

Decision No. 621

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

SCHERING-PLOUGH CORPORATION

and

ORGANON BIOSCIENCES N.V.

The Commission: David Caygill

Donal Curtin Anita Mazzoleni

Summary of Application: The acquisition by Schering-Plough Corporation of up to

100% of the ordinary shares of Organon BioSciences N.V. including the proposed divestment of Schering-Plough

Corporation's Campylovexin product.

Determination: Pursuant to section 66(3)(a) of the Commerce Act 1986, the

Commission determines to give clearance to the proposed

acquisition.

Date of Determination: 4 October 2007

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EXECUTIVE SUMMARY

- E1. A notice pursuant to section 66(1) of the Commerce Act 1986 (the Act) was registered on 5 July 2007 (the Application). The notice sought clearance for Schering-Plough Corporation (Schering-Plough) or any interconnected body corporate of Schering-Plough, to acquire 100 percent of the shares in, or assets of, Organon BioSciences N.V. (Organon BS).
- E2. Subsequent to that notice, a divestment undertaking dated 1 October 2007 was provided by Schering-Plough to the Commission pursuant to section 69A of the Act. The undertaking states that Schering-Plough would undertake to divest the Campylovexin campylobacter vaccine business after the acquisition.
- E3. The Commission accepted the undertaking under section 69A(1) of the Act. It considered whether Schering-Plough's application with the divestment would have, or would be likely to have, the effect of substantially lessening competition in any of the relevant markets.

Relevant Markets

- E4. The relevant markets for the Application are national markets for the manufacture/import and wholesale supply of:
 - intramammary (mastitis) treatments for dry cows;
 - intramammary (mastitis) treatments for lactating cows;
 - antimicrobials for ruminant animals;
 - prostaglandins;
 - ectoparasiticides for cattle;
 - ectoparasiticides for sheep;
 - endoparasiticides for sheep; and
 - campylobacter vaccines for sheep.

Competition Analysis

E5. Divestment of Schering-Plough's campylobacter vaccine for sheep, Campylovexin, will ensure that existing competition remains to constrain the combined entity in the factual scenario in this market. In the market for intramammary treatments for dry cows, the combined entity will be constrained by existing and potential competition. In the remaining markets, the combined entity would be constrained by existing competition. Accordingly, the Commission concludes that the proposed acquisition with the divestment undertaking will not have, nor will be likely to have, the effect of substantially lessening competition in any of the relevant markets.

Overall Conclusions in Relation to the Acquisition

E6. The Commission is satisfied that the proposed acquisition will not have the effect, nor the likely effect, of substantially lessening competition in the relevant markets.

Determination of Notice Seeking Clearance

E7. Pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance for the proposed acquisition by Schering-Plough Corporation of 100 percent of the shares in, or assets of, Organon BioSciences N.V., subject to the divestment undertaking dated 1 October 2007 provided by Schering-Plough Corporation to the Commission pursuant to section 69A of the Commerce Act 1986.

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THE PROPOSAL

- 1. A notice pursuant to section 66(1) of the Commerce Act 1986 (the Act) was registered on 5 July 2007 (the Application). The notice sought clearance for Schering-Plough Corporation (Schering-Plough) or any interconnected body corporate of Schering-Plough, to acquire 100 percent of the shares in, or assets of, Organon BioSciences N.V. (Organon BS).
- 2. Subsequent to that notice, a divestment undertaking dated 6 September 2007 was provided by Schering-Plough to the Commission pursuant to section 69A of the Act. The terms of that undertaking were subsequently revised, and a replacement undertaking dated 1 October 2007 was provided to the Commission. The undertaking states that Schering-Plough would undertake to divest the Campylovexin campylobacter vaccine business after the acquisition.

PROCEDURE

- 3. Section 66(3) of the Act requires the Commission either to clear, or to decline to clear, the acquisition referred to in a section 66(1) notice within 10 working days unless the Commission and the person who gave notice agree to a longer period. Extensions of time were agreed between the Commission and the Applicant such that a decision was ultimately required to be made by 5 October 2007. The decision was made on 4 October 2007.
- 4. The Applicant sought confidentiality for specific aspects of the Application and the provisions of the Official Information Act 1982 apply.
- 5. The Commission's approach to analysing the proposed acquisition is based on principles set out in the Commission's *Merger and Acquisition Guidelines*. ¹

STATUTORY FRAMEWORK

- 6. Under section 66 of the Act, the Commission is required to consider whether the Acquisition is, or is likely to have, the effect of substantially lessening competition in a market. If the Commission is satisfied that the proposal would not be likely to substantially lessen competition then it is required to grant clearance to the application. Conversely if the Commission is not satisfied it must decline the application. The standard of proof that the Commission must apply in making its determination is the civil standard of the balance of probabilities.²
- 7. The substantial lessening of competition test was considered in *Air New Zealand & Qantas v Commerce Commission*, where the Court held:³

We accept that an absence of market power would suggest there had been no substantial lessening of competition in a market but do not see this as a reason to forsake an analysis of the counterfactual as well as the factual. A comparative judgment is implied by the statutory test which now focuses on a possible change along the spectrum of market power rather than on whether or not a particular position on that spectrum, i.e. dominance has been attained. We consider, therefore, that a study of likely outcomes, with and without the proposed Alliance, provides a more rigorous framework for the comparative analysis required and is likely to lead

² Foodstuffs (Wellington) Cooperative Society Limited v Commerce Commission (1992) 4 TCLR 713-722.

¹ Commerce Commission, Mergers and Acquisition Guidelines, January 2004.

³ Air New Zealand & Oantas Airways Limited v Commerce Commission (2004) 11 TCLR 347, Para 42.

to a more informed assessment of competitive conditions than would be permitted if the inquiry were limited to the existence or otherwise of market power in the factual.

- 8. In determining whether there is a change along the spectrum which is significant, the Commission must identify a real lessening of competition that is more than nominal and not minimal.⁴ Competition must be lessened in a considerable and sustainable way. For the purposes of its analysis the Commission is of the view that a lessening of competition and creation, enhancement or facilitation of the exercise of market power may be taken as being equivalent.
- 9. When the impact of market power is expected to be predominantly upon price, for the lessening, or likely lessening, of competition to be regarded as substantial, the anticipated price increase relative to what would otherwise have occurred in the market has to be both material, and ordinarily able to be sustained for a period of at least two years or such other time frame as may be appropriate in any given case.
- 10. Similarly, when the impact of market power is felt in terms of the non-price dimensions of competition such as reduced services, quality or innovation, for there to be a substantial lessening, or likely substantial lessening of competition, these also have to be both material and ordinarily sustainable for at least two years or such other time frame as may be appropriate.

ANALYTICAL FRAMEWORK

- 11. The Commission applies a consistent analytical framework to all its clearance decisions. The first step the Commission takes is to determine the relevant market or markets. As acquisitions considered under section 66 are prospective, the Commission uses a forward-looking type of analysis to assess whether a lessening of competition is likely in the defined market(s). Hence, an important subsequent step is to establish the appropriate hypothetical future with and without scenarios, defined as the situations expected:
 - with the acquisition in question (the factual); and
 - in the absence of the acquisition (the counterfactual).
- 12. The impact of the acquisition on competition is then viewed as the prospective difference in the extent of competition in the market between those two scenarios. The Commission analyses the extent of competition in each relevant market for both the factual and the counterfactual, in terms of:
 - existing competition;
 - potential competition; and
 - other competition factors, such as the countervailing market power of buyers or supplies.
- 13. When an applicant considers that it is appropriate to undertake to make a structural divestment as part of its application for clearance, s69A of the Act provides that the Commission may accept such undertakings in writing given by, or on behalf of, an applicant to dispose of assets or shares. An undertaking given

⁴ Fisher & Paykel Limited v Commerce Commission (1996) 2 NZLR 731, 758 and also Port Nelson Limited v Commerce Commission (1996) 3 NZLR 554.

- to the Commission is deemed to form part of any clearance given by the Commission.⁵
- 14. In establishing the likely factual position with the acquisition, the Commission assumes an applicant will be under an obligation to divest the assets or shares which are the subject of the undertaking, on the terms offered by the applicant. The comparison between the factual and the counterfactual will test whether the divestment would, of itself, or in combination with other market conditions, enable the Commission to be satisfied that the proposed acquisition will not have the effect, or likely effect, of substantially lessening competition.
- 15. Divestments are to some extent uncertain as to their eventual impact on the market. If much rests on the divestment in terms of the future levels of competition in the relevant markets, the Commission must be satisfied that the divested business and assets will be capable of constraining the combined entity in the factual. If the divested business fails or is an ineffective competitor, then a substantial lessening of competition may occur, and consumers will be harmed. Thus it is important for the Commission to consider all the relevant risks associated with a divestment proposal.
- 16. In order to make this assessment, the Commission will consider:
 - composition risks that the scope of the divestiture package may be too constrained, or not appropriately configured, to attract a suitable purchaser, or may not allow a purchaser to operate effectively and viably in the market;
 - purchaser risks that a suitable purchaser is not available or that the merger parties will dispose to a weak or otherwise inappropriate purchaser; and
 - asset risks that the competitive capability of a divestiture package will deteriorate prior to completion of divestment, for example, through loss of customers or key members of staff.⁶
- 17. These risk assessments are made and taken into account when establishing the factual, and in the competition assessment.

THE PARTIES

Schering-Plough

18. Schering-Plough is a New Jersey based corporation, listed on the New York Stock Exchange. It is a global science-based healthcare company with activities in the prescription and over-the-counter (OTC) pharmaceutical, consumer and animal health sectors. In New Zealand, Schering-Plough's animal health business trades as Schering-Plough Coopers. It has one New Zealand company, Schering-Plough Animal Health Limited.

⁵ Commerce Act, section 69A(3).

⁶ This framework is based on the approach used by the United Kingdom Competition Commission. The Commission recognises that the United Kingdom Competition Commission has greater power to recommend actions (structural and/or behavioural) to be taken by the applicant, to remedy, mitigate or prevent a substantial lessening of competition arising from the acquisition. Nevertheless, the Commission considers that this categorisation of types of risk provides a useful way for the Commission to ensure it has made a thorough assessment of all issues pertinent to the divestment and establishing the factual.

- 19. Of relevance to this clearance application are Schering-Plough's activities in the animal health business where it develops, manufactures and markets OTC and prescription veterinary pharmaceuticals, biologicals (vaccines) and speciality products for ruminants (cattle, sheep, goats and deer), pigs, poultry, horses, companion animals (cats and dogs) and others. Schering-Plough's campylobacter vaccine for sheep, Campylovexin, is of particular significance to this acquisition.
- 20. Schering-Plough conducts research in its own right, and is also engaged in various collaborative projects with others to develop and manufacture human and animal health products.

Organon BS

- 21. Akzo Nobel N.V. (Akzo) is incorporated in The Netherlands. Organon BS was incorporated in The Netherlands on 1 September 2006 to be the holding company for the human and animal health activities of Akzo. Organon BS develops, manufactures and markets products that target selected therapeutic areas in human pharmaceuticals, and that cover a range of species in animal health.
- 22. Organon BS trades in New Zealand as two discrete business units: Organon, the human pharmaceutical business, and Intervet, the animal remedies business. There is one local New Zealand company, Intervet Limited, ⁷ which is ultimately owned by Akzo.
- 23. Organon develops, manufactures and markets women's health products, mental care health products, anaesthesia, and products for other therapeutic uses, including oncology and urology products. In addition, Organon has research and development activities in the [
 -]. Organon also generates revenues from third-party manufacturing and sales of active pharmaceutical ingredients as well as from services and royalties received from third parties.
- 24. Intervet is active in research and development and in the manufacture and sale of animal health products, providing a portfolio of pharmaceuticals and biologicals to treat farm animals such as ruminants, poultry, equine, swine and companion animals. In addition, Intervet generates limited revenues from other sources, mainly the production of medicinal feed additives on behalf of third parties. Intervet's campylobacter vaccine for sheep, Campyvax4, is of particular significance to this acquisition.

Other Relevant Parties

Pfizer New Zealand Limited (Pfizer NZ)

- 25. Pfizer Incorporated, founded in 1849, is the world's largest research-based biomedical and pharmaceutical company. Its animal health business is one of the largest in the world. Its corporate headquarters are located in New York, with major research and development locations in the United States and England.
- 26. Pfizer NZ has grown to be one of New Zealand's leading providers of prescription medicines, consumer healthcare products and animal health products, including vaccines.

