Public Competition Assessment

18 November 2009

Pfizer Inc - proposed acquisition of Wyeth Corp

INTRODUCTION

1. On 30 September 2009, the Australian Competition and Consumer Commission (**ACCC**) announced its decision not to oppose the proposed acquisition of Wyeth Corp (**Wyeth**) by Pfizer Inc (**Pfizer**) (the **proposed acquisition**), subject to a section 87B undertaking offered by Pfizer and accepted by the ACCC on 30 September 2009 (the **undertaking**). The ACCC was of the view that the proposed acquisition, when considered in light of the undertaking, would be unlikely to have the effect of substantially lessening competition in any relevant market in contravention of section 50 of the *Trade Practices Act 1974* (the **Act**).

2. The ACCC formed its view on the basis of the information provided by the merger parties and information arising from its market inquiries. This Public Competition Assessment outlines the basis on which the ACCC has reached its decision on the proposed acquisition, subject to confidentiality considerations.

PUBLIC COMPETITION ASSESSMENT

3. To provide an enhanced level of transparency and procedural fairness in its decision making process, the ACCC issues a Public Competition Assessment for all transaction proposals where:

   - a merger is opposed;
   - a merger is subject to enforceable undertakings;
   - the merger parties seek such disclosure; or
   - a merger is not opposed but raises important issues that the ACCC considers should be made public.

4. This Public Competition Assessment has been issued because Pfizer's proposed acquisition of Wyeth is subject to court enforceable undertakings.

5. By issuing Public Competition Assessments, the ACCC aims to provide the public with a better understanding of the ACCC's analysis of various markets and the associated merger and competition issues. It also alerts the public to the circumstances where the ACCC's assessment of the competition conditions in particular markets is changing, or likely to change, because of developments.

6. Each Public Competition Assessment is specific to the particular transaction under review by the ACCC. While some transaction proposals may involve the same or related markets, it should not be assumed that the analysis and decision outlined in one Public Competition Assessment will be conclusive of the ACCC's view in respect of other transaction proposals, as each matter will be considered on its own merits.

7. Many of the ACCC's decisions will involve consideration of both non-confidential and confidential information provided by the merger parties and market participants. In order to maintain the confidentiality of particular information, Public Competition Assessments do not contain any confidential information or its sources. While the ACCC aims to provide an appropriately detailed explanation of the basis for the ACCC decision, where this is not possible, maintaining confidentiality will be the ACCC's paramount concern, and accordingly a Public Competition Assessment may not definitively explain all issues and the ACCC's analysis of such issues.

THE PARTIES

The acquirer: Pfizer

8. Pfizer is a publicly owned global research and development company that produces prescription pharmaceuticals and animal health products. Its shares are listed on the New York, Euronext and Swiss stock exchanges.

9. In Australia, Pfizer's operations are conducted by Pfizer Australia Pty Limited. Pfizer discovers, develops, manufactures and markets prescription medicines and supplies a small number of consumer (over-the-counter) healthcare products.[1] Pfizer also offers a broad range of animal health products for livestock and companion animals. Pfizer has manufacturing facilities located in Australia, producing both human and animal health products.

10. Pfizer also imports both human and animal health products produced by its overseas manufacturing operations.

The target: Wyeth

11. Wyeth is a global research and development company that produces prescription pharmaceuticals, animal health and consumer healthcare products. It is listed on the

[1] The majority of Pfizer's consumer healthcare products were sold to Johnson and Johnson in 2006.

New York Stock Exchange.

12. Wyeth is active in the discovery, development, manufacturing and marketing of human pharmaceuticals, vaccines and consumer healthcare products. In Australia, Wyeth's human health business is operated by Wyeth Australia Pty Ltd. Wyeth imports products manufactured by its overseas operations, but does not manufacture human health products in Australia.

13. Wyeth's animal health business is operated in Australia by Fort Dodge Australia (**Fort Dodge**). Fort Dodge supplies products for livestock and companion animals. Fort Dodge's only manufacturing facility for animal health products in Australia is located in Penrith, New South Wales. Fort Dodge also imports animal health products produced by its overseas manufacturing operations.

Other market participants

14. Pharmaceutical manufacturers can be broadly categorised as being either 'innovator' or 'generic' companies. Innovator companies are those that focus on investing in research and development for the purpose of bringing new chemical molecules to market. Both Pfizer and Wyeth are innovator companies. Generic manufacturers make generic versions of existing products (that is, versions that use the same active ingredient or formulation) once the patent on the original active ingredient or formulation expires. Some innovator companies also manufacture generic brands of their own innovative pharmaceutical products.

15. There are several global pharmaceutical companies which manufacture and/or supply human healthcare products in Australia including AstraZeneca Plc (**AstraZeneca**), sanofi-aventis, Bayer AG (**Bayer**), Eli Lilly and Company (**Eli Lilly**), Roche Holding AG (**Roche**), GlaxoSmithKline plc (**GSK**), Novartis AG (**Novartis**), H. Lundbeck A/S **(Lundbeck)** and Merck & Co Inc **(Merck)**.[2] A number of these companies also have Australian based operations. Manufacturers of generic pharmaceuticals in Australia include Alphapharm, Sigma Pharmaceuticals Limited (**Sigma**) and Apotex Pty Ltd (**Apotex**).

16. There are several global research-based pharmaceutical companies which manufacture and/or supply animal health products in Australia, including Schering-Plough Corporation (**Schering-Plough**) (through Intervet Australia Pty Ltd (**Intervet**)), Virbac SA (**Virbac**), Boehringer Ingelheim Vetmedica Inc (**BI**), Merial Limited (**Merial**),[3] Novartis and Bayer.

17. Bioproperties Pty Ltd and Jurox Pty Ltd are both Australian-based companies which also supply animal health products.

[2] On 14 October 2009, the ACCC announced that it would not oppose Schering-Plough's proposed acquisition of Merck, subject to an undertaking offered by the parties pursuant to section 87B of the Act.
[3] Merial was a joint venture between Merck and sanofi-aventis. On 17 September 2009, Merck sold its interest to sanofi-aventis.

