive to promote its second-generation characteristics. At some point in time - for example, when the product comes off patent - there may also be an incentive to engage in price competition with Zovirax. If the merger proceeds, the potential for enhanced competition between the two brands disappears. The removal of the potential for such competitive dynamics is further indicative of a strengthening of dominance, which is likely to be more than *de minimis.* Again, in this context it must be remembered that a dominance threshold is not involved. The scheme of section 47(1) requires the Commission to take a restrictive view of markets where a dominant person is endeavouring to strengthen its position.

Conclusion on Strengthening

134. Having regard to the above factors, including the principles of strengthening as articulated by the Courts, the Commission is not satisfied that the acquisition would not result, or would not be likely to result, in GWNZ strengthening its existing dominant position in the relevant market.

Undertaking

135. To remove concerns that implementation of the acquisition may result in the strengthening of GWNZ's existing dominance, the Commission has considered an Undertaking by the Applicants to divest certain assets in New Zealand, and globally, to [ ] within 12 months of the Commission giving clearance for the acquisition. The assets that the parties intend to divest include the relevant intellectual property rights for *penciclovir* (which is marketed under the brand name Vectavir) in New Zealand.

136. Section 69A(2) of the Act prohibits the Commission from accepting an undertaking other than one which complies with section 69A(1), which requires a written undertaking by, or on behalf of, the person making an acquisition, to dispose of specified assets and/or shares. The Commission takes the view that any other undertakings relating to how an applicant will conduct their business or dealings regarding the shares or assets to be disposed of, do not comply with the statute and, therefore, cannot form part of an undertaking given under section 69A.

137. The Commission also notes that the decision as to whether to accept an undertaking in giving a clearance, or granting an authorisation, is a discretionary matter for the Commission. As the Court of Appeal said in *Goodman Fielder Ltd & Wattie Industries Ltd v Commerce Commission (*1987) 2 TCLR 270 at 279:

> When a proposal, original or revised, includes some divestment, it will be for the Commission to decide the bearing of that element in determining whether in its opinion the proposal would result or be likely to result in market dominance or, if so, would result or be likely to result in any outweighing public benefit. The decision must be a discretionary one for the commission. For instance, it may be satisfied with a contract, to be settled after clearance, or it may insist on completed divestment before clearance. Or it may be satisfied with an undertaking, having regard to factors including the terms of the undertaking and its confidence in those who have proffered the undertaking.

138. The Commission has two concerns in deciding whether to accept an undertaking under section 69A. The first is that it meets the statutory criteria in section 69A, and the second is that the outcome of the divestment has sufficient commercial likelihood to satisfy the Commission that any acquisition or strengthening of dominance will not result, or will not be likely to result, from the acquisition for which clearance or authorisation is sought.

139. The Commission considers that the Undertaking provided by the Applicants satisfies the two concerns outlined above. First, the statutory criteria in section 69A is satisfied because the Undertaking relates to the disposal of assets. Secondly, the Commission is satisfied that the Undertaking meets the concern relating to commercial likelihood. This is because the Undertaking would remove the Commission's concerns that the acquisition may lead to GWNZ strengthening its existing dominant position in the market for the distribution of anti-topical virals in New Zealand. Further, the divestment of the rights to *penciclovir* in New Zealand forms part of a world-wide sale to [ ], thus ensuring that the purchaser would have access to the product from an independent source of supply.

Conclusion on the Market for Topical Anti-Viral Products

140. After taking into account the divestment arising from the Undertaking, the Commission concludes that the proposed acquisition would not give rise to competition concerns in the relevant market. The Commission concludes, therefore, that it is satisfied that implementation of the acquisition would not result, and would not be likely to result, in GWNZ strengthening a dominant position in the topical anti-viral market.

The Market for Diuretic Products

Market Concentration

141. The market shares for diuretic products have been determined using the IMS Health data, as described in paragraph 87. These market shares are shown below in Table 2.

Table 2
Market Shares in the Diuretics Market

Supplier	**Unit Sales (year ended May 2000)**	**Revenue (year ended May 2000)**	**Market Shares**
GWNZ	[ ]	[ ]	[ ]%
SBNZ	[ ]	[ ]	[ ]%
Combined entity	**[ ]**	**[ ]**	**[ ]%**
Pacific	[ ]	[ ]	[ ]%
Douglas	[ ]	[ ]	[ ]%
Servier	[ ]	[ ]	[ ]%
Other	[ ]	[ ]	[ ]%
Total	**[ ]**	**[ ]**	**100%**

142. On the basis of the above figures, the combined entity would have a market share of [ ]%. This figure places the combined entity well within the Commission's "safe harbours" (refer paragraph 84).

143. There are numerous competitors supplying diuretic products in New Zealand. All parties spoken to by Commission staff commented that there is strong competition in this market, and this is expected to continue post-merger.

144. A further constraint upon any party attempting to exercise market power is provided by PHARMAC. As diuretic products are subsidised, all products are reference priced against the lowest-priced product available.

Conclusion on the Market for Diuretic Products

145. On the information provided, the market share of the combined entity falls well within the Commission's "safe harbours". The combined entity is likely to be constrained post-merger by the continuing competition effected by current suppliers, and the countervailing power exercised by PHARMAC.

146. On the basis of these factors, the Commission is satisfied that the acquisition would not result, and would not be likely to result, in the Applicants acquiring a dominant position in the market for diuretic products.

OVERALL CONCLUSION

147. The Commission has considered the impact of the proposed acquisition in the following markets:

- the national market for the wholesale distribution of topical anti-viral products for the treatment of cold sores; and
- the national market for the wholesale distribution of diuretic products.

148. Having regard to the factors set out in section 3(9) of the Act, and all other relevant factors, including the Undertaking, the Commission is satisfied that implementation of the proposed acquisition would not result, or would not be likely to result, in GWNZ strengthening a dominant position in the national market for the wholesale distribution of topical anti-viral products for the treatment of cold sores. Further, the Commission is satisfied that implementation of the proposed acquisition would not result, or would not be likely to result, in the Applicants acquiring a dominant position in the national market for the wholesale distribution of diuretic products.

DETERMINATION ON NOTICE OF CLEARANCE

149. Accordingly, pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance to Glaxo Wellcome Plc and SmithKline Beecham Plc to merge by means of a scheme of arrangement between the companies under section 425 of the United Kingdom Companies Act to the extent that the merger would result in the amalgamation of the companies' subsidiaries incorporated in, or carrying on business in New Zealand. This clearance is subject to the Undertaking as given on 1 September 2000 on behalf of Glaxo Wellcome plc and SmithKline Beecham plc.

Dated this day of September 2000

M J Belgrave
Chair