⁷ Intervet Australia Pty Limited, an Australian company, is also registered in New Zealand.

27. Of the markets relevant to this merger, Pfizer NZ is active in intramammary treatments for dry and lactating cattle, antibiotics for ruminant animals, and prostaglandins. Pfizer NZ sells its products through veterinary channels only.

Fort Dodge New Zealand Limited (Fort Dodge NZ)

- 28. Fort Dodge Animal Health was founded in 1912 and has been a division of Wyeth Holdings Corporation since 1945. Fort Dodge NZ reports to Fort Dodge Australia. Its products are manufactured in Australia and imported to New Zealand.
- 29. Fort Dodge Animal Health is a leading manufacturer and distributor of prescription and OTC animal health care products for the livestock and companion animal industries. Fort Dodge Animal Health distributes products in more than 100 countries. It currently ranks first in veterinary vaccine sales in North America.
- 30. Of the markets relevant to this merger, Fort Dodge NZ is active in ectoparasiticides for cattle and endoparasiticides for sheep.

Ancare New Zealand Limited (Ancare)

- 31. Ancare commenced operations in New Zealand in 1985. Ancare is a supplier of animal health products to the New Zealand market and is also a growing supplier internationally, with associate companies in Australia and Ireland as well as distributors in a number of other locations.
- 32. Of the markets relevant to this merger, Ancare is active in ectoparasiticides and endoparasiticides. Ancare supplies its products through veterinary channels only.

Bomac Laboratories Limited (Bomac)

- 33. Bomac is New Zealand's largest privately owned animal health company. It was founded in 1958 as a dedicated supplier of generic animal health products.
- 34. Bomac is based in Auckland and manufactures over 400 products for sale in New Zealand and in over 60 countries worldwide. It has products in the bovine, equine, pig and poultry, sheep and companion animal categories.
- 35. Of the markets relevant to this merger, Bomac is active in intramammary treatments for dry cattle, antibiotics for ruminant animals and endoparasiticides for sheep.

Merial New Zealand Limited (Merial NZ)

- 36. Merial NZ was formed in 1997 as a joint venture between Merck & Co and Aventis SA (formerly Rhone-Poulenc).
- 37. Merial S.A.S., its parent company, has the largest research and development investment in the animal health industry with nine research and development centres around the world and has a network of 15 manufacturing sites globally.
- 38. Of the markets relevant to this merger, Merial NZ is active in endoparasiticides for sheep.

Virbac New Zealand Limited (Virbac NZ)

39. Virbac NZ is a subsidiary of Virbac Australia Pty Limited, and has been operating in New Zealand since 1984. Virbac Australia Pty Limited's parent company designs, manufactures and markets a broad range of products and services for

- veterinarians and animal owners, and operates in 22 countries, exporting to 100 countries worldwide.
- 40. Virbac NZ supplies a number of animal health products to the New Zealand market; half of its business relates to companion animal products. Virbac NZ also supplies the New Zealand market with Leptospirosis vaccines for cattle, fertility vaccines for sheep, minerals and calf products. Its vaccines are manufactured in Australia and the United States.
- 41. Of the markets relevant to this merger, Virbac NZ is active in intramammary treatments for dry and lactating cattle, antibiotics for ruminant animals and ectoparasiticides for cattle.

Bayer New Zealand Limited (Bayer NZ)

- 42. Bayer AG is an international, research-based group of companies with major business in healthcare, nutrition and material. Bayer AG has a portfolio of over 5,000 products and operations in nearly all countries of the globe. Worldwide operations are managed from the Group's headquarters in Germany.
- 43. Bayer NZ was incorporated in 1964. Bayer NZ imports products from Germany and other third party distributors; it has some products toll manufactured in New Zealand and in Australia by third parties.
- 44. Of the markets relevant to this merger, Bayer NZ is active in ectoparasiticides for sheep, ectoparasiticides for cattle, endoparasiticides for sheep, and antibiotics for ruminant animals.

Norbrook New Zealand Limited (Norbrook NZ)

- 45. Norbrook Laboratories Limited (Norbrook) was established in 1968. Norbrook manufactures a comprehensive range of generic veterinary and medical pharmaceuticals, contract manufactured products and pharmaceutical active ingredients (raw materials) and finished dose forms. It exports to over 110 countries.
- 46. Norbrook NZ was incorporated in New Zealand and is operated from Australia.
- 47. Of the markets relevant to this merger, Norbrook NZ is active in intramammary treatments for dry and lactating cattle, antibiotics for ruminant animals and endoparasiticides for sheep.

Boehringer Ingelheim NZ Limited (Boehringer Ingelheim NZ)

- 48. Boehringer Ingelheim Auslandsbeteiligungs GmbH (Boehringer Ingelheim), which has some 140 affiliated companies in 42 countries worldwide, focuses on human pharmaceuticals and animal health. It has a wide range of products covering vaccines, pharmaceuticals and natural health care segments of the animal health industry.
- 49. Boehringer Ingelheim NZ has been operating in New Zealand since 1973.
- 50. Of the markets relevant to this merger, Boehringer Ingelheim NZ is active in intramammary treatments for dry and lactating cattle and antibiotics for ruminant animals.

Jurox Pty Limited (Jurox)

- 51. Jurox is an Australian-based privately-owned veterinary pharmaceuticals company mostly active in Australia and New Zealand. Jurox now offers more than 200 proprietary veterinary lines to diverse animal health markets internationally.
- 52. Jurox New Zealand Limited (Jurox NZ) was incorporated in 1996 and is a wholly-owned family company which services the New Zealand market.
- 53. Of the markets relevant to this merger, Jurox NZ is active in prostaglandins, ectoparasiticides for cattle, ectoparasiticides for sheep and endoparasiticides for sheep.

Ravensdown Fertiliser Co-operative Limited (Ravensdown)

- 54. Ravensdown is 100% owned by New Zealand farmers and directly supplies more than half of all the fertiliser used in New Zealand agriculture.
- 55. Ravensdown entered the ecto/endoparasiticide markets in 2005 by becoming licensed to distribute Jurox products, which it rebrands under the Ravensdown name and sells directly to farmers, thereby removing the reseller margins.

Stockguard Laboratories (NZ) Limited (Stockguard)

- 56. Stockguard is a private New Zealand company incorporated in 1987 that specialises in the development and manufacture of veterinary products. Stockguard is the only manufacturer of veterinary antibiotic products in New Zealand.
- 57. Of the markets relevant to this merger, Stockguard is active in intramammary treatments for lactating cattle and antibiotics for ruminant animals.

Novartis International AG (Novartis)

- 58. Novartis is a multinational pharmaceutical company based in Basel, Switzerland. Novartis Animal Health is a company that focuses on the well-being of companion animals and on the health and productivity of farm animals.
- 59. Novartis Animal Health manufactures a number of vaccines in the United States for cattle and sheep.
- 60. Novartis New Zealand Limited (Novartis NZ), previously Sandoz Pharma Limited, was incorporated in New Zealand in 1955.
- 61. Of the markets relevant to this merger, Novartis NZ is active in ectoparasiticides for sheep, endoparasiticides for sheep and ectoparasiticides for cattle.

Parnell Laboratories (Aust) Pty Limited (Parnell)

- 62. Parnell was founded over 40 years ago in Australia. Parnell is now an international supplier of generic animal health products.
- 63. Parnell New Zealand Limited (Parnell NZ) was incorporated in 1988.
- 64. Of the markets relevant to this merger, Parnell NZ is active in intramammary treatments for cattle and prostaglandins.

INDUSTRY BACKGROUND

- 65. The Application relates to an 11 billion euro global acquisition in the health industry. The human pharmaceutical side is the main impetus for the Acquisition. In New Zealand, however, the Acquisition causes aggregation mainly in animal health markets. This decision considers the impact of this acquisition both in regard to human health products and animal health products.
- 66. The main customers of the affected products are a combination of veterinarians, veterinary wholesalers and rural supply stores. The ultimate end users of all the products are farmers.
- 67. Customers for prescription animal remedies relevant to this acquisition (i.e. intramammary treatments for dry and lactating cows, prostaglandins and antimicrobials for ruminant animals) are veterinarians or veterinary wholesalers. Veterinarians purchase these products either directly from the suppliers or through one of two veterinary wholesalers. Campylobacter vaccines for sheep are sold directly to veterinarians by Schering-Plough and Intervet.
- 68. The veterinary wholesalers are significant customers in the sense that they are purchasers of the relevant products, and because they supply a significant proportion of the ultimate acquirers/users of the product, i.e. veterinarians.
- 69. The customers for ectoparasiticides and endoparasiticides are a mixture of veterinarians, wholesalers and rural supply stores.

Retailers/Wholesalers

PGG Wrightson Limited (PGG Wrightson)

- 70. PGG Wrightson was formed in 2005 through the merger of Pyne Gould Guinness Limited and Wrightson Limited. The company has many different lines of business, including approximately 124 PGG Wrightson rural supply stores. The stores supply farms nationwide with many products including animal health and nutrition products.
- 71. [

RD1

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- 72. RD1 is New Zealand's largest retailer of agricultural supplies to dairy farmers. It operates a network of over 40 stores in the North Island, and seven in the South Island. RD1 is focused primarily on the dairy sector through its involvement with Fonterra Co-operative Group Limited.
- 73. RD1 retailers purchase separately, but collectively accounted for approximately [] of sales of Schering-Plough's ectoparasiticides for cattle in 2006.

Combined Rural Traders Co-operative (CRT)

- 74. CRT is a farmer co-operative, owned by farmers in the South Island.
- 75. CRT is a significant customer of both Intervet's and Schering-Plough's ectoparasiticides for sheep. [

Farmlands Trading Society Limited (Farmlands)

- 76. Farmlands was formed in 1962 when a group of farmers and growers joined together to purchase goods. It is owned by its customer shareholders, and offers a number of products to the rural sector, including animal remedies.
- 77. Farmlands outlets are significant purchasers of Schering-Plough's ectoparasiticides for sheep.

SVS Veterinary Supplies Limited (SVS)

- 78. SVS is a New Zealand owned wholesaler of veterinary products. SVS supplies approximately 5,000 different products to the New Zealand market with 50% relating to companion animals, 45% to dairy and 4% to sheep.
- 79. [

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Provet Australasia Pty Limited (Provet)

- 80. Provet is Australasia's leading veterinary distributor.
- 81.

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Veterinarians

82. There are a number of large veterinary operations in New Zealand. [

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83. Veterinarians may choose to purchase other animal remedies either directly or through either SVS or Provet.

PREVIOUS COMMISSION DECISIONS

Decision 398 - Glaxo Wellcome Plc and SmithKline Beecham Plc

84. The Commission gave clearance to the acquisition of SmithKline Beecham Plc by Glaxo Wellcome Plc on 1 September 2000. This decision is relevant to the market definitions in the human health side of the current application. The Commission adopted the approach used by the European Commission in its decision on the Glaxo Wellcome and SmithKline Beecham merger proposal.⁸

Decision 496 - Pfizer Laboratories Limited and Pharmacia Limited

85. The Commission gave clearance to the acquisition of Pharmacia by Pfizer on 3 April 2003. The markets involved that are relevant to the current application were the markets for antibiotics for the treatment of mastitis in dry and lactating cows. Separate product markets were defined for intramammary treatments for dry and lactating cows.

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 $^{^8}$ Glaxo Wellcome/SmithKline Beecham, Case No COMP/M.1846, 8 May 2000.

Decision 549 – Provet NZ Party Limited and National Veterinary Supplies Limited

86. The Commission gave clearance to this acquisition on 5 May 2005. In that decision, the market relevant to the current application was that for the wholesale supply of livestock animal remedies. The market was not further broken down by product type.

Investigation

87. In May 2004, the Commission also completed an internal investigation into an acquisition by Pfizer of CSL Limited's Animal Health Division in the United States, Australia and New Zealand. This was in relation to the market for "all-inone" vaccines for cats and dogs. It was concluded that there was sufficient existing competition in this market and no further action was required.