THE PROPOSED TRANSACTION

18. On 25 January 2009, Pfizer and Wyeth entered into an agreement under which Pfizer proposed to acquire Wyeth. The ACCC wrote to Pfizer in late January 2009 requesting a submission and advised of its intention to review the proposed acquisition. Following the receipt of a full submission from Pfizer on 29 May 2009 covering both human and animal health markets the ACCC commenced its public review of the proposed acquisition on 3 June 2009.

19. The proposed transaction was considered by a number of international competition agencies and the ACCC consulted with these agencies regarding the proposed acquisition and divestitures occurring at the international level.

TIMING

20. The following table outlines the timeline of key events in this matter.

Date	Event
3 June 2009	ACCC commenced review under the Merger Review Process Guidelines.
19 June 2009	Closing date for submissions from interested parties.
29 June 2009	ACCC announced that it would set an indicative decision date for its review upon receipt of a draft undertaking from Pfizer relating to a number of animal health products which Pfizer proposed to divest.
4 September 2009	Draft 87B undertaking proffered by Pfizer. ACCC commenced market inquiries on the draft undertaking.
11 September 2009	Closing date for submissions relating to draft 87B undertaking.
30 September 2009	ACCC announced it would not oppose the proposed acquisition, subject to court enforceable undertaking offered by Pfizer. Section 87B undertaking accepted by ACCC. The ACCC requested further information from Pfizer during this review, resulting in the timeline being suspended for 36 business days.

MARKET INQUIRIES

21. The ACCC conducted market inquiries with a range of industry participants, including competitors, customers, wholesalers, industry bodies, regulatory agencies and other interested parties. Submissions were sought in relation to the substantive competition issues and the proposed undertaking.

WITH/WITHOUT TEST

22. In assessing a merger pursuant to section 50 of the Act, the ACCC must consider

the effects of the transaction by comparing the likely competitive environment post-merger if the transaction proceeds (the "with" position) to the likely competitive environment post-merger if the transaction does not proceed (the "without" position).

23. The ACCC focuses on the foreseeable future when considering the future with and without the transaction, the market definition and any likely competitive harm attributable to the proposed acquisition.

24. At the same time as considering Pfizer's proposed acquisition of Wyeth, the ACCC also conducted a review of the proposed acquisition of Merck by Schering-Plough. With Merck's sale of its interest in Merial (see footnote 3), Merck's presence in animal health products disappeared. There are a number of product areas in animal health which Merck and Schering-Plough overlap with Pfizer and Wyeth.

25. Information presented to the ACCC confirmed that Schering-Plough's proposed acquisition of Merck was likely to be completed subsequent to, but shortly following, Pfizer's proposed acquisition of Wyeth. The completion of the Merck and Schering-Plough merger was not contingent on the outcome of the Pfizer-Wyeth merger and was likely to proceed independently of it. For this reason, the ACCC concluded that the competitive environment in both the "with" and "without" scenarios was likely to be characterised by a merged Merck and Schering-Plough.

26. The ACCC concluded that, in the absence of the proposed acquisition, Pfizer and Wyeth would continue to operate as viable, independent pharmaceutical businesses.

AREAS OF FOCUS

27. Given the nature of the operations of Pfizer and Wyeth, the ACCC considered that the broad product areas of relevance to the assessment of the likely competitive effect of the proposed acquisition were human health[4] and animal health products. These areas are dealt with separately below.

HUMAN HEALTH

Background

Research and development

28. Pharmaceutical research and development consists of several stages, beginning with drug discovery where new chemical molecules are discovered. Successful

[4] Pfizer manufactures and supplies a small number of consumer healthcare products; however, there is no overlap with the consumer (over-the-counter) healthcare products of Wyeth. Accordingly, in relation to human healthcare, the ACCC focussed on those prescription pharmaceuticals products where there is overlap between Pfizer and Wyeth.

chemical molecules from the discovery process are subjected to three stages of clinical trials, which test the molecules' effectiveness and side effects. Once a new chemical molecule is discovered the inventor will ordinarily apply for a patent which can provide protection from the use by competitors of the relevant active ingredient or formulation for up to 25 years.

Regulatory environment

29. The *Therapeutic Goods Act 1989* provides a national framework for the regulation of therapeutic goods[5] in Australia to ensure the quality, safety and efficacy of medicines and medical devices. Essentially, all therapeutic goods must be either listed or registered on the Australian Register of Therapeutic Goods (**ARTG**) before they can be supplied in Australia. The ARTG is administered by the Therapeutic Goods Administration (**TGA**). All prescription medicines are assessed as having a higher level of risk and must be registered on the ARTG. The registration process involves lodging an application, providing data which demonstrates safety, quality and efficacy of the product and payment of a registration fee.

30. Manufacturers of therapeutic goods must also be licensed by the TGA, and their manufacturing processes must comply with the Australian Code of Good Manufacturing Practice for Medicinal Products or an equivalent "Good Manufacturing Practice" (**GMP**) for overseas manufacturers.[6]

31. The Pharmaceutical Benefits Scheme (**PBS**) aims to provide reliable and affordable access to a wide range of medicines. The PBS entitles Australians who hold a Medicare card to receive medicines at a subsidised price. In determining whether a medicine should obtain listing on the PBS, the Pharmaceutical Benefits Advisory Committee considers the effectiveness and cost of a medicine compared to alternative therapies.[7] Generally, a pharmaceutical company will aim to have its pharmaceutical products listed on the PBS, as it would ordinarily be expected to result in higher sales volumes.

Market definition

32. The ACCC considered the effect of the proposed acquisition on markets for human health products where the parties supplied competing products.

33. The ACCC formed the view that there were separate national markets for the manufacture and supply of each of the following:

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[5] A therapeutic good is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use. Therapeutic goods include prescription medicines, consumer health care products, complementary medicines and medical devices.

[6] GMP describes a set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured are safe, reliable and of consistent high quality.

[7] http://www.health.gov.au.

- hormonal contraceptives, which includes combination and progestrogen-only oral contraceptive pills and long-term hormonal contraceptive products such as injectable hormones, implants, contraceptive rings and intrauterine devices;

- anti-depressants, which includes products used to treat Major Depressive Disorder and some anxiety disorders through a variety of mechanisms;

- metastatic renal cell carcinoma treatments (**mRCC treatments**); and

- anti-bacterial products that treat *vancomycin resistant Enterococcus sp*[8] (**anti-bacterials**).

34. In coming to the conclusion that each of these products constituted a distinct market, the ACCC considered the views of market participants and government regulators regarding the clinical use and treatment profile, the mechanism of action, the mode of administration and design, the active ingredient and the side effect profile. The ACCC considered that each of these factors influenced the substitution possibilities available to customers.

35. Other product areas relevant to the ACCC's assessment were anti-ulcerants and immunosuppressive agents.

36. As noted above, Pfizer's and Wyeth's products overlap in a number of the product areas described above (including mRCC treatments, anti-bacterials, anti-ulcerants and immunosuppressive agents); however, within these categories, the products of Pfizer and Wyeth exhibit distinguishing features in terms of the specific therapeutic application. In order to ensure that any potential anti-competitive effects associated with the proposed acquisition were adequately examined, the ACCC proceeded to examine the markets in a way that captured the products of both Pfizer and Wyeth in each product area. It is noted, however, that if a narrower approach to market definition were adopted, there would be unlikely to be any competitive overlap in relation to the products manufactured and supplied by Pfizer and Wyeth in these product categories. The significance of the degree of rivalry between Pfizer and Wyeth is examined where relevant in the competition analysis below.

37. In relation to the geographic scope of the market, the ACCC considered that, given that pharmaceutical manufacturers compete to market and supply products nationally, the appropriate basis on which to consider each of the product markets was national.

38. Pfizer and Wyeth also have a number of products in research and development (also referred to as 'pipeline products'). Given the potential for future competitive overlap, the ACCC considered it appropriate to assess the impact of the proposed

[8] Some bacteria have become resistant to treatment using an antibiotic which is commonly used in a hospital environment, Vancomycin. Such bacteria are collectively known as *vancomycin resistant Enterococcus sp*.

acquisition on products in the research and development stage. The ACCC's analysis focussed on those products that had progressed to Phase 3 clinical trials, where the likelihood of products entering the market in the foreseeable future is greatest.[9]

39. The product areas relevant to the ACCC's assessment in this regard were:

- rheumatoid arthritis treatments;
- Alzheimer's disease treatments;
- osteoporosis treatments; and
- oncology products.

40. The ACCC did not reach a concluded view on market definition in relation to these pipeline product areas because the competition analysis remains unchanged regardless of the market definition adopted.

Competition analysis

41. Generally, market participants did not raise competition concerns in relation to the human health markets affected by the proposed acquisition.

42. The ACCC considered that the proposed acquisition was unlikely to lead to a substantial lessening of competition in respect of any relevant human health market for the following reasons:

- remaining competitors, including those producing generic products, would continue to constrain the merged firm post- acquisition; and
- in a number of markets, the parties are not each other's closest competitors.

43. In the market for hormonal contraceptives, the ACCC formed the view that, while the merged firm would have a significant share of the market post-acquisition and that the proposed acquisition would result in the removal of a source of competitive constraint in the market, the merged firm would continue to be constrained by remaining competitors. In particular, the ACCC considered that the continued presence of the market leader, Bayer, would likely act as a significant constraint on the merged firm post-acquisition.

44. Additionally, given that most of the hormones used to manufacture hormonal

[9] A Phase 3 clinical trial is the final phase entered into prior to products being made available to the market. In a Phase 3 trial, the drug is tested on a larger population and further information is gathered about the effectiveness and safety of the experimental drug. Phase 3 trials generally form the basis for any benefit-risk assessment. Further testing (referred to as Phase 4) continues once the drug has been successfully brought to market.

contraceptives are no longer protected by patent, the ACCC considered that the merged firm would continue to be constrained by other manufacturers (including generic manufacturers). The absence of a significant degree of patent protection also lowers barriers to entry in the market for hormonal contraceptives.

45. Market inquiries further suggested that the products produced by each of the merger parties were no longer actively promoted and had been available on the market for some time, and neither Pfizer nor Wyeth were regarded as particularly innovative. Accordingly, the ACCC concluded that the proposed acquisition of Wyeth would not be likely to result in the removal of a particularly vigorous and effective competitor.

46. In the market for anti-depressants, the ACCC concluded that a number of remaining independent competitors would continue to act to constrain the post-acquisition behaviour of the merged firm. Specifically, the ACCC considered that the merged firm would be likely to continue to be constrained in its post-acquisition behaviour by significant competitors including GSK, Eli Lilly and Lundbeck. Suppliers of generic products include Alphapharm, Sigma and Apotex, all of which the ACCC considered would continue to constrain the merged firm post-acquisition.

47. Regarding the competitive impact of the proposed acquisition in the market for mRCC treatments, the ACCC concluded that, in the absence of the proposed acquisition, Pfizer and Wyeth would not be each other's closest competitors given that their products have different clinical uses, mechanisms of action, side effects and administration. Accordingly, the ACCC considered that while the proposed acquisition would remove a source of competitive tension in the market for mRCC treatments, remaining competitors, including Roche and Bayer, would continue to constrain the merged firm's post-acquisition behaviour such that a substantial lessening of competition was unlikely to occur.

48. In the market for anti-bacterials, the ACCC considered that Pfizer and Wyeth were not particularly close competitors, given that their products have a different mode of administration and target different bacteria. Market inquiries also supported the view that Pfizer and Wyeth were not close competitors in this market. Accordingly, the ACCC concluded that a substantial lessening of competition was unlikely to occur.

49. For anti-ulcerant products and immunosuppressive agents, the ACCC noted that Pfizer and Wyeth have a very limited presence and that the proposed acquisition represented a very small aggregation in each of these product areas. Additionally, the ACCC considered that there would remain a large number of competitors post-acquisition that would be likely to constrain the merged firm's behaviour. This led the ACCC to conclude that a substantial lessening of competition was unlikely in relation to any of these markets.

50. Regarding the various products at the research and development stage, the ACCC considered that Pfizer and Wyeth were not particularly close competitors.

Additionally, for some product areas, existing and pipeline products manufactured by competitors would be likely to continue to constrain the merged firm post-acquisition. Having regard to these factors, the ACCC considered that a substantial lessening of competition was unlikely in relation to any market where Pfizer's and Wyeth's products were at the research and development stage.

ANIMAL HEALTH

Background

Vaccines

51. Vaccines, which are a biological product, trigger a protective immune response in animals against viral and bacterial disease agents and/or certain parasitic or fungal infections.