MARKET DEFINITION

- 88. The Act defines a market as:
 - "... a market in New Zealand for goods or services as well as other goods or services that, as a matter of fact and commercial common sense, are substitutable for them." ¹⁰
- 89. For the purpose of competition analysis, the internationally accepted approach is to assume the relevant market is the smallest space within which a hypothetical, profit-maximising, sole supplier of a good or service, not constrained by the threat of entry would be able to impose at least a small yet significant and non-transitory increase in price, assuming all other terms of sale remain constant (the SSNIP test). The smallest space in which such market power may be exercised is defined in terms of the dimensions of the market discussed below. The Commission generally considers a SSNIP to involve a five to ten percent increase in price that is sustained for a period of one year.

Product Market

- 90. The greater the extent to which one good or service is substitutable for another, on either the demand side or supply side, the greater the likelihood that they are bought and supplied in the same market.
- 91. Close substitute products on the demand side are those between which at least a significant proportion of buyers would switch when given an incentive to do so by a small change in their relative prices.
- 92. Close substitute products on the supply side are those between which suppliers can easily shift production, using largely unchanged production facilities and little or no additional investment in sunk costs, when they are given a profit incentive to do so by a small change to their relative prices.
- 93. In this case, Schering-Plough and Intervet are both active in respect of human health products and animal health products. The Commission has considered the extent of aggregation (if any) in a number of relevant product markets within both human and animal health.

⁹ Livestock were considered to be sheep, cattle, deer, swine and poultry.

¹⁰ S 3(1) of the Commerce Act 1986.

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Human Health

94. In previous decisions, the Commission has, in defining human health markets, referred to the "Anatomical Therapeutic Chemical" (ATC) classification system, which subdivides medicines into different therapeutic classes. The ATC system was devised by the European Pharmaceutical Marketing Research Association (EphMRA) and is maintained by EphMRA and Intercontinental Medical Statistics (IMS). The ATC is used internationally and is controlled by the World Health Organisation Collaborating Centre for Drug Statistics Methodology.

- 95. The ATC classification was used by the Commission as a starting point for the definition of markets in Decisions 398 and 496. However, in the former, the Commission noted 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".
- 96. The ATC system is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC1) is the most general and the fourth level (ATC4) the most detailed. The third level (ATC3) allows medicines to be grouped in terms of their therapeutic indications (their intended use), and can therefore be useful in defining markets on the demand-side. These groups of products generally have the same therapeutic indication and cannot be substituted for products belonging to other ATC3 classes.
- 97. Schering-Plough submitted that there is no aggregation in any specific human health market as a result of the proposed acquisition, although it acknowledges that there are two areas of broad overlap in the parties' human health products: cardiovascular (anti-thrombosis) products and cancer therapies/oncology products.

Cardiovascular (Anti-thrombosis) Products

- 98. Schering-Plough sells the anti-thrombosis product Integrilin. Integrilin is an anti-platelet, and is classified in the ATC3 classification B1C platelet aggregation inhibitors. Organon sells the anti-thrombosis product Organan. Organan is an anti-coagulant product, and is classified in the ATC3 classification B1B heparins (and ATC4 classification B1B9 other heparins).
- 99. Anti-thrombosis products are used to prevent blood clots (thrombi). Blood clots form through aggregation of platelets and fibrin in the blood. Blood clots can form in either the arteries (arterial thrombi) or the veins (venous thrombi), with the composition of the clot varying in each. Arterial thrombi are composed mainly of platelets, while venous thrombi are mainly composed of fibrin.
- 100. Anti-platelets, such as Schering-Plough's Integrilin, treat arterial thrombi by inhibiting the ability of platelet aggregates to bind together and form a clot. Anti-coagulants treat venous thrombi by inhibiting aggregation of fibrin. Organon's product Organan is a particular type of anti-coagulant that treats blood clots caused by heparin.
- 101. The European Commission has previously considered market definition in antithrombosis products. In the Hoechst/Rhone-Poulenc merger, ¹¹ the European Commission found that products in the ATC4 classification B1B9 were in a separate product market from other products in the ATC3 classification B1B. In

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¹¹Case No. IV/M.1378.

- the Monsanto/Pharmacia/Upjohn merger, ¹² the European Commission found that anti-platelets in ATC3 classification B1C constituted a separate market that could be further narrowed into first line and second line platelet aggregation inhibitors.
- 102. Market investigations also confirmed that Integrilin and Orgaran compete in separate product markets. On this basis, and the evidence discussed above, the Commission considers that Integrilin and Orgaran are not substitutes. Accordingly, there is no aggregation in cardiovascular (anti-thrombosis) products and the Commission does not further consider this aspect of the Application.

Cancer Therapies/Oncology Products

- 103. Organon sells the oncology product OncoTICE, which is indicated for the treatment of bladder cancer. Schering-Plough sells Intron A, which is primarily for the treatment of Hepatitis B and C and melanoma, but which has been used for the treatment of bladder cancer.
- 104. Intron A does not currently have an approved indication for the treatment of bladder cancer, and Schering-Plough states that it does not market or promote Intron A as a treatment for bladder cancer, as it is legally prevented from doing so. The Commission is therefore of the view that the products are not demand-side substitutes.
- 105. The Commission also considered whether the products are supply-side substitutes, such that Intron A could be considered a 'near competitor'. This would be the case if Intron A could be registered and sold as a treatment for bladder cancer in a short timeframe (within one year) without significant tangible or intangible investment (including marketing investment).
- 106. The Commission questioned Schering-Plough about the likelihood of Intron A entering the market for the treatment of bladder cancer by registering with MedSafe. Schering-Plough stated that prior to applying for registration, a significant clinical programme of between two to five years would need to be undertaken. Intron A is an off-patent medication and is therefore late in its product lifecycle, meaning that further investment in a clinical programme is unlikely. At the end of a clinical programme, there would be a registration period of 12 to 18 months for Intron A to be approved for such a use. Assuming that the application was complete and not challenged in any way, Schering-Plough estimated that the approval process would in total take between three and five and a half years.
- 107. In summary, Schering-Plough submitted that it does not believe there is any prospect of Intron A ever being approved for the treatment of bladder cancer. In addition, there would likely be significant marketing investment involved in establishing a credible and profitable position in the market. On this basis, the Commission formed the view that Intron A is not a near competitor to OncoTICE.
- 108. Market investigations also confirmed that OncoTICE and Intron A compete in separate product markets. On this basis, and the evidence discussed above, the Commission considers that OncoTICE and Intron A are not substitutes.
- 109. The Commission concludes that there is no aggregation in relation to products for the treatment of bladder cancer, and the Commission does not further consider this aspect of the Application.

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¹² COMP/M.1835.

Animal Health

110. Schering-Plough has submitted that the relevant animal health product markets in which there would be aggregation as a result of the proposed acquisition are:

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- intramammary (mastitis) treatments for dry cows;
- intramammary (mastitis) treatments for lactating cows;
- antimicrobials for ruminant animals;
- prostaglandins;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for sheep; and
- campylobacter vaccines for sheep.

Intramammary (Mastitis) Treatments for Dry and Lactating Cows

- 111. Mastitis in cattle is a condition that involves the inflammation of the mammary gland caused by specific disease-producing micro organisms that gain entrance via the teat openings. Intramammary treatments for mastitis are designed for infusion into individual cow quarters via the teat canal. 13
- 112. There are two different types of mastitis infections: chronic (or sub-clinical) mastitis; and acute (or clinical) mastitis. Sub-clinical mastitis has no observable symptoms, and is typically treated during the time of the year when a cow is not milked ("dried off"). Clinical mastitis is identified by symptoms such as a swelling of the udder, and typically occurs (and is treated) during the lactation period (when the cow is producing milk).
- 113. Different intramammary products are used for the treatment of sub-clinical mastitis in dry cows and clinical mastitis in lactating cows. The primary difference between these products is the length of time the antibiotic is maintained in the udder (above a certain allowed threshold), and thus the period for which any milk produced must be withheld from human consumption. Dry cow products have milk withholding periods of between 28 and 49 days, while lactating cow products have milk withholding periods ranging from two to six days.
- 114. In Decision 496 the Commission noted that there is no demand-side substitutability between dry cow intramammary treatments and lactating cow intramammary treatments. The Commission's market investigations have again confirmed this.
- 115. In investigations by the European Commission into the Akzo Nobel/Hoechst Roussel Vet¹⁴ and Pfizer/Pharmacia¹⁵ mergers, the European Commission further narrowed the markets for dry cow intramammary treatments and lactating cow intramammary treatments by active substance.

¹⁵ Case No. COMP/M.2922.

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¹³ There are also some treatments for mastitis in cattle in injectable form. However, these treatments are typically broad spectrum antibiotics that also treat other diseases, and as such are considered to be part of the antibiotics market rather than the market for mastitis treatments.

¹⁴ Case No. COMP/M.1681.

- 116. In Decision 496, however, the Commission noted that "different products contain different active substances, although most products contained some form of penicillin. Further, each product may contain more than one active substance. There are likely to be different degrees of substitutability between the different active substances". In that case, the Commission did not narrow the dry cow and lactating cow markets by active substance.
- 117. Market investigation in the present acquisition confirmed substitution between dry cow intramammary treatments with different active substances does occur. Similarly there is substitution between lactating cow intramammary treatments with different active substances. Thus, neither of these markets needs to be further narrowed by active substance.
- 118. In relation to dry cow intramammary treatments, Schering-Plough submits that nearly all cows in New Zealand are dried off for a six week period from 31 May each year. In contrast, Schering-Plough notes that in many European countries, the dry period can be either short or long and thus farmers need to use a short-acting or long-acting dry cow intramammary treatment. However, Schering-Plough submits that since the drying off periods in New Zealand do not vary, there is no need to further narrow the dry cow intramammary market into markets for short-acting and long-acting treatments.
- 119. The market investigation did not support this view. Most market participants indicated that there is variation in the length of the dry period in New Zealand, both across different farms and even within a herd on a given farm. Moreover, dry cow intramammary products in New Zealand have different durations of effectiveness, based on the length of time the antibiotic is maintained in the udder at effective levels to treat mastitis. For most (although not all) products, the longer the period in which the antibiotic is effective in the udder, the longer is the milk withholding period over which any milk obtained from the cow cannot be sold for human consumption.
- 120. A number of market participants considered that dry cow intramammary products fall into two separate markets of short-acting and long-acting treatments, with the length of the milk withholding period used as the differentiating factor. Whilst there appears to be limited demand-side substitutability between short-acting and long-acting products, the Commission found that there is no clear break in the chain in terms of milk withholding period between what constitutes a short-acting product and what constitutes a long-acting product. Specifically, while products of 28-30 day milk withholding periods can generally be considered short-acting, and products of 49 day milk withholding periods are considered long-acting, there are some remaining products with 35 day milk withholding periods where it is not clear if they should be considered as short-acting or long-acting products.
- 121. Further, some products claim to provide effective antibiotic levels for longer periods than their milk withholding periods suggest. The Commission understands that such claims can be made because the milk withholding period is based on reducing the antibiotic level below an allowed level, but even below that level the antibiotic can still be effective in treating mastitis.
- 122. The Commission is of the view that, for the purposes of the present Application, it is not necessary to come to a firm conclusion on the precise definition of the market concerning intramammary treatments for dry cows. Whilst there may be

narrower markets for short-acting and long-acting treatments, this further breakdown is not necessary as it will not alter the competition analysis in this case. A broad market definition is consistent with the Commission's market definition in Pfizer/Pharmacia, although there was no discussion in that decision regarding short-acting or long-acting treatments.

- 123. In summary, the relevant product markets in relation to intramammary treatments for mastitis for the purposes of this acquisition are:
 - the market for intramammary treatments for mastitis in lactating cows; and
 - the market for intramammary treatments for mastitis in dry cows.