52. Vaccines are used to prevent future infection, to reduce the clinical signs associated with infection, or to reduce the degree of shedding[10] by an infected animal. Vaccines can be directed against bacteria or viruses and can be either live or inactivated. Live vaccines are made from organisms that are non-virulent and are generally more effective at stimulating a protective immune response, but can create side-effects. Inactivated, or "killed", vaccines are made from killed virulent or inactivated parts of organisms.

53. All vaccines are produced from "master seeds"—that is, the biological products created from an isolated strain of a particular virus or bacteria which are then used as the starting micro-organisms to grow antigens.

Pharmaceuticals

54. Pharmaceuticals encompass a wide group of products that contain a variety of active substances which prevent or treat a large range of animal diseases and disorders.

55. Parasiticides are products used to control internal and/or external animal parasites. Endoparasiticides are a type of parasiticide and are used to control internal parasites only. Endectocides are a type of parasiticide that treat both external and internal parasites.

56. Other pharmaceutical products are designed to treat bacterial and viral infections or to provide pain relief to infected animals.

57. Pharmaceutical products are produced by mixing the active pharmaceutical ingredient with other chemical substances. The exact nature of the manufacturing process for active pharmaceutical ingredients and finished pharmaceutical products

[10] 'Shedding' refers to the excretion of a virus by an animal.

varies depending on the product in question.

58. Active pharmaceutical ingredients, once off patent, tend to be manufactured by third parties (usually in China or India) and are supplied on a global basis.

Regulatory environment

Australian Pesticides and Veterinary Medicines Authority

59. The supply, use and distribution of animal health products in Australia are all regulated under the National Registration Scheme for Agricultural and Veterinary Chemicals (the **Scheme**). The Scheme is administered by the Australian Pesticides and Veterinary Medicines Authority (**APVMA**).

60. All veterinary chemical products sold in Australia must be registered with the APVMA. The registration process involves lodging an application, paying an application fee and providing relevant data to demonstrate the efficacy and safety of the product on the animal. The length of the approval process and type of data which needs to be provided to the APVMA differs according to the type of animal health product being registered.

61. In addition, an APVMA manufacturers' licence is required by anyone engaged in any step of the manufacture of animal health products—this is designed to assure the quality of animal health products; a requirement of the licence is that products are manufactured using GMPs.[11]

Australian Quarantine and Inspection Service

62. Suppliers of all imported products containing ingredients of biological origin must obtain an import permit from the Australian Quarantine and Inspection Service (**AQIS**). Manufacturers may be required to obtain a Quarantine Approved Premises (**QAP**) license from AQIS.

63. To obtain an import permit, a supplier must demonstrate that the vaccine, including all of the biological material it is produced from, does not pose a biosecurity risk to Australia. By international standards, Australia's quarantine policy is considered to be relatively strict.

64. Suppliers of certain chemical pharmaceutical products will require an import permit if the active pharmaceutical ingredients are manufactured through a partial biological process. These products tend to pose a lower biosecurity risk than vaccines.

[11] In the animal health context, GMPs include a system of quality assurance which ensure that suitable facilities, personnel and equipment are used in the manufacture of veterinary chemical products and that materials used in production are appropriately tested.

Distribution of animal health products

65. The majority of animal health products are distributed through animal health wholesalers. There are separate distribution channels for livestock products, veterinary products and intensively farmed animal (for example, pig and poultry) products.

66. Livestock products are sold through rural resellers while companion (for example, dog and cat) animal products are sold through veterinary wholesalers. Products for intensively farmed animals are mostly sold directly to vets (often employed by large intensive farming companies), who prescribe them for use.

Market definition

67. In examining the impact of the proposed acquisition on animal health products, the ACCC considered those areas in which Pfizer's and Wyeth's products currently overlap. As noted previously, Wyeth's animal health business in Australia is operated by Fort Dodge.

68. Broadly, the areas of relevance to the assessment of the proposed acquisition in the area of animal health related to vaccines and pharmaceuticals.

Animal health vaccines

69. The ACCC considered that the markets relevant to the supply of vaccines could be distinguished on the basis of:

- the species of animal—most vaccines target a single animal species and are generally not substitutable, even in circumstances where they target the same disease;
- the indication of use—vaccines for different diseases are generally not substitutable, even within the same species group; and
- whether they are monovalent or multivalent vaccines—vaccines can be monovalent (i.e. designed to protect against a single disease) or multivalent (i.e. capable of protecting against several diseases). Monovalent and multivalent vaccines are generally not considered to be substitutable.

70. The ACCC considered the likely effect of the proposed acquisition on markets in which both Pfizer and Wyeth currently supply products and those markets in which the merger parties were considered to be likely to supply products in the foreseeable future.

71. The operations of Pfizer and Wyeth overlap in relation to the production of both companion animal (that is, dog and cat) and livestock (that is, swine, cattle and sheep) vaccines. The relevant product markets within these categories are outlined below.

Companion animal vaccines

72. Based on the factors outlined above, in relation to companion animal vaccines, the ACCC considered the impact of the proposed acquisition on each of the following markets for the manufacture and supply of:

    - multivalent cat vaccines;
    - multivalent dog vaccines; and
    - *B.bronchispetica* (**canine cough**) multivalent and monovalent vaccines. [12]

73. The ACCC considered that each of the abovementioned markets was national, on the basis that vaccines are supplied from a single manufacturing location and participants compete to market and supply productions nationally.

Livestock animal vaccines

74. Based on the factors outlined above, in relation to livestock vaccines, the ACCC considered the proposed acquisition in the context of the following markets for the manufacture and supply of each of:

    - *Mycoplasma hyopneumoniae* vaccines for swine;
    - multivalent clostridial vaccines for cattle;
    - multivalent clostridial vaccines for sheep;
    - botulinum vaccines for cattle;
    - leptospirosis vaccine for cattle; and
    - vibriosis vaccines for cattle.

75. The ACCC considered that each of the abovementioned markets was national, on the basis that vaccines are supplied from a single manufacturing location and participants compete to market and supply productions nationally.