Antimicrobials for Ruminant Animals

- 124. Antimicrobials are used to treat infections such as respiratory infections, gastrointestinal infections, eye infections, etc. There are a large number of antimicrobials for ruminant animals, with different active substances, indicated for different treatments, and in injectable, oral or topical forms (although the majority are injectable).
- 125. Schering-Plough submits that there is substitutability between different antimicrobials with different active substances, and the same antimicrobial can be used on different ruminant animals. Accordingly, Schering-Plough submits that the market is for the supply of antimicrobials for ruminant animals.
- 126. The market investigation found a range of views on whether a broader or narrower market was appropriate.
- 127. Dr Nigel Coddington, of Totally Vets, believed that antimicrobials with different families of active substance (such as penicillins, tetracyclines, and beta-lactams) are not substitutable. He noted that the different families of active substance have different powers of penetration for treating particular diseases. Dr Coddington gave the example of bone infections, where beta-lactams provide the most efficacious treatment, while penicillins provide an average treatment and tetracyclines have very little effect.
- 128. Similarly, Stockguard noted that different antimicrobial products are specific to different diseases and, for example, a disease may be treated with a penicillin-based product but not with a tetracycline-based product.
- 129. However, Pfizer and Bomac had differing views. Both noted that there is substitutability between antimicrobials with different active substances and that the broad market, as defined by Schering-Plough, is appropriate.
- 130. An examination of the product lines for antimicrobials, as recorded in the 2007 IVS Annual, reveals that there is a high degree of product differentiation. Products are differentiated in terms of (among other factors): family of active substance and the specific active substance within each family; amount of the active substance; route of administration (although, as noted above, the majority of antimicrobials are injectable); treatment for which the product is indicated for; range of animals that can be treated; and withholding times for milk and/or meat.
- 131. The Commission is of the view that, on balance, for the purposes of the present acquisition, it is not necessary to come to a firm conclusion on the precise definition of the market concerning antimicrobials in ruminant animals. For the

purposes of this acquisition, the Commission will analyse the competitive effects using a broad market definition of all antimicrobials for ruminant animals.

Prostaglandins

- 132. Prostaglandins are a particular type of endocrine (hormone) treatment. Endocrine treatments in general are used to regulate an animal's physiological processes leading to improved performance, while prostaglandins in particular are a specific hormone used (among other things) for the management of the oestrus cycle to induce labour or abortions, and for the treatment of ovarian and uterine disorders.
- 133. A starting point for market definition in endocrine treatments is the particular hormone that a specific treatment contains. Endocrine treatments contain one of the following four hormones:
 - gonadotrophin releasing hormones;
 - gonadotrophins;
 - prostaglandins; and
 - progestagens.
- 134. In the merger between Akzo Nobel and Hoechst Roussel Vet, ¹⁶ the European Commission defined separate product markets according to the type of hormone used in the product.
- 135. Schering-Plough submitted that it is appropriate to define separate product markets for individual hormones. In the present Application the only aggregation is in relation to prostaglandins, and thus Schering-Plough submitted that the relevant market is for prostaglandin products.
- 136. The market investigation confirmed that a separate product market for prostaglandins is appropriate. Thus for the purposes of the present Application, the Commission defined a discrete market for prostaglandin products.

Ectoparasiticides for Cattle

- 137. Ectoparasiticides treat external parasites such as flies and lice that invade the animal. Ectoparasiticide products for cattle in New Zealand are either combination products, which treat both flies and lice, or products that treat only lice. There are no products that treat only flies in cattle.
- 138. Schering-Plough has submitted that the market should be defined as the broad market for all ectoparasiticides for cattle. It has suggested that demand for cattle fly treatments is generally restricted to farms in warmer climates north of Taupo and only during the summer months. Moreover, Schering-Plough submitted that combination fly/lice treatments are priced to ensure competitiveness with lice only products. Schering-Plough argued that fly control is thus largely ancillary to lice control, and combination fly/lice treatments and lice-only treatments should be in the same market.
- 139. The market investigation confirmed that fly problems for cattle are generally restricted to the summer months. However, there were different accounts given of the geographic extent of the problem, with views from industry participants suggesting the problem can extend from north of Levin or even north of

¹⁶ Case No. COMP/M.1681.

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- Canterbury, and others agreeing that only farms north of Taupo are affected. Nonetheless, there was general agreement that the cattle fly problem is relatively small in New Zealand. Lice are generally a more significant problem for cattle, occurring predominantly in the winter months and nationwide.
- 140. Some industry participants have suggested that there are separate markets for fly control in summer and lice control in winter. However, as there are no fly-only products and combination fly and lice products would span both markets, the Commission considered whether combination fly/lice products and lice-only products fall into discrete product markets. Schering-Plough submitted that "if the combined entity attempted to increase the price of a combination fly and lice product, it would lose significant sales to suppliers of lice products such as to undermine that attempted increase". There appears to be some merit in this argument. For example, Dr John Harrison, of Veterinary Enterprises Group, noted that the majority of the sales of combination fly/lice products through Veterinary Enterprises Group are for lice treatments, and that this determines the price of these products. Thus, a hypothetical monopolist of combination fly/lice products, when imposing a SSNIP, would face significant substitution towards lice-only products, such that these two groups of products would be in the same market.
- 141. The Commission is therefore of the view that, for the purposes of assessing the proposed acquisition, the market is at least as broad as the market for ectoparasiticides for cattle.
- 142. One remaining issue is whether the market is in fact broader than ectoparasiticides and includes endectocides for cattle, which are products that treat both external parasites (flies and lice) and internal parasites (worms). Schering-Plough submitted that endectocides impose a constraint on the pricing of ectoparasiticides, but did not place the products in the same market for the purpose of calculating market shares because neither Schering-Plough nor Intervet supply endectocides.
- 143. In the merger of Merck and Rhone-Poulenc-Merial, ¹⁷ the European Commission considered whether endectocides compete with ectoparasiticides and/or endoparasiticides (which treat internal parasites only). The European Commission noted that the differences between endectocides and ectoparasiticides/endoparasiticides in terms of parasite treated, efficacy, and consumer uses, as well as large absolute price differences, may mean there is a separate relevant market for endectocides. However, it also found that endectocides have been progressively replacing ectoparasiticides/endoparasiticides and there is a "certain degree of interchangeability" between the products. The European Commission did not come to any final conclusion on market definition in this instance, although it did conservatively adopt separate narrow markets of ectoparasiticides, endoparasiticides and endectocides for the purposes of determining market shares.
- 144. Market investigations found that, in New Zealand, there has been a substantial shift from ectoparasiticides/endoparasiticides to endectocides in recent years, suggesting a large degree of demand-side substitutability between the two

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¹⁷ Case No. IV/M.885.

products. The Commission understands that this shift been motivated by a various factors, including that:

- organo-phosphates, the family of active substances in many ectoparasiticides, are considered to be less environmentally friendly than the active substances in endectocides;
- endectocides are more convenient, as they replace two animal treatments with one; and
- endectocides are considered to be more efficacious.
- 145. Moreover, on the arguments presented above for combination fly/lice and lice only ectoparasiticide products, endectocides could be placed in the same relevant market as both ectoparasiticides and endoparasiticides. That is, a hypothetical monopolist of endectocides, when imposing a SSNIP, would likely face substitution to ectoparasiticides and endoparasiticides, such that these three groups of products would be in the same market. However, Schering-Plough advises that neither Schering-Plough nor Intervet supply endectocides, and further, there is no aggregation with respect to endoparasiticides in cattle.
- 146. Accordingly, the Commission's view is that, for the purposes of assessing the proposed acquisition, competitive effects in the factual scenario are best analysed with a product market consisting only of ectoparasiticides for cattle.

Ectoparasiticides for Sheep

- 147. The market definition issues for ectoparasiticides for sheep are similar to those identified above for cattle, although the extent of the problem differs. Flies are a larger problem for sheep than they are for cattle (as flies are attracted to wet or dirty wool and to docking wounds) and occur throughout the country, as do lice on sheep. There is a similar seasonal occurrence as for cattle generally, flies in summer and lice in winter although the boundaries are not necessarily well defined, as discussed below.
- 148. Because the extent of the fly problem is more significant for sheep than it is for cattle, there are a number of fly-only treatments for sheep, as well as lice-only and combination fly/lice products. While there are some products that are marketed as endectocides for sheep, the Commission understands that these products are mainly used as endoparasiticides as their primary activity is against internal parasites.
- 149. An argument could be made that distinct product markets can be defined for fly control products in summer and lice control products in winter. However, combination fly/lice products would span both markets, creating a chain of substitution between fly-only and lice-only products. If combination fly/lice treatments were to be defined as a separate product market, then a hypothetical monopolist of combination treatments, when imposing a SSNIP, would likely face substitution to fly-only and lice-only treatments, such that these three groups of products would in fact be in the same market.
- 150. Moreover, one veterinarian noted that there is some overlap in the seasonal use of fly and lice products for sheep. Dr Ian Walker, of Vet Services Hawkes Bay, noted that in autumn a farmer may use either a combination fly/lice product or a lice only product. A combination product would be used to give some fly protection in the remaining months before winter, while at the same time

- providing lice protection for winter. Dr Walker also suggested that a farmer might use a combination fly/lice product in summer to provide lice protection for the forthcoming winter, as some products offer up to 12 months lice protection. This suggests that the break between fly treatments in summer and lice treatments in winter is not well defined.
- 151. The Commission is therefore of the view that, for the purposes of assessing the proposed acquisition, the relevant market is the market for ectoparasiticides for sheep.

Endoparasiticides for Sheep

- 152. Endoparasiticides treat internal parasites, such as worms, that live inside the host animal. There are a significant number of endoparasiticides on the market, differentiated by factors including the active substance and the type of worm treated.
- 153. All the endoparasiticide products on the market have active substances from one of three "action families":
 - Macrocylic Lactones: includes active substances such as abamectin, ivermectin and moxidectin;
 - Levamisoles: includes the active substance levamisole; and
 - Benzimidazoles: includes active substances such as oxfendazole and albendazole.
- 154. Products with active substances from different action families can be used to treat the same types of worms and are generally substitutable for one another. In addition, there are a number of products that have combinations of two or all three of the action families, as a means of overcoming worm resistance to a particular action family.
- 155. Most products are broad spectrum, treating a number of different worm species, although there are a small number of products that treat only a particular species of worm. Nonetheless, worm species that are treated by such narrow spectrum products can also typically be treated by other broad spectrum products.¹⁸
- 156. As noted in paragraph 148, some products are marketed as endectocides for sheep, and the Commission understands these products to be mainly used as endoparasiticides. Schering-Plough submitted that "[w]hile there are numerous sheep endectocides available in New Zealand, their primary activity is against internal parasites rather than external parasites such as flies and lice". ¹⁹ Neither Schering-Plough nor Intervet supplies endectocides in New Zealand. Therefore no aggregation in endectocides would occur as a result of this acquisition.
- 157. Accordingly, the Commission's view is that, for the purposes of assessing the proposed acquisition, competitive effects in the factual scenario are best analysed with a product market consisting only of endoparasiticides for sheep.

¹⁹ Letter from Bell Gully to the Commerce Commission, 16 August 2007.

¹⁸ For example, Novartis' product Fasinex 10 is indicated for the treatment of liver fluke only. Schering-Plough's broad spectrum products Scanda and Valbazen are both indicated for the treatment of a number of worm species including liver fluke, as are other products on the market.

Campylobacter Vaccines for Sheep

- 158. The purpose of a vaccine is to protect the animal against future disease or illness caused by bacterial, viral parasitical or fungal infection. Campylobacter is a specific bacterial disease. Its main effect in sheep is to cause abortions in pregnant ewes affected by the disease.
- 159. The only two suppliers of campylobacter vaccines for sheep in New Zealand are Schering-Plough, with Campylovexin, and Intervet, with Campyvax4.
- 160. Campylobacter vaccines have a specific use, and cannot be substituted on the demand side for/by other vaccines or medicines. Nor is there any supply-side substitution, as it is unlikely that entry would be timely enough to suggest the presence of near competitors (the timeliness of entry is discussed later in this Decision). Therefore, for the purpose of the present Application, the Commission is of the view that the market should be defined as a discrete product market for campylobacter vaccines for sheep.

Functional Markets

- 161. Some animal health products in the relevant product markets are manufactured in New Zealand, while others are manufactured overseas and imported into New Zealand. For example, Schering-Plough manufactures its campylobacter vaccine at its plant in Upper Hutt, while Intervet manufactures its campylobacter vaccine in Australia and imports it into New Zealand.
- 162. Manufacturers and importers of animal health products are also involved in the wholesale supply/distribution of the products to rural resellers and veterinarians. As a general principle, manufacturers/importers do not sell products directly to end consumers (i.e., farmers). The exception is Ravensdown, which is a rural reseller that has recently entered some of the relevant product markets via a manufacturing agreement with Jurox. Nonetheless, such arrangements only occur at the margin.
- 163. The Commission concludes that the appropriate functional level is that for the manufacture/import and wholesale supply of the product markets identified above.

Geographic Markets

- 164. The Commission defines the geographic dimension of a market to include all of the relevant, spatially dispersed sources of supply to which buyers would turn should the prices of local sources of supply be raised.
- 165. In the supply of animal health products, distribution by suppliers is undertaken on a national level. Further, in the Pfizer/Pharmacia merger, the Commission considered the geographic market for the supply of animal health products to be a national one.
- 166. The Commission concludes that the appropriate geographic market for the product markets identified above is a national one.

Conclusion on Market Definition

- 167. The Commission concludes that the relevant markets are national markets for the manufacture/import and wholesale supply of:
 - intramammary (mastitis) treatments for dry cows;
 - intramammary (mastitis) treatments for lactating cows;

- antimicrobials for ruminant animals;
- prostaglandins;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for sheep; and
- campylobacter vaccines for sheep.

COUNTERFACTUAL

168. In reaching a conclusion about whether an acquisition is likely to lead to a substantial lessening of competition, the Commission makes a comparative judgment considering the likely outcomes between two hypothetical situations, one with the acquisition (the factual) and one without (the counterfactual). The difference in competition between these two scenarios is then able to be attributed to the impact of the acquisition.

Counterfactual

- 169. The Commission considered the appropriate counterfactual. It noted a media release dated 25 January 2007 on Intervet's international website stating that Akzo had reconfirmed its intention to list approximately 20 to 30 percent of the shares in Organon BS. The release stated that Akzo had received preliminary expressions of interest from a number of parties upon its original announcement, but remained committed to the listing approach.²¹
- 170. In response to Commission enquiries, Akzo Nobel stated that a number of options would be open to it, including the status quo, an Initial Public Offering, or a sale to or a joint venture with a third party. It did not feel able to say with any certainty which of these options (if any) is more likely than another.
- 171. The Commission questioned Mr Andrew McPherson, the General Manager of the Intervet New Zealand operation, about what he considers to be the most likely counterfactual if the acquisition by Schering-Plough does not go ahead. He expressed the view that in terms of the New Zealand market, Intervet is [

] and that any animal health company's future depends on what it has in the research pipeline.

172. Industry participants expressed the view that if the acquisition by Schering-Plough did not proceed, they considered it was most likely that Intervet would be purchased by another international pharmaceutical company as it was an attractive target. Some industry participants commented that Intervet was already beginning to lose some staff, possibly in anticipation of an acquisition.

Conclusion on the Counterfactual

173. The Commission considers the relevant counterfactual to be either the status quo, or that Intervet would be sold to a third party. If Intervet was not sold, then the

²⁰ Air New Zealand & Qantas Airways Limited v Commerce Commission (no 6) (2004) 11 TCLR 347, Para 42

²¹ http://www.intervet.com/news/akzo-nobel-reconfirms-listing-of-organon-biosciences.asp

status quo would be maintained. If Intervet proceeded with an Initial Public Offering, then it would continue to run the business and the status quo would be maintained. If Intervet was sold to another party, and assuming no competition concerns arose from the sale, then the outcome would be similar to the status quo.

Factual

- 174. The Commission has to reach a view on the likely factual position assuming the acquisition does proceed. The term "the combined entity" refers to the entity that comes into being if Schering-Plough acquires Intervet.
- 175. When an Applicant undertakes to divest shares or assets, the undertaking forms part of the clearance application. In establishing the factual, the Commission must therefore predict the likely state of the market subsequent to the proposed acquisition and divestment.
- 176. As outlined in paragraph 16, to make this assessment, the Commission has regard to the categories of composition risk, purchaser risk, and asset risk. These risks are considered with respect to the market for campylobacter vaccines for sheep, as Schering-Plough has undertaken to divest its Campylovexin vaccine.
- 177. The Commission considers that the risk framework provides a useful way of identifying the risks that are inherent in divestment undertakings and ensures that the Commission has made a thorough analysis of all factors relevant to the factual.

Composition Risks

- 178. In examining the composition risks of the proposed divestment undertaking, the Commission has assessed whether the terms of the proposed divestment undertaking contain all the components integral to producing the product or operation being divested, and whether Campylovexin, in the hands of a competitor, is strong enough to continue to provide a constraint to Campyvax4.
- 179. The Commission tested the divestment offer with potential purchasers by asking whether they thought the divestment of the Campylovexin business under the terms specified could work, and what support the new owner would require from Schering-Plough.
- 180. In general terms, industry participants considered that the divestment package was feasible. Finding a suitable manufacturer was viewed as time-consuming, but achievable.
- 181. Several industry participants expressed concern that Campylovexin is a declining product. Some even went as far as to suggest that its market share would be likely to decline to zero under Schering-Plough within a few years, absent the acquisition. Most competitors expressed the view that for Campylovexin to succeed in the market, it would have to be further developed.
- 182. Campylovexin is viewed by veterinarians as reliable and effective. However, the perception appears to be that, on the whole, it is inferior to Campyvax4. Despite this, Schering-Plough earns healthy margins on the sale of Campylovexin ([

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] of Campylovexin in the coming season. [
]. Given these margins, a

new owner of the product should be able to compete on price while still making a reasonable profit margin.

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Conclusion on Composition Risks

183. The Commission's view is that the divestment undertaking includes all the necessary components for the successful operation of the Campylovexin business. The Campylovexin product is likely to be strong enough to provide a significant constraint to Campyvax4 after the divestment.

Purchaser Risks

- 184. The Commission has assessed purchaser risks that could arise with the divestment of the Campylovexin brand, namely:
 - finding suitable buyers for the Campylovexin business; and
 - the combined entity selling to a weak buyer.
- 185. The Commission investigated whether there were any companies that would be both suitable and interested in purchasing the Campylovexin business.
- 186. The pool of suitable buyers will be constrained by the necessity to arrange manufacture of the vaccine. The Commission considers that any of the existing major competitors in the New Zealand animal health market would be suitable buyers and could arrange manufacture of the vaccine.
 -]²² Some of these companies have a relatively small presence in New Zealand, but are backed by strong multinational parent companies.
- 187. The combined entity could strategically divest the Campylovexin brand to a weak or 'stand-alone' buyer with the knowledge that it is unlikely to be as strong a competitor as a purchaser that is able to bundle other product lines for sale to resellers. The Commission would include as a stand-alone buyer those sellers of animal remedies sellers that do not sell any products into the vet channels, such as Ravensdown, a distributor of Jurox products in New Zealand.
- 188. A weak competitor might quickly lose market share to a well-resourced and aggressive combined entity to the point where Campylovexin might be forced to exit, which would allow the combined entity a monopoly position in the market.
- 189. The Applicant has indicated that its "firm view is that a purchaser of the Campylobacter Business would be an existing competitor in the animal health industry, in which case this is not a situation where the Campylovexin Business might be sold to a stand-alone buyer lacking industry experience, and thus the concern that the Commission expressed in Decision 545 on this issue is not relevant here," and that, "this is not an asset that would attract a private equity or other non-industry buyer." The Commission accepts this submission.
- 190. The Applicant also indicated that expressions of interest in the purchase of Campylovexin had been received from [] had expressed interest in a campylobacter vaccine.

told the

Commission that they would not be interested in the Campylovexin product when the initial undertaking was explored with them. Schering-Plough subsequently strengthened the divestment undertaking.

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²³ Letter from Bell Gully to the Commerce Commission, 13 September 2007.

- 191. Commission enquiries found that many of the existing competitors had concerns about their ability to compete against Schering-Plough with what was perceived as the weaker of the two current campylobacter vaccines. A company's chances of competing favourably would be increased if it had an existing complementary product portfolio.
- 192. Of the existing participants in the animal health market in New Zealand, Pfizer, Fort Dodge, Virbac, Ancare and Bomac all have vaccine experience. None of these companies manufacture vaccines in New Zealand, but all supply vaccines to the New Zealand market.

Conclusion on Purchaser Risks

193. Although Schering-Plough is not constrained by its undertaking insofar as to whom it will sell Campylovexin, the Commission considers that it is not an asset that is likely to attract a stand-alone buyer. In addition, there is sufficient interest in the product by suitable buyers to satisfy the Commission that a suitable buyer is most likely to purchase the product. The Commission concludes that purchaser risk is low.

Asset Risks

- 194. The Commission spoke with a number of industry participants including veterinarians, existing competitors, and potential buyers in respect of the Campylovexin vaccine. Notwithstanding Campylovexin's reputation as a strong competitor in the campylobacter vaccine market, the Commission identified a number of asset risks which are discussed below.
- 195. A major asset risk is the potential for sales (and therefore market share) of Campylovexin to decline during the divestment period (between the acquisition and the completion of the divestment).
- 196. A decline in Campylovexin's market share and competitiveness during the divestment period might result from the following factors:
 - uncertainty in the market about the continued supply of Campylovexin;
 - a disincentive to promote or maintain the Campylovexin brand after acquiring control of Campyvax4; and
 - incentives for the combined entity to switch customers to Campyvax4.

Each of these factors is considered in further detail below.

- 197. The terms of the proposed divestment undertaking require Schering-Plough to divest the Campylovexin brand within [] months of acquiring 100 per cent of the shares of Organon BS or by [], whichever occurs earlier. The Commission considers that there are three phases of the proposed acquisition that would be likely to have a competitive impact on the campylobacter vaccine market:
 - after the clearance and prior to the acquisition, where both Campylovexin and Campyvax4 remain competitors, but uncertainty remains over the future of the Campylovexin brand;

- after the acquisition and prior to the divestment, where the combined entity has control over the Campylovexin and Campyvax4 brands; and
- following the divestment, where Campylovexin would be owned by another party.
- 198. The Commission has assessed the first two phases in respect of the factual, while the third phase is considered in the competition analysis.

After the Clearance and Prior to the Acquisition: Uncertainty about Campylovexin

- 199. As an undertaking has been given by Schering-Plough to sell Campylovexin to an unknown entity, some uncertainty as to the continued supply of Campylovexin may exist in the market.
- 200. Any uncertainty that does exist after clearance, but before the acquisition, will be mitigated by the fact that Schering-Plough has control of Campylovexin and has an incentive to maintain sales of the product during this time. The product is seasonal, with the purchase period peaking between December and March. Schering-Plough has stated that it "aims to have the vast majority of the season's first orders received and processed by the end of November." ²⁴

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After the Acquisition and Prior to the Divestment: Combined Entity's Incentives to Maintain Campylovexin

- 202. In a divestment situation, the combined entity could have conflicting incentives between obtaining the highest price for the divested business, and therefore preserving its present market share, and eroding the assets of the divested brand, thereby reducing its market share and the ability of a new owner to provide an effective competitive constraint. In addition, the divested brand could be unintentionally neglected while under the control of the combined entity, and may fail to enjoy the full support available to the combined entity's other brands.
- 203. The Commission considered whether there would be any incentive for the combined entity to erode the market share of the Campylovexin brand during the divestment period.
- 204. After the acquisition, the combined entity may have an incentive to reduce the level of service and marketing support for Campylovexin while under its control, instead promoting the Campyvax4 vaccine. This would encourage current users of Campylovexin to switch to Campyvax4. The Applicant may strategically choose to maintain the Campylovexin brand only to a level that ensures it is a saleable asset rather than investing additional resources to further develop the brand.
- 205. The Commission notes that Clause 8 of the divestment undertaking provides several assurances with respect to this risk (see Appendix 1). [

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²⁴ Letter from Bell Gully to the Commerce Commission, 2 October 2007.

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- 206. Schering-Plough makes several points with respect to this risk:
 - it has already incurred the cost of manufacture of all the Campylovexin product for the 2007/08 season and has budgeted for the forecast profit;
 - the marketing plan is agreed and finalised, and prices are supplied in mid-October to veterinarians; and
 - the marketing campaign for 2007/08 is aggressive and includes references to the negligible effect of *Campylobacter jejuni* (which Campyvax4 vaccinates against) vaccination on New Zealand farms.
- 207. Schering-Plough has also stated that it would be detrimental to its reputation if it did not maintain the Campylovexin brand pending divestment.²⁵
- 208. The Commission concludes that the various factors at play in this divestment situation serve to reduce the asset risk after the acquisition and prior to the divestment.

Conclusion on Asset Risks

- 209. The asset risk has been minimised by the terms of the divestment undertaking, to the extent that the Commission is satisfied that it is a small risk.
- 210. These risks are relevant to the Commission's assessment of the likelihood of the divested Campylovexin business constraining the combined entity, which is further discussed in the Existing Competition section below.