Animal health pharmaceuticals

76. Pharmaceuticals for animal use can be divided into parasiticides, antimicrobials, endocrine treatments, anti-inflammatories and analgesics. The primary area of overlap between the merger parties is in the area of parasiticides for worm control in cattle and sheep.

[12] The ACCC considered that in relation to canine cough vaccines, multivalent and monovalent vaccines were substitutable if they contain *B.bronchispetica* as the primary pathogen. This is because *B.bronchiseptica* is considered to be the primary canine cough causing pathogen.

77. The operations of the merger parties also overlap to a more limited extent in the supply of parasiticides for the prevention of heartworm in dogs, companion animal antibiotics and companion animal anti-inflammatories.

78. The relevant product markets in relation to each of these areas are outlined below.

Pharmaceuticals for worm control in sheep and cattle

79. The ACCC considered the impact of the proposed acquisition on the separate markets for the supply of:

- endectocides for worm control in cattle; and
- endoparasiticides and endectocides for worm control in sheep.

80. Parasiticides for worm control in cattle and sheep are commonly referred to as 'drenches'. The active ingredients used in cattle and sheep drenches primarily belong to the following active groups: macrocyclic lactones (**MLs**); benzimidazoles (**BZs**) and levamisole (**LV**).

81. Drenches containing BZs and LV are classified as endoparasiticides because they treat only internal parasites; drenches containing MLs are classified as endectocides because they treat internal and external parasites concurrently.

82. The ACCC considered that there is a separate market for the supply of endectocides for worm control in cattle. Market inquiries suggested that endoparasiticides are not substitutable with endectocides for worm control in cattle. This was largely because:

- the pour-on application (which is used for ML products) is the most convenient method of application for cattle worming products. BZs can only be administered orally, and this is not a convenient method of application for cattle worming products;
- MLs tend to have greater longevity of action against target worms than BZs and LV;
- MLs are more effective than BZs and LV at killing important target worms; in particular, inhibited *Ostertargia ostertagi*; and
- MLs are more effective than BZs and LV in killing worms generally and have a broader spectrum of activity.

83. Regarding worm control in sheep, the ACCC considered that there is a single market for the supply of endoparasiticides and endectocides for worm control in sheep. The ACCC's inquiries revealed that, unlike relevant cattle applications, endoparasiticides tend to be substitutable for endectocides for worm control in sheep.

84. Relevantly, market inquiries suggested the existence of parasite resistance to chemicals used in drenches is a much greater problem in sheep than cattle. Accordingly, farmers:

- rotate sheep drenches to minimise the risk of developing parasite resistance; and
- use the different chemical groups in combination formulations to increase efficacy and manage drench resistance where resistance is an existing problem.

85. Additionally, BZs, LVs and MLs can all be administered orally to sheep and this is the most convenient method of administration of sheep drenches.

86. The ACCC considered that the relevant worm control markets are national, on the basis that each product in Australia is supplied from a single manufacturing location and participants compete to market and supply productions nationally.

Companion animal pharmaceuticals

87. The ACCC also considered the proposed acquisition in the context of national markets for the supply of:

- endectocides and endoparasiticides for the prevention of heartworm in dogs;
- companion animal antibiotics; and
- companion animal anti-inflammatories.

88. In relation to parasiticides for the prevention of heartworm in dogs, in order to ensure that any potential anti-competitive effects associated with the proposed acquisition were adequately examined, the ACCC proceeded to examine this market in a way that captured the products of both Pfizer and Wyeth. It is noted that if a narrower approach to market definition were adopted, there would be unlikely to be any competitive overlap in relation to the products supplied by Pfizer and Wyeth in this area.

89. Similarly, in relation to antibiotic and anti-inflammatory products for companion animals, the very limited competitive overlap in relation to products manufactured by Pfizer and Wyeth in these areas meant that the ACCC did not consider it necessary to reach a concluded view on market definition.

Competition analysis

Animal health vaccines

Companion animal vaccines

90. Pfizer supplies the following branded products in each of the relevant animal vaccine markets:

- multivalent cat vaccines: Fevac;
- multivalent dog vaccines: Canvac; and
- canine cough vaccines: Canvac.

91. As indicated above, Wyeth's animal health presence is through Fort Dodge, which supplies the following branded products:

    - multivalent cat vaccines: Fel-o-vax;
    - multivalent dog vaccines: Duramune, Protech; and
    - canine cough vaccines: Protech.

92. Other than Pfizer and Fort Dodge, only Virbac and Intervet supply products in the relevant companion animal vaccine markets. Intervet has a manufacturing facility in Bendigo, Victoria, and supplies multivalent cat and multivalent dog vaccines under the brands Companion and Nobivac respectively. Virbac supplies the Feligen and Canigen ranges of multivalent cat and multivalent dog vaccines respectively. Both Intervet and Virbac also supply canine cough vaccines.

93. In respect of multivalent cat vaccines, the ACCC considered that the proposed acquisition would result in significant aggregation within the market—bringing together the two most significant market participants—and significantly reduce the level of competitive tension in the market. While Intervet and Virbac would remain as independent competitors post-acquisition, it was considered that they would be unlikely to provide an effective competitive constraint on the merged firm going forward.

94. Similarly, the ACCC considered that the aggregation of Pfizer's and Fort Dodge's activities would lead to a significant concentration in the supply of both multivalent dog vaccines and canine cough vaccines in Australia and, accordingly, a significant reduction in the competitive tension between remaining suppliers would be likely to result.

95. Further, the ACCC concluded that barriers to entry in the relevant animal health vaccine markets are high and that the threat of timely new entry would be unlikely to constrain the merged firm for the following reasons:

    - Establishing a manufacturing facility in Australia would require significant capital investment. Further, the facility would require accreditation from the APVMA and, if biological products are imported to the facility, a QAP licence from AQIS, both of which are lengthy processes.
    - The production of vaccines requires a high degree of technical expertise and is complex. Even once a master seed has been developed and/or appropriate licences to import a master seed have been secured, bringing a vaccine to

market is still a lengthy process, as successful vaccine production is conducted on a trial-and-error basis, even with a proven master seed.

- As vaccines are based on living organisms, they do not necessarily grow the same way twice. Manufacturers could use identical ingredients, follow the same process and come up with different results in producing a vaccine. Therefore, new entry via the production of a generic vaccine product is not feasible.