Conclusion on the Factual

- 211. In assessing the composition, purchaser, and asset risks, the Commission has reviewed all matters relevant to the divestment, considered how they relate to each other, and identified areas of uncertainty.
- 212. The terms of the proposed divestment undertaking offered by the Applicant go some way to ensuring that Campylovexin could be practically divested. The divestment undertaking includes all the necessary components for the successful operation of the Campylovexin business.
- 213. In respect of purchaser risks, the Commission considers that it is very unlikely that a weak buyer would purchase the Campylovexin brand. The companies that would be most likely to be interested in purchasing the brand would be established animal remedies companies, many of which have multi-national ownership.
- 214. Although any divestment remedy carries an inherent degree of risk, ²⁶ the asset risks have been greatly reduced by the terms of the divestment undertaking, including [] and by the assurances provided in Clause 8 (see Appendix 1).
- 215. The risks discussed above will be taken into account in the following Competition Analysis section.

²⁶ European Commission, *Merger Remedies Study*, Public Version, October 2005; and Competition Commission, *Application of Divesture Remedies in Merger Inquiries: Competition Commission Guidelines*, December 2004.

²⁵ Letter from Bell Gully to the Commerce Commission, 13 September 2007.

- 216. The Commission considers the factual would be that the Campylovexin brand would be:
 - sold with an asset base as a going concern, and sales resumed by the new owner []; and
 - sold to a business currently involved in the animal remedies industry.

COMPETITION ANALYSIS

The Market for Intramammary (Mastitis) Treatments for Dry Cows

Existing Competition

- 217. Existing competition occurs between those businesses in the market that already supply the product, and those that could readily do so by adjusting their productmix (near competitors).
- 218. An examination of concentration in a market can provide a useful indication of the competitive constraints that market participants may place upon each other, providing there is not significant product differentiation. Moreover, the increase in seller concentration caused by a reduction in the number of competitors in a market by an acquisition is an indicator of the extent to which competition in the market may be lessened.
- 219. A business acquisition is considered unlikely to substantially lessen competition in a market where, after the proposed acquisition, either of the following situations exist:
 - the three-firm concentration ratio (with individual firms' market shares including any interconnected or associated persons) in the relevant market is below 70%, the combined entity (including any interconnected or associated persons) has less than in the order of 40% share; or
 - the three-firm concentration ratio (with individual firms' market shares including any interconnected or associated persons) in the relevant market is above 70%, the market share of the combined entity has less than in the order of 20%.
- 220. The Commission has estimated market shares in each of the relevant markets by sales value, using sales data for 2006 obtained from industry participants. The sales data represent ex-factory sales to veterinarians and rural resellers.
- 221. Table 1 shows the estimated market shares for the market for intramammary treatments for dry cows. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is outside the Commission's safe harbour guidelines. However, the level of aggregation is relatively low, at only [].

Table 1: Market Shares for the Dry Cow Intramammary Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Boehringer Ingelheim	[]	[]
Bomac	[]	[]
Jurox	[]	[]
Norbrook	[]	[]
Parnell	[]	[]
Pfizer	[]	[]
Virbac	[]	[]
Total	[]	100

Source: Information provided by market participants

- 222. There are a number of existing competitors in the dry cow intramammary market, although many of them have small market shares relative to that of the combined entity. Only Pfizer and Bomac have a substantial market share, which will impose some constraint on the pricing of the combined entity. Nonetheless, after the acquisition, the market shares of Pfizer and Bomac will be [] the share of the combined entity.
- 223. Schering-Plough's dry cow intramammary product Cepravin, which is a long-acting product, is considered by many industry participants to be the market leader across all dry cow intramammary products. Some market participants expressed concern that the proposed acquisition would lead to Schering-Plough enhancing its already strong position in the market, even though the level of aggregation is low.

Conclusion on Existing Competition

224. The Commission considers that in the dry cow intramammary market, the combined entity would be constrained to some extent by existing competition, particularly Pfizer and Bomac. However, this constraint on its own may not be sufficient to prevent a substantial lessening of competition.

Potential Competition

225. An acquisition is unlikely to result in a substantial lessening of competition in a market if the businesses in that market continue to be subject to real constraints from the threat of market entry. The Commission's focus is on whether businesses would be able to enter the market and thereafter expand should they be given an inducement to do so, and the extent of any barriers they might encounter should they try.

Barriers to Entry

226. The likely effectiveness of the threat of new entry in preventing a substantial lessening of competition in a market following an acquisition is determined by the nature and effect of the aggregate barriers to entry into that market. The Commission is of the view that a barrier to entry is best defined as anything that

- amounts to a cost or disadvantage that a business has to face to enter a market that an established incumbent does not face.
- 227. The Commission has identified the following as the key requirements for entry into the market for dry cow intramammaries:
 - product research and development;
 - establishing Good Manufacturing Practice (GMP) manufacturing facilities;
 - sourcing product ingredients;
 - testing the safety and efficacy of the product;
 - registration of the product with the New Zealand Food Safety Authority (NZFSA) Agricultural Compounds and Veterinary Medicine (ACVM) Group;
 - manufacturing; and
 - marketing and distribution.
- 228. The entry requirements are similar for other animal health pharmaceuticals. The following entry analysis is thus generally applicable to all the other animal health pharmaceutical markets in the present acquisition (which covers all the relevant markets identified in the present acquisition, with the exception of the market for campylobacter vaccines for sheep), although the focus at this point remains on the market for dry cow intramammary treatments.
- 229. The extent to which product research and development represents a barrier to entry will depend on whether the product is novel or generic. A novel product is one which is based on original research into an active substance or combination of active substances, while a generic product is essentially a copy of a novel product and its (off-patent) active substance(s). A novel product would require a significant investment in research and development, which is likely to act as a high entry barrier. Indeed, Fort Dodge stated that [
 -]. In contrast, developing a generic product requires very little in the way of research and development investment, as the formulations of existing novels formulations are readily available and can be easily copied (provided the novel product is off-patent).
- 230. Schering-Plough submitted that establishing a manufacturing facility for an animal health pharmaceutical in New Zealand is not a high entry barrier, as the cost is not great and a facility could be established within six to nine months for plant and equipment, and 18 months for all necessary approvals and validations. NZFSA estimates that the most recent sterile manufacturing facility built in New Zealand, by South Pacific Sera, took two years to design and get approved (although it was a relatively innovative design), one year to build and about six to nine months to validate.
- 231. A manufacturing facility must be approved and validated as being compliant with the standard for GMP, as assessed by NZFSA. GMP requires that all manufacturing and testing equipment has been qualified as suitable for use, and that all operational methodologies and procedures (such as manufacturing, cleaning, and analytical testing) utilised in the drug manufacturing process have been validated, to demonstrate that they can perform their purported function(s).

- The GMP approval itself by NZFSA is a relatively quick process, which usually takes between two and four days provided NZFSA has been involved during the development of the facility. Validation that the facility works as it is purported to do can be a longer process, with NZFSA stating that Schering-Plough's Upper Hutt manufacturing facility, for example, took 18 months to validate.
- 232. It is not necessary for an entrant to have its own manufacturing facility, as entry could be achieved by having the product toll manufactured by an existing manufacturer, based either in New Zealand or overseas. Such arrangements are relatively commonplace in the animal health industry, and appear to be relatively straightforward to establish, at least in the case of animal health pharmaceuticals.
- 233. Sourcing product ingredients is not considered to be a high barrier to entry. Schering-Plough submits that access to raw materials is not difficult, with the ingredients for many products able to be sourced from China. Colin Harvey, of Ancare, stated that a company would need the right contacts to source product ingredients, but having those contacts is just part of being in the animal health industry.
- 234. All animal health products imported, manufactured, sold or used in New Zealand must be registered with NZFSA under the Agricultural Compounds and Veterinary Medicines Act 1997. Registration requires submission of a data package to be assessed by NZFSA. This package sets out technical and scientific data, including, among other things, data relating to the:
 - chemical formulation of the product;
 - manufacturing process;
 - safety of the product in the target animal;
 - efficacy of the product; and
 - product's compliance with maximum residue limits.
- 235. In Decision 496, the Commission noted that industry participants indicated the costs and timeliness of testing lactating cow intramammary products were not significant. The same is likely to be the case for dry cow intramammary treatments, although the testing requirements for a novel product may be more onerous. The Commission understands that the testing requirements (in the registration process with NZFSA) for generic products can often be cross-referenced to the testing of the novel product on which the generic is based.
- 236. NZFSA's assessment of the registration package itself is generally not considered to be particularly onerous in terms of either time or cost. NZFSA stated that it aims to complete the process in 40 working days for a generic product and 75 working days for a novel product. The cost is based on an hourly rate, but the total charge is typically in the range of \$5,000 to \$7,000. The Commission is of the view that registration is thus a relatively low barrier to entry.
- 237. In relation to marketing a product and building market share, one market participant noted that branding may act as an entry barrier, in that a generic entrant may struggle against established brands. Nonetheless, the success of companies such as Ancare and Stockguard, which supply generic products, shows that this barrier can be overcome.

238. Some industry participants suggested that access to distribution channels can be difficult, as veterinarians and rural resellers tend to stock only their preferred brands or look for suppliers able to offer a wide range of products across different markets. This may act as a relatively high barrier to entry for a de novo entrant with a few or no existing animal health products.

Conclusion on Barriers to Entry

239. The Commission concludes that, overall, the barriers to entry in the dry cow intramammary market (and in other animal health pharmaceutical markets more generally) are relatively low, at least for a generic product. The largest barrier is likely to be establishing a manufacturing facility, although this is not a necessary requirement as toll manufacturing is reasonably common for pharmaceutical products. Barriers to entry for a novel product appear to be higher, largely due to the significant investment required in research and development and testing.

The "LET" Test

- 240. In order for market entry to be a sufficient constraint, entry of new participants in response to a price increase or other manifestation of market power must be:
 - Likely in commercial terms;
 - sufficient in Extent to cause market participants to react in a significant manner; and
 - Timely, i.e. feasible within two years from the point at which market power is first exercised.

Likelihood of Entry

- 241. A number of market participants have stated that they are always looking for opportunities to enter other markets that they are not already active in, and there are a number of existing animal healthcare companies without dry cow intramammary products that could be considered potential entrants.
- 242. Market investigations supported this observation. In particular, [

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243. More generally, there are numerous other examples of recent or impending entry into other animal health pharmaceutical markets by companies with an existing range of animal healthcare products. For example, Bomac has recently launched a generic product in the lactating cow intramammary market, while [

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244. Accordingly, the Commission considers that entry is likely in the dry cow intramammary market after the acquisition, [].

Extent of Entry

245. The extent of entry into the dry cow intramammary market is likely to be dependent on the marketing of the product and the ability to overcome branding as an entry barrier. As noted earlier, generic products may struggle to build market share against established brands (although there are some companies which are counter-examples to this). Schering-Plough's dry cow product Cepravin is considered by many to be a strong brand in this market, which may limit the extent to which an entrant can gain market share.

246. Nonetheless, [

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247. The Commission therefore considers that entry into the dry cow intramammary market will be sufficient in extent.

Timeliness of Entry

248. Most market participants considered that entry into any animal health pharmaceutical market would be relatively timely, at least for a generic product. For example, Bomac's recent launch of a lactating cow intramammary product took approximately [] years from concept to entry. [

] Fort Dodge estimated that a generic product would take approximately two years to enter the market, while a novel product would take approximately 10 years.

249. [

] Moreover, it is likely that a generic product could enter the market within the two year timeframe considered acceptable by the Commission. The Commission therefore concludes that entry into the dry cow intramammary market is likely to be timely.

Conclusion on Potential Competition

250. The Commission concludes that, after the acquisition, the combined entity would face some constraint from potential competition, []. This is because barriers to entry for generic products are relatively low, and entry is likely, sufficient in extent and timely.

Overall Conclusion on the Market for Intramammary (Mastitis) Treatments for Dry Cows

251. The Commission concludes that the proposed acquisition will not result in a substantial lessening of competition in the dry cow intramammary market. The combined entity would be constrained to some extent by existing competitors, particularly Pfizer and Bomac. The combined entity would also be constrained by potential competition [], and the threat of entry due to relatively low entry barriers for generic products.

The Market for Intramammary (Mastitis) Treatments for Lactating Cows

Existing Competition

252. Table 2 shows the estimated market shares for the market for intramammary treatments for lactating cows. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is inside the Commission's safe harbour guidelines.

Table 2: Market Shares for the Lactating Cow Intramammary Market

Company	2006 Revenue (\$)	Market Share (%)	
Schering-Plough	[]	[]	
Intervet	[]	[]	
Combined Entity	[]	[]	
Boehringer Ingelheim	[]	[]	
Norbrook	[]	[]	
Pfizer	[]	[]	
Stockguard	[]	[]	
Virbac	[]	[]	
Total	[]	100	

Source: Information provided by market participants

Conclusion on Existing Competition

253. Given the low level of aggregation that would occur and the constraint from existing competitors, the Commission is satisfied that there is unlikely to be a substantial lessening of competition in the lactating cow intramammary market as a result of the proposed acquisition. Thus, the Commission does not consider it necessary, for the purposes of the present Application, to consider other constraints that may be present.

The Market for Antimicrobials for Ruminant Animals

Existing Competition

254. Table 3 shows the estimated market shares for the market for antimicrobials for ruminant animals. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is inside the Commission's safe harbour guidelines.

Table 3: Market Shares for the Antimicrobials for Ruminant Animals Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Boehringer Ingelheim	[]	[]
Bomac	[]	[]
Jurox	[]	[]
Norbrook	[]	[]
Pfizer	[]	[]
Stockguard	[]	[]
Virbac	[]	[]
Total	[]	100

Source: Information provided by market participants

Conclusion on Existing Competition

255. The Commission is satisfied that there is unlikely to be a substantial lessening of competition in the market for antimicrobials for ruminant animals as a result of the proposed acquisition, due to a significant constraint from existing competitors and the low level of aggregation. Thus, the Commission does not consider it necessary, for the purposes of the present Application, to consider other constraints that may be present.

The Market for Prostaglandins

Existing Competition

256. Table 4 shows the estimated market shares for the prostaglandins market. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is outside the Commission's safe harbour guidelines.

Table 4: Market Shares for the Prostaglandins Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Jurox	[]	[]
Parnell	[]	[]
Pfizer	[]	[]
Total	[]	100

Source: Information provided by market participants

- 257. The prostaglandins market is relatively concentrated, with only a small number of competitors. After the acquisition, the combined entity would have the [market share. However, it would be constrained to some degree by existing competitors, particularly Parnell, which has over [] share of this market, and Pfizer, which are both strong competitors.
- 258. Bomac has also recently entered the market with the prostaglandin product Ovuprost. This product did not enter the market until 2007 and thus is not shown in the market share data in Table 4. However, Bomac is expecting to generate sales revenue of approximately [] from this product in 2007 [], which would give it a significant market share to further constrain the merged entity.

Conclusion on Existing Competition

259. In conclusion, the Commission is satisfied that there is unlikely to be a substantial lessening of competition in the prostaglandins market as a result of the proposed acquisition, due to a significant constraint from existing competitors. Thus, the Commission does not consider it necessary, for the purposes of the present Application, to consider other constraints that may be present.

The Market for Ectoparasiticides for Cattle

Existing Competition

260. Table 5 shows the estimated market shares for the market for ectoparasiticides for cattle. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is outside the Commission's safe harbour guidelines.

Table 5: Market Shares for the Ectoparasiticides for Cattle Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Ancare	[]	[]
Bayer	[]	[]
Fort Dodge	[]	[]
Jurox	[]	[]
Virbac	[]	[]
Total	[]	100

Source: Information provided by market participants

- 261. After the acquisition, the combined entity will have the largest share of this market. However, it is likely to face some constraint on its ability to raise prices after the acquisition, particularly from Ancare, and to a lesser extent from Bayer and Fort Dodge. All three of these companies sell lice-only ectoparasiticides for cattle, but as noted in paragraph 138, these products are likely to constrain the pricing of the combined entity's combination fly/lice products.
- 262. Ravensdown is a new entrant into this market with the product Cattle Lice Pouron, which is a combination fly/lice treatment. [

] On this evidence, the presence of Ravensdown is likely to place another constraint on the combined entity.

- 263. Further, there is likely to be an additional constraint from endectocides, which treat both external and internal parasites. While for the present acquisition the Commission considered that the competition effects are best analysed without endectocides included in the relevant market, the Commission found evidence to suggest such products are nonetheless a significant constraint.
- 264. A number of market participants stated that there has been a trend towards endectocides replacing ectoparasiticides for cattle, and that there is relatively little price difference between endectocides and ectoparasiticides/endoparasiticides purchased separately. Quantitative evidence also supports this proposition. For example, on an analysis of [] sales data of cattle ectoparasiticides and

- endectocides, sales of the former decreased by an average of [] per annum from 2003 to 2006, while sales of the latter increased by an average [] per annum over the same period.
- 265. The market for cattle endectocides is large relative to the cattle ectoparasiticides market, with approximately [] in annual sales in 2006 compared to approximately [] for cattle ectoparasiticides. There are a number of strong players with cattle endectocide products, including Ancare and Merial, with annual sales of endectocides of [] and [] respectively. These companies will place an additional constraint on the pricing of the combined entity's ectoparasiticide products.

Conclusion on Existing Competition

266. The Commission concludes that the proposed acquisition will not result in a substantial lessening of competition in the market for ectoparasiticides for cattle. The combined entity would be constrained by existing competitors, particularly Ancare, Bayer and Fort Dodge. The combined entity would also be constrained by a number of strong competitors with endectocide products.

The Market for Ectoparasiticides for Sheep

Existing Competition

267. The estimated market shares in the market for ectoparasiticides for sheep are shown in Table 6. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is outside the Commission's safe harbour guidelines.

Table 6: Market Shares for the Ectoparasiticides for Sheep Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Ancare	[]	[]
Bayer	[]	[]
Jurox	[]	[]
Novartis	[]	[]
Total	[]	100

Source: Information provided by market participants

- 268. While the combined entity faces only four competitors in this market, three are relatively strong players, each with a market share in excess of []. Further, each of these participants has a number of differentiated products in this market, which could be positioned to compete against the combined entity. Novartis has seven products, Ancare has six and Bayer has four, while the combined entity will have seven products.
- 269. No concerns were expressed by industry participants regarding competition in this market as a result of the proposed acquisition.

Conclusion on Existing Competition

270. In conclusion, the Commission is of the view that the proposed acquisition will not result in a substantial lessening of competition in the market for ectoparasiticides for sheep. The combined entity would be constrained by existing competitors, particularly Ancare, Bayer and Novartis, which make up a large share of the market.

The Market for Endoparasiticides for Sheep

Existing Competition

271. Table 7 shows the estimated market shares for the market for endoparasiticides for sheep. After the acquisition, the combined entity would have a market share of [] and the three-firm concentration ratio would be []. This is inside the Commission's safe harbour guidelines. The level of aggregation is also low, with Schering-Plough increasing its market share by only [] after the acquisition.

Table 7: Market Shares for the Endoparasiticides for Sheep Market

Company	2006 Revenue (\$)	Market Share (%)
Schering-Plough	[]	[]
Intervet	[]	[]
Combined Entity	[]	[]
Ancare	[]	[]
Bomac	[]	[]
Fort Dodge	[]	[]
Jurox	[]	[]
Merial	[]	[]
Norbrook	[]	[]
Novartis	[]	[]
Ravensdown	[]	[]
Virbac	[]	[]
Total	[]	100

Source: Information provided by market participants

Conclusion on Existing Competition

272. Given the low level of aggregation and the presence of a number of strong competitors, the Commission concludes that the proposed acquisition will not result in a substantial lessening of competition in the market for endoparasiticides for sheep.

The Market for Campylobacter Vaccines for Sheep

Existing Competition

273. In the market for campylobacter vaccines for sheep, in the factual scenario the combined entity would divest the Campylovexin product while retaining the Campyvax4 product. Table 8 sets out the product shares and revenues for the two campylobacter vaccines from 2004-2007.

Table 8: Market Shares for Campylobacter Vaccines 2004-2007

	Campylovexin		Campyvax3/4	
Year to 30 June	Market share	Revenue (\$)	Market Share	Revenue
2004	[]	[]	[]	[]
2005	[]	[]	[]	[]
2006	[]	[]	[]	[]
2007	[]	[]	[]	[]

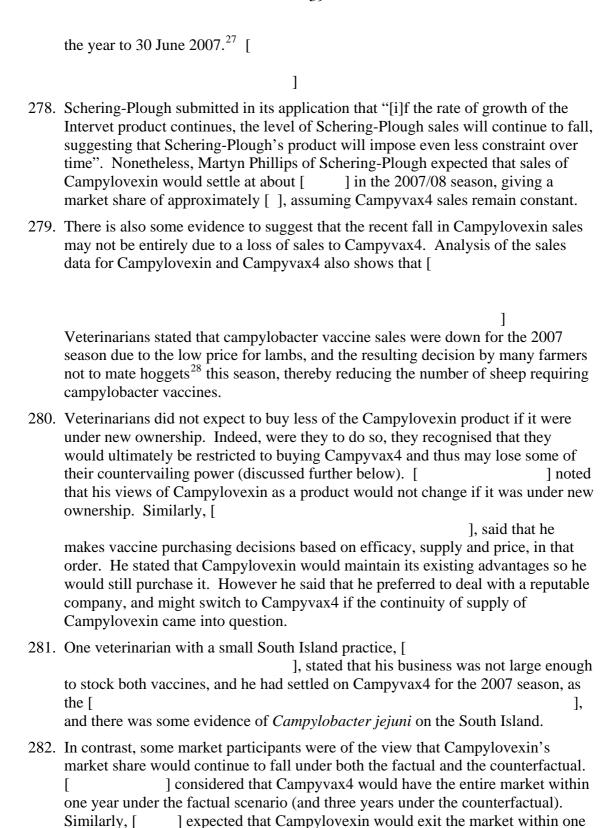
Source: Information provided by Schering-Plough and Intervet

- 274. Absent the divestment, the combined entity would have 100% of this market, and thus the constraint from existing competitors would be lost. However, in assessing the present Application, the Commission considers the factual to be the proposed acquisition with the divestment of Campylovexin. While an existing competitor therefore remains in this market, the Commission needs to consider whether that competitor will place sufficient constraint on the combined entity such that it is unlikely a substantial lessening of competition will occur in the factual relative to the counterfactual.
- 275. To assess the extent of this constraint, the Commission has considered the ability of the purchaser of Campylovexin to maintain and expand sales. In particular, the Commission has considered:
 - how market share would hold up after divestment;
 - the relative strength of the Campylovexin brand;
 - the ability of the Campylovexin purchaser to compete by bundling across product lines;
 - the ability of the Campylovexin purchaser to compete through volume-based rebates:
 - the ability of the Campylovexin purchaser to invest in research and development relating to the product; and
 - disadvantages faced by the purchaser of Campylovexin.

The following sections discuss each of these aspects in more detail.

Changes in Market Share

- 276. It is difficult to assess what would be likely to happen to market shares for Campylovexin under new and separate ownership of the product. However, the Commission has assessed recent changes in market share of the product under Schering-Plough's ownership, and evidence from veterinarians on expected changes.
- 277. Schering-Plough stated in its Application that, in the year since the introduction of Campyvax4, Intervet has rapidly grown sales. Table 8 shows the recent change in market shares for each product, calculated by sales revenue in each year to 30 June over the last four years. It should be noted that Campyvax3 was introduced in December 2003, and replaced by Campyvax4 in November 2005. The market share of Campylovexin has fallen from [] in the year to 30 June 2004, to [] in



²⁷ Note that figures are based on June years, as the most recent data were available to June 2007. Thus the market shares for 2006 are not directly related to the figures based on the 2006 calendar year in the preceding tables for the other relevant markets. Also, the year to 30 June 2004 for sales of Campyvax3 commenced in December 2003, when Campyvax3 was first introduced. ²⁸ Lambs are considered hoggets in their second spring or summer.

season under the factual scenario. [

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- 283. Despite these comments, the Commission is not convinced that there is evidence to show that the market shares of Campylovexin will materially decline in the factual. The Commission considers that, due to the healthy profit margins of [] currently earned by Schering-Plough on Campylovexin, there would be room for a new owner to lower the price and compete more on price for market share. Furthermore, the veterinarians, as purchasers of the vaccines, have indicated that they would support Campylovexin under new ownership, providing supply, quality and price were competitive.
- 284. In conclusion, it is not certain how Campylovexin's market share will hold up under new ownership and there are conflicting views. On balance the Commission's view is that there is sufficient evidence to suggest that Campylovexin will continue to impose a competitive constraint on Campyvax4.