- The threat of entry or expansion by overseas suppliers who manufacture finished vaccine products or master seeds is unlikely to provide a constraint on the merged firm given the highly complex and lengthy process for obtaining regulatory approval from AQIS to import biological materials.

- There is unlikely to be entry or expansion through licensing or toll manufacturing arrangements due to there only being a small number of vaccine suppliers and few manufacturing facilities in Australia.

96. In light of the above factors, the ACCC considered that the proposed acquisition was likely to result in a substantial lessening of competition in each of the following markets:

- multivalent cat vaccines;

- multivalent dog vaccines; and

- canine cough vaccines.

97. Pfizer offered a court enforceable undertaking to address these competition concerns. The impact of the undertaking is discussed at paragraphs 143-147 below.

Livestock vaccine products

98. As indicated above, the ACCC considered the impact of the proposed acquisition in the markets for the manufacture and supply of each of:

- *Mycoplasma hyopneumoniae* vaccines for swine;

- multivalent clostridial vaccines for cattle;

- multivalent clostridial vaccines for sheep;

- botulinum vaccines for cattle;

- leptospirosis vaccine for cattle; and

- vibriosis vaccines for cattle.

99. In each of the markets for the supply of *Mycoplasma hyopneumoniae* vaccines for swine and botulinum vaccines for cattle, the merged firm would become the only

supplier post-acquisition. The ACCC considered that the removal of Fort Dodge as the only other independent supplier would result in a significant reduction in competitive tension post-acquisition.

100. Further, the ACCC considered that, for the reasons outlined at paragraph 95 above, the merged firm would be unlikely to be constrained in its post-acquisition behaviour by the threat of new entry.

101. Accordingly, the ACCC considered that the proposed acquisition would be likely to result in a substantial lessening of competition in the markets for the supply of *Mycoplasma hyopneumonia* vaccines for swine and botulinum vaccines for cattle.

102. In the markets for the supply of multivalent clostridial vaccines for cattle and sheep, the ACCC concluded that combining Pfizer's and Fort Dodge's market leading brands (Glanvac, Ultravac and Websters and Clepto respectively)[13] would be likely to remove a significant source of constraint in each of these markets. Post-acquisition, Intervet would be the sole independent competitor to the merged firm and the ACCC considered that its relatively limited presence would be unlikely to provide an effective competitive constraint going forward.

103. Further, for the reasons outlined at paragraph 95 above, the ACCC concluded that limited constraint would be provided from the threat of entry post-acquisition in these vaccine markets.

104. Accordingly, the ACCC considered that the proposed acquisition would be likely to result in a substantial lessening of competition in each of the markets for the supply of multivalent clostridial vaccines for cattle and sheep.

105. Prior to the proposed acquisition, in the markets for the supply of leptospirosis and vibriosis vaccines Pfizer was the sole supplier in Australia. Fort Dodge has maintained current product registrations with the APVMA for leptospirosis and vibriosis vaccines, however it did not supply these vaccines. The ACCC considered that the existence of current product registrations put Fort Dodge in a good position to enter the markets and that, in the absence of the proposed acquisition, Fort Dodge's positioning would be likely to provide an effective competitive constraint on Pfizer's behaviour. Post acquisition, this constraint would disappear.

106. Accordingly, the ACCC concluded that the proposed acquisition would be likely to substantially lessen competition in the markets for the supply of leptospirosis and vibriosis vaccines.

107. Pfizer offered court enforceable undertakings to address the concerns in each of the relevant livestock vaccine markets. The impact of the undertaking is discussed at paragraphs 148-152 below.

[13] Including Fort Dodge's Eweguard and Weanerguard products.

Animal health pharmaceuticals

Companion animal pharmaceuticals

108. As discussed above, the ACCC considered the effect of the proposed acquisition on a range of companion animal pharmaceutical markets relating to heartworm, antibiotics and anti-inflammatories.

109. In relation to the markets for the supply of companion animal antibiotics and anti-inflammatories, the ACCC noted the very limited presence of Pfizer and Fort Dodge in these markets and the existence of numerous significant competitors to the merged firm post-acquisition. On this basis, the ACCC considered that a substantial lessening of competition in each of these markets was unlikely.

110. Regarding the market for the supply of heartworm treatments for companion animals, market inquiries suggested that, post-acquisition, the merged firm would continue to be constrained by existing competitors including Novartis and Bayer. Market inquiries also revealed that the parties were not considered to be each other's closest competitors, with Fort Dodge's Proheart product considered to be a relatively unique heartworm treatment (in that, unlike other products in this market, it is in the form of a once-a-year injection rather than a monthly spot on treatment). Accordingly, the ACCC considered that the competitive position with regard to the spot on and once-a-year treatments was likely to remain largely unchanged by the proposed acquisition.

111. These factors led the ACCC to conclude that a substantial lessening of competition in the market for the supply of heartworm treatments was unlikely.

112. In response to submissions from market participants, the ACCC also considered whether the proposed acquisition would provide the merged firm with the ability and incentive to bundle Proheart with Revolution to reduce competition for other endectocides that compete with Revolution. The ACCC considered that this bundling strategy was unlikely to be effective because Revolution and Proheart are considered as substitutes rather than complements by consumers, competitors to the merged firm would be unlikely to exit the market and the merged firm would have little ability to influence the product stocking decisions of veterinarians.

Pharmaceuticals for worm control in sheep and cattle

113. As indicated above, the ACCC considered the impact of the proposed acquisition on the separate markets for the supply of each of:

    - endectocides for worm control in cattle; and

    - endoparasiticides and endectocides for worm control in sheep.

Endectocides for worm control in cattle

114. In the market for endectocides for worm control in cattle, Pfizer supplies the 'Dectomax' brand of products and Fort Dodge supplies the 'Cydectin' brand of products.

115. The ACCC found that the proposed acquisition would substantially increase the merged firm's market share in the cattle endectocides market, giving it the largest share of sales in this market.

116. Both Dectomax and Cydectin contain active ingredients for which the patents have only recently expired (the active ingredients are doramectin and moxidectin respectively). There are currently no generic alternatives to Dectomax and Cydectin available in Australia.

117. The ACCC's market inquiries suggested that other endectocides for worm control in cattle include Ivomec and Avomec (supplied by Merial), Paramax (supplied by Intervet), Baymec (supplied by Bayer) and Virbamec (supplied by Virbac). Each of these products is manufactured using either the active ingredient ivermectin or abamectin, neither of which is protected by patent. Generic versions of these products are available.

118. Market participants submitted that Cydectin and Dectomax are technically superior (for example, in terms of protection period against important target worms such as *Ostertagia*), market leading products and that this technical superiority is heavily marketed and valued by customers. The ACCC further found that, prior to the proposed acquisition, Pfizer and Fort Dodge competed vigorously on price and service levels with respect to the Cydectin and Dectomax brands. The ACCC considered that, in the absence of the proposed acquisition, this competitive tension would be likely to continue.

119. For animal health pharmaceutical products the ACCC concluded that timely new entry by new pharmaceutical products[14] was unlikely to provide a sufficient constraint on the behaviour of the merged firm given the time and technical expertise required to develop a new chemical molecule, conduct clinical trials, compile the relevant data demonstrating the efficacy and safety of the product and obtain relevant regulatory approvals from the APVMA and, if necessary, AQIS.

120. On this basis, the ACCC concluded that the most likely form of new entry would be likely be in relation to new generic pharmaceutical products utilising existing active ingredients and/or formulations. However, the ACCC noted that there remains a significant lag associated with even generic entry, due to the time taken to produce a product, have it registered and bring it to market. In addition, for generic entry to

[14] This excludes new animal health pharmaceutical products which may be in the process of gaining regulatory approval and hence have already gone through the research and development and clinical trial stages.

provide a constraint, the active ingredient used in a product needs to be available at a competitive price and of appropriate quality.

121. As noted above, the active ingredients in the Cydectin and Dectomax products are no longer protected by patents. However, the ACCC's inquiries revealed that there are difficulties relating to the availability, cost and quality of the alternative supply of the active ingredients. Additionally, the existence of formulation patents on some Cydectin and Dectomax products also represents a barrier to entry.

122. In summary, the ACCC considered that the proposed acquisition would result in a significant reduction in competitive tension between the two market leading endectocides. Further, generic alternatives to these market leaders were unlikely to be available in the market in the foreseeable future and other endectocides would be unlikely to adequately constrain post-acquisition behaviour of the merged firm. Accordingly, the ACCC concluded that the proposed acquisition was likely to result in a substantial lessening of competition in the market for the supply of cattle endectocides.

123. Pfizer offered the ACCC a court enforceable undertaking to address these competition concerns. The impact of the undertaking is discussed at paragraphs 153-158 below.

Endoparasiticides and endectocides for worm control in sheep

124. In relation to the market for endoparasiticides and endectocides for worm control in sheep, Fort Dodge currently supplies Cydectin branded products, and Eweguard and Weanerguard, which are products that combine a sheep clostridial vaccine with the Cydectin sheep worming product. Given the nature of these products, the ACCC considered the competitive effects of Eweguard and Weanerguard in relation to both markets for the supply of multivalent sheep clostridial vaccines and sheep endectocides/endoparasiticides. Pfizer does not currently supply a sheep endoparasiticide or endectocide in Australia.

125. It was noted that Pfizer has regulatory approval to supply a Dectomax product for sheep in Australia but had not entered the market; Pfizer advised the ACCC that it had no intention to enter the market.

126. However, given the positioning of Pfizer, the ACCC considered that, absent the proposed acquisition, Pfizer would be able to readily commence supply of Dectomax for sheep in Australia.

127. The ACCC's market inquiries suggested that there are several existing products that would continue to compete with the merged firm in the market for endectocides and endoparasiticides for worm control in sheep post-acquisition. These products include Ivomec (supplied by Merial), Virbamec (supplied by Virbac) and Fasimec (supplied by Novartis). These products contain the active ingredients ivermectin or abamectin, of which generic versions are available. There are also many existing products that contain BZs or LV as their active ingredients which would also

continue to compete with the merged firm.

128. However, given the propensity of sheep to develop resistance to a particular active ingredient, the level of resistance is a determinative factor for consumers in deciding which endoparasiticide or endectocide product to use. Market inquiries indicated that resistance is more prevalent in relation to older active ingredients, such as BZs, LV and older MLs including ivermectin and abamectin, than in relation to the active ingredient used in Fort Dodge's product, Cydectin. Accordingly, the ACCC considered that products utilising BZs, LV or older MLs as their active ingredient would be unlikely to effectively constrain Cydectin.

129. Further, the ACCC considered that Pfizer's Dectomax product, if supplied, would be likely to compete closely with Fort Dodge's Cydectin range. The threat of entry by Pfizer in relation to sheep endectocides and endoparasiticides, combined with the potential technical advantages of the Dectomax product, led the ACCC to conclude that, in the absence of the proposed acquisition, Pfizer would be a significant constraining influence in the market, particularly with regard to the Cydectin product. The ACCC was concerned that the proposed acquisition would remove this constraint.

130. The ACCC considered that for the reasons outlined at paragraphs 119 - 120 above, entry by new pharmaceutical products was unlikely to provide sufficient constraint on the merged firm and that the most likely form of new entry was in relation to new generic pharmaceutical products.

131. Similar to the conclusion in the cattle endectocide market, the ACCC formed the view that generic entry was unlikely to be timely or effective in the future given the difficulties associated with accessing the active ingredient used to make the Cydectin and Dectomax sheep worming products.

132. Accordingly, the ACCC concluded that the proposed acquisition was likely to result in a substantial lessening of competition in the market for the supply of sheep endoparasiticides and endectocides.

133. Pfizer offered the ACCC a court enforceable undertaking to address these competition concerns. The impact of the undertaking is discussed at paragraphs 153-158 below.

Bundling of livestock pharmaceutical and vaccine products

134. The ACCC was also concerned that the proposed acquisition may give the merged firm the ability and incentive to bundle or leverage its position with its range of vaccines to reduce competition in other animal health markets. In particular, the ACCC was concerned that the merged firm would be able to leverage its position in the supply of animal health vaccines to maintain the market position of Cydectin and inhibit or limit entry of generic worming products which contain the same active ingredient as Cydectin.

135. Given Pfizer's offer to divest the Cydectin range of sheep and cattle worming products (discussed at paragraphs 153-158 below), the ACCC did not consider further an increase in the ability of the merged firm to bundle its range of vaccines with the Cydectin range of worming products.