Brand Reputation

- 285. In its letter related to the divestment offer dated 13 September 2007, Schering-Plough submitted that Campylovexin is "well recognised and has been present in the New Zealand market for many years", and also that it is "a well known and trusted brand".
- 286. Some industry participants expressed similar sentiments regarding Campylovexin's brand reputation. For example, Tony Brenton-Rule, former founding CEO of AgVax, noted that Campylovexin is a strong brand that competes strongly with Campyvax4.
- 287. Veterinarians with large practices stated that the product has been in the market for a long time, and on those farms where it has worked over the years, and absent a favourable price differential, there has been no incentive to switch to Campyvax4. Campylovexin is seen as a reliable brand.

Bundling and Rebates

- 288. Commission investigations revealed that many animal health companies bundle the supply of their products to veterinarians and rural resellers, in the sense that the supplier offers a range of products across multiple categories (intramammaries, antibiotics, parasiticides, vaccines, etc³⁰). The pricing of these products, including any rebate scheme, is then tied to the bundle of products rather than individual product categories. This benefits veterinarians and rural resellers as they are able to source a variety of products from only one or a small number of suppliers, thereby lowering transaction costs.
- 289. A number of market participants noted that Schering-Plough has a strong rebate programme with veterinarians and that this may create a barrier to the purchaser

²⁹ [

- of Campylovexin maintaining or expanding market share, in that it would not be able to match the discounts offered on Schering-Plough's bundle of products (which under the factual would include Campyvax4).
- 290. Veterinarians are likely to value variety of products, such that they can prescribe different products based on their relative advantages and disadvantages. Schering-Plough's rebates therefore do not explicitly exclude veterinarians from purchasing Campylovexin from the acquirer of this product.
- 291. There is evidence to suggest veterinarians currently stock both campylobacter vaccines, despite Schering-Plough's rebate programme. Ian Walker, of Vet Services Hawkes Bay, stated that his practice uses both products, [

The Commission notes, however, that whether or not a vet will continue to stock Campylovexin in the factual scenario may depend to some extent on the reputation or strength of the new supplier.

- 292. This bundling strategy may act as a barrier to maintaining or expanding market share to the purchaser of Campylovexin, thus reducing the extent to which the purchaser can compete against Campyvax4. Indeed, under the factual, the combined entity would offer a wide range of products across a number of different markets, and thus would be able to offer a bundled package to veterinarians that includes Campyvax4.
- 293. However, the extent to which this is a constraint depends on whether the purchaser also has a range of other products. Many potential acquirers of Campylovexin already supply a wide range of animal health products, and could easily compete via bundling across markets. In contrast, a stand-alone purchaser of Campylovexin, or a purchaser with only a small number of products, would be unlikely to be able to use bundling to compete against the combined entity.
- 294. The Commission considers it likely that a purchaser of Campylovexin could compete via bundling.

Investment in Research and Development

295. [

] This would suggest that it is worth assessing whether the need to invest in research and development would constrain the purchaser of Campylovexin from competing in the factual.

296. Schering-Plough's divestment offer includes all the necessary intellectual property rights relating to Campylovexin, so this will not act as a constraint on the purchaser. Nonetheless, [

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297. The divestment also includes all the master seeds for *Campylobacter fetus fetus* used in the production of Campylovexin. These could be used as an input into any research and development that aims to build on and improve the existing vaccine.

However, [

]

298. The Commission is of the view that the likely purchasers of Campylovexin would not be constrained by the need to invest in research and development.

Other Constraints on the Divested Business' Ability to Compete

- 299. The new owner of Campylovexin, whether complementary or stand-alone, would also face other disadvantages to maintaining and expanding sales because the combined entity:
 - would hold commercially sensitive trading information about Campylovexin; and
 - would own Campyvax4 and benefit from the experience of previous manufacture.
- 300. The Commission considers that these disadvantages would place some constraint, albeit not significant, on the purchaser of Campylovexin to compete against the combined entity.

Conclusion on Existing Competition

301. The Commission considers that Schering-Plough could easily switch customers from Campylovexin to Campyvax4 following the divestment if there was no change in the pricing or composition of Campylovexin. However, the Commission considers that [] of Campylovexin, such that a new owner could still compete and constrain Campyvax4. Campylovexin is viewed by veterinarians as a trusted brand, and the likely purchasers could compete across existing broad product ranges, and invest in further developing the product if required.

Countervailing Power

- 302. In some circumstances the potential for the combined entity to exercise market power may be sufficiently constrained by a buyer or supplier to eliminate concerns that an acquisition may lead to a substantial lessening of competition.
- 303. Campylobacter vaccines in New Zealand are only sold through veterinarians. Many veterinarians are relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry. For example, Veterinary Enterprises Limited, [] has seven veterinarian practices and an approximate annual turnover of \$23 million.³¹
- 304. Under the factual, veterinarians have two different suppliers of campylobacter vaccines: the combined entity and the purchaser of Campylovexin. [

] believed that his company did have buyer power over the suppliers, and that there were other large veterinarian groups or practices that would have similar countervailing power. Other veterinarians spoken to by the Commission said that the availability of both products was important as it allows them to play one off the other.

³¹ See http://www.vetent.co.nz/profile.htm

Conclusion on Countervailing Power

305. The Commission concludes that veterinarians, many of whom have significant buying power, would have sufficient countervailing power to constrain the combined entity from exercising market power in the counterfactual, due to the presence of an alternative supplier of a campylobacter vaccine for sheep.

Overall Conclusion on the Market for Campylobacter Vaccines for Sheep

306. The Commission concludes that, following the divestment, the combined entity will face constraint from the new owner of the Campylovexin vaccine and from the countervailing power of veterinarians.

OVERALL CONCLUSION

- 307. The Commission considers that the counterfactual is the status quo. In relation to the market for campylobacter vaccines for sheep, this means that the two companies with these vaccines would continue to compete vigorously. In the remaining markets, competition would continue at its current levels.
- 308. The Commission has considered the probable nature and extent of competition that would exist, subsequent to the proposed acquisition, in the relevant markets.
- 309. Divestment of Schering-Plough's campylobacter vaccine for sheep, Campylovexin, will ensure that existing competition remains to constrain the combined entity in the factual scenario in this market. In the market for intramammary treatments for dry cows, the combined entity will be constrained by existing and potential competition. In the markets for intramammary treatments for lactating cows, antimicrobials for ruminant animals, prostaglandins, ectoparasiticides for cattle, ectoparasiticides for sheep and endoparasiticides for sheep, the combined entity would be constrained by existing competition.
- 310. The Commission is therefore satisfied that the proposed acquisition would not have, nor be likely to have, the effect of substantially lessening competition in any market.

DETERMINATION ON NOTICE OF CLEARANCE

311. Pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance for the proposed acquisition by Schering-Plough Corporation of 100 percent of the shares in, or assets of, Organon BioSciences N.V., subject to the divestment undertaking dated 1 October 2007 provided by Schering-Plough Corporation to the Commission pursuant to section 69A of the Commerce Act 1986.

Dated this 4th day of October 2007

David Caygill Division Chair Commerce Commission

Appendix 1: Schering-Plough's Proposed Divestment Undertaking

DIVESTMENT UNDERTAKING PURSUANT TO SECTION 69A OF THE COMMERCE ACT 1986

- On 12 March 2007, Schering-Plough made an irrevocable offer to Akzo Nobel N.V. (Akzo) to
 enter into a share purchase agreement with Akzo, pursuant to which Schering-Plough will acquire
 100 per cent of the shares of Organon BioSciences N.V. (Organon BS), a wholly owned
 subsidiary of Akzo (the Agreement). Intervet is the animal health business of Organon BS.
- On 5 July 2007, Schering-Plough gave notice to the Commerce Commission (the Commission) pursuant to section 66(1) of the Commerce Act 1986 (the Act) seeking clearance to acquire 100 per cent of the shares in, or assets of, Organon BS or any interconnected body corporate of Organon BS (the Notice).
- Pursuant to section 69A of the Act, in giving a clearance under section 66(1), the Commission
 may accept a written undertaking given by or on behalf of the person seeking such clearance to
 dispose of assets or shares specified in the undertaking.
- 4. Subject to the conditions described in paragraph 7 of this undertaking, Schering-Plough undertakes to:
 - (a) divest, or procure the divestiture of, the Campylovexin business insofar as it relates to New Zealand (the Campylovexin Business) as a going concern to a purchaser which is not an interconnected body corporate (as defined by section 2(7) of the Act) or an associated person (as defined by section 47(3) of the Act) of Schering-Plough (the Purchaser), within

, whichever occurs earlier. Such divestment will proceed by way of an asset transaction, including transfer, sale, assignment and/or licence as the case may be and in so far as legally permissible. The divestment shall include, to the extent they are necessary to conduct the Campylovexin Business:

- all tangible and intangible assets (including the relevant intellectual property rights), by way of transfer, sale, assignment or licence, which are necessary to ensure the viability and competitiveness of the Campylovexin Business;
- all licences, permits and authorisations issued by any governmental organisation for the benefit of the Campylovexin Business;
- (iii) all contracts, commitments and customer orders;
- (iv) all customer, credit and other records,

(the Assets); and

- (v) at the option of the Purchaser, the benefit, for a transitional period of
 the sale of the Campylovexin Business to the Purchaser
 (Completion) and on terms and conditions equivalent to those at present afforded to
 the Campylovexin Business, of all current arrangements under which ScheringPlough or its interconnected bodies corporate supply Campylovexin, and/or
 reasonable technical assistance to the Purchaser to assume responsibility for the
 manufacture, sale and marketing of the Campylovexin Business for such period as is
 required by the Purchaser to establish the Campylovexin Business as a viable and
 independent business, but not exceeding
- 5. The undertaking at 4(a)(v) above includes the entry into, by Schering-Plough or an interconnected body corporate of Schering-Plough, at the option of the Purchaser, a supply or toll-manufacturing arrangement with the Purchaser for the supply or toll-manufacturing of Campylovexin in New Zealand for an appropriate period of time, not to exceed

on a reasonable cost plus basis to be agreed with the Purchaser.

- In exceptional circumstances, and at the option of the Purchaser, Schering-Plough will extend the
 period referred to in 4(a)(v) and 5 above for a further
 months.
- For the avoidance of doubt, the divestment of the Campylovexin Businesses shall not, inter alia, include:
 - (a) any manufacturing facilities of Schering Plough;
 - (b) any personnel of Schering-Plough;
 - (c) intellectual property rights which do not contribute to the current operation or are not necessary to ensure the viability, marketability and competitiveness of the Campylovexin Business;
 - (d) the Schering-Plough, Akzo Nobel, Organon BioSciences, and Intervet names and logos in any form, or the right to use any packaging format, style or colour that is the same or substantially similar to that used by Schering-Plough in respect of any other product;
 - (e) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that copies of such documents necessary for the Campylovexin Business shall be provided to the Purchaser, upon request; and
 - (f) general books of account and books of original entry that comprise Schering Plough's permanent accounting or tax records, provided that copies of such documents necessary for the Campylovexin Business shall be provided to the Purchaser, upon request.
- 8. Pending divestment, Schering-Plough will:
 - (a) use reasonable endeavours to operate the Campylovexin Business as a viable business;
 - (b) preserve the economic viability, marketability and competitiveness of the Campylovexin Business in accordance with good business practice; and
 - (c) minimise as far as possible any risk of loss of competitive potential for the Campylovexin Business, and in particular:
 - commits to provide the same level of technical and sales support as is currently afforded to the Campylovexin Business;
 - (ii) commits to implement the proposed marketing campaign for Campylovexin for the 2007/08 season and will, and will procure that its sales representatives will, follow that campaign through to its fullest extent:
 - (iii) will not actively solicit sales for the 2008/09 season over and above what would be expected in the normal course of business; and
 - (iv) will not interfere with the current arrangements for bonuses paid to sales representatives insofar as those bonuses relate to sales of Campylovexin, and will not do anything that would otherwise be likely to influence its sales representatives' incentives to sell Campylovexin.
- The provisions of this undertaking are subject to the Agreement becoming unconditional and to the Commission granting a clearance to the Notice.

DATED this 1st day of 0 = 2007

Signed for and on behalf of Schering-Plough Corporation by:

Thomas J. Sabatino, Jr.

Executive Vice President and General Counsel

Schering-Plough Corporation