UNDERTAKING

136. As noted above, on 30 September 2009 the ACCC accepted a court enforceable undertaking offered by Pfizer pursuant to section 87B of the Act. The undertaking was offered by Pfizer to address the ACCC's competition concerns in a number of animal health markets.

137. Broadly, the undertaking requires Pfizer to:

- divest Fort Dodge's companion animal vaccine business in Australia to the approved purchaser, BI; and
- divest Fort Dodge's livestock business in Australia to a purchaser to be approved by the ACCC.

138. The assets to be divested include brands, relevant intellectual property rights and, in the case of the livestock business, biological and raw materials, Fort Dodge's manufacturing facility, and the transfer of employees.

139. An independent manager will manage both the companion animal vaccine business and the livestock business until they are divested. Pfizer's compliance with the undertaking will be monitored by an independent auditor.

140. The objective of the undertaking is to address the ACCC's competition concerns by creating or strengthening a viable, effective, stand-alone, independent and long term competitor for the supply of the divested products.

141. A copy of the undertaking is available on the *Undertakings Register (s.87B)* at http://www.accc.gov.au. A copy is also included at Attachment A to this Public Competition Assessment.

142. The impact of the undertaking on each area of concern is outlined below.

Animal health vaccines

Companion animal vaccines

143. The undertaking provides for Pfizer to divest Fort Dodge's range of companion animal vaccines in the relevant markets to the approved purchaser, BI.

144. BI is a global research based pharmaceutical company that has operations in human and animal health in Australia. Whilst BI's headquarters are in Germany, it also has operations throughout Europe, the Americas, Africa, Asia and Australasia. BI

currently supplies pharmaceutical products for companion animals but does not offer any companion animal vaccine products.

145. Pfizer will divest to BI the necessary trademarks and other intellectual property rights relating to the manufacture, marketing and/or sale in Australia of the divested products. BI will purchase Fort Dodge's companion animal business (including relevant manufacturing facilities) in the United States, and will have the capability to manufacture the divested products in those facilities. The divestitures in relation to companion animal vaccines do not include any manufacturing facilities in Australia.

146. The undertaking is designed to provide BI with the ability to compete with Pfizer as a viable, effective, stand-alone, independent and long term competitor in Australian markets for the supply of multivalent cat vaccines, multivalent dog vaccines, and canine cough vaccines.

147. Accordingly, the ACCC considers that, in light of the undertaking offered by Pfizer, a substantial lessening of competition in any relevant companion animal vaccine market is unlikely.

Livestock vaccines

148. The undertaking provides for Pfizer to divest Fort Dodge's range of livestock vaccines in the relevant markets to a purchaser to be approved at a later date by the ACCC. Several of these vaccines are currently manufactured at Fort Dodge's facility in Penrith, New South Wales. The remainder of the vaccines are either imported or are not currently supplied by Fort Dodge in Australia.

149. Pfizer will divest tangible and intangible assets that will enable the approved purchaser to manufacture, market and sell the livestock vaccines in Australia. These tangible and intangible assets include:

- biological and other raw materials required to produce the vaccines, including master seeds;
- finished goods inventory and work in progress of the vaccines;
- all sales and marketing material used with respect to the vaccines;
- assignment or licence of the intellectual property rights necessary to give the purchaser a right to non-exclusively manufacture the vaccines anywhere in the world and to exclusively market and sell the vaccines in Australia;
- all current and pending APVMA registrations in relation to the vaccines; and
- relevant dossiers, clinical reports, data and records.

150. Pfizer will also divest to the approved purchaser Fort Dodge's manufacturing plant

located in Penrith, and will offer the purchaser the option to transfer those employees necessary for the operation of the business.

151. The undertaking is designed to provide the approved purchaser with the ability to compete with Pfizer as a viable, effective, stand-alone, independent and long term competitor in Australian markets for the supply of multivalent clostridial vaccines for cattle and sheep, botulinum vaccines for cattle, leptospirosis vaccines for cattle, vibriosis vaccines for cattle and *Mycoplasma hyopneumoniae* vaccines for swine.

152. Accordingly, the ACCC considers that, in light of the undertaking, a substantial lessening of competition in any relevant livestock vaccine market is unlikely.

Pharmaceuticals for worm control in cattle and sheep

153. In addition to the divestiture of Fort Dodge's livestock vaccines, the undertaking provides for Pfizer to divest Fort Dodge's Cydectin branded endectocides for sheep and cattle to a purchaser to be approved at a later date by the ACCC.

154. The Cydectin endectocides are to be divested with the livestock vaccines—together, these products comprise the "livestock business" referred to in the undertaking.

155. Pfizer will divest tangible and intangible assets that will enable the approved purchaser to manufacture, market and sell Cydectin endectocides in Australia. These tangible and intangible assets include:

- existing stocks of raw materials at the Penrith facility which are required to produce the endectocides;
- finished goods inventory and work in progress of the endectocides;
- all sales and marketing material used with respect to the endectocides;
- assignment or licence of the intellectual property rights necessary to give the purchaser a right to non-exclusively manufacture the endectocides anywhere in the world and to exclusively market and sell the Cydectin branded endectocides in Australia;
- all current and pending APVMA registrations in relation to the endectocides; and
- relevant dossiers, clinical reports, data and records.

156. Pfizer will also divest the livestock business on terms which include interim arrangements for the supply or toll manufacturing of the Cydectin injection and long acting injection for cattle, and the relevant active pharmaceutical ingredient (moxidectin).

157. The undertaking is designed to provide the approved purchaser with the ability to compete with Pfizer as a viable, effective, stand-alone, independent and long term competitor in Australian markets for the supply of endectocides for worm control in cattle and endectocides and endoparasiticides for worm control in sheep.

158. Accordingly, the ACCC considers that, in light of the undertaking offered by Pfizer, a substantial lessening of competition in any relevant market for the supply of pharmaceutical products for cattle and sheep worming is unlikely.

Conclusion

159. On the basis of the above, including taking into account the enforceable undertaking, the ACCC formed the view that the proposed acquisition of Wyeth by Pfizer would not be likely to result in a substantial lessening of competition in any relevant market in contravention of section 50 of the Act.