

***Case No COMP/M.1878 -  
PFIZER / WARNER-  
LAMBERT***

Only the English text is available and authentic.

**REGULATION (EEC) No 4064/89  
MERGER PROCEDURE**

---

Article 6(1)(b) NON-OPPOSITION  
Date: 22/05/2000

*Also available in the CELEX database  
Document No 300M1878*



COMMISSION OF THE EUROPEAN COMMUNITIES

**Brussels, 22/05/2000**

SG(2000)D/103824

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 4064/89 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE  
6(2) DECISION

To the notifying parties

**Subject: Case No Comp./M. 1878 – Pfizer/ Warner-Lambert**

Notification of 03.04.2000 pursuant to Article 4 of Council Regulation No 4064/89<sup>1</sup>

1. On April 3, 2000, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EEC) No 4064/89 (“the Merger Regulation”) by which the US pharmaceutical companies Pfizer Inc. (“Pfizer”) and Warner Lambert Inc. (“W-L”) notified their intention to enter into a full merger within the meaning of Art. 3(1)a of the Merger Regulation.
2. In the course of the proceedings, the parties submitted undertakings designed to eliminate competition concerns identified by the Commission, in accordance with Article 6(2) of the Merger Regulation. In the light of these modifications, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation as amended and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

**I. THE PARTIES**

3. Pfizer is a global pharmaceutical company based in the USA, active in the following main business areas:

---

<sup>1</sup> OJ L 395, 30.12.89 p.1; corrigendum OJ L 257 of 21.09.90, p.13; Regulation as last amended by Regulation (EC) No 1310/97 (OJ L 180, 09.07.97, p.1, corrigendum OJ L 40, 13.02.98, p.17).

- Pharmaceuticals: prescription pharmaceuticals for treating cardiovascular diseases, infectious diseases, central nervous system disorders, diabetes, erectile dysfunction, allergies, arthritis and other disorders, as well as non-prescription self-medications.
  - Consumer healthcare: over-the-counter healthcare products (“OTC-products”), covering treatments including pain relief, eye care, skincare and sleeping problems.
  - Animal health: antiparasitic, anti-infective and anti-inflammatory medicines as well as vaccines for live stock and pets.
4. W-L is a US company engaged in the world-wide manufacture and sale of products in the following main business areas:
- Pharmaceuticals: extensive line of prescription pharmaceuticals and biologicals under trademarks and trade names such as Parke-Davis and Goedecke. W-L is also a world-wide producer of empty hard-gelatine capsules used by pharmaceutical companies for their production of encapsuled products.
  - Consumer healthcare: OTC-products including antacids, dermatological products, antibiotic ointments and creams, cold preparations and sinus preparations.
  - Shaving products: razors, blades and other shaving products marketed under the Schick and Wilkinson Sword trademarks.
  - Pet care products: various pet care products for ornamental fish and reptiles, including aquarium products.
  - Confectionery products: chewing gums, breath mints, candies and cough drops.

## **II. THE OPERATION**

5. The proposed concentration is a merger in the meaning of Article 3(1)(a) of the Merger Regulation.
6. Pursuant to an Agreement and Plan of Merger dated February 6, 2000 (“Agreement”) the concentration is a merger by way of a private agreement between Pfizer and W-L. The merger will be accomplished through a wholly owned subsidiary of Pfizer, created specifically for the purpose of this transaction, which will be merged with and into W-L, thus W-L becoming a wholly owned subsidiary of Pfizer.

## **III. CONCENTRATION**

7. Under the Agreement, Pfizer will exchange 2.75 shares of Pfizer Common stock for each outstanding share of W-L stock. All shares of W-L common stock will cease to be outstanding and will be cancelled, retired and cease to exist. Following the share exchange, the original Pfizer shareholders will hold 60% and W-L shareholders will hold 40% of the resulting entity. The operation described above will result in a full merger between Pfizer and W-L and, therefore, is a concentration within the meaning of Article 3(1)(a) of the Merger Regulation.

#### IV. COMMUNITY DIMENSION

8. Pfizer and W-L have a combined aggregate world-wide turnover in excess of EUR 5.000 million (in 1999 Pfizer: EUR 15.202,7 million, W-L: EUR 12.127,6 million). Each of them have a Community-wide turnover in excess of EUR 250 million (in 1999 [Pfizer: EUR 2.000 – 2.500 million, W-L: EUR 2.000 – 2.500 million]), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension but it does not qualify for co-operation with the EFTA surveillance authority pursuant to the EEA Agreement.

#### V. COMPETITIVE ASSESSMENT

##### A. Relevant product markets

9. The only area of overlap arising from the merger is in the research, development and production of prescription and OTC human pharmaceutical products.
10. The Commission has on many occasions dealt with the definition of the relevant market in the case of pharmaceutical products and has established a number of principles in its previous decisions<sup>2</sup>. On the basis of these decisions, product markets in the pharmaceutical industry can be grouped into pharmaceutical specialities, active substances and future products. No issues related to active substances arise in this case.

##### 1. Pharmaceutic specialities

11. Pharmaceutical products are used for the treatment of human illnesses and diseases. Prescription/ethical medicines are pharmaceutical products exclusively accessible by way of medicinal prescription and subject, for the main part, to reimbursement through social security schemes. OTC drugs are over-the-counter pharmaceutical products certain of which can also be prescribed by a doctor and may be reimbursable through a social security scheme.
12. In its previous decisions, the Commission noted that medicines may be subdivided into therapeutic classes by reference to the “Anatomical Therapeutic Chemical” classification (ATC), which is recognised and used by the World Health Organisation and utilised by Intercontinental Medical Statistics (IMS) as a starting point in pharmaceutical products market definition. The ATC is hierarchical and has 16 categories (A, B, C, D etc.), each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as an operational market definition. These groups of products generally have the same

---

<sup>2</sup> Case IV/M.072 – Sanofi/Sterling Drug; IV/M.323 – Procordia/Herbamond; IV/M.426 – Rhône-Poulenc/Cooper; IV/M.457 – la Roche/Syntex; IV/M.500 – AHP/Cynamid; IV/M.555 – Glaxo/Wellcome; IV/M.495 – Behringwerke AG/Armour Pharmaceutical Co.; IV/M.587 – Hoechst/Marion Merell Dow; IV/M.631 – Upjohn/Pharmacia; IV/M.737 – Ciba-Geigy/Sandoz; IV/M.950 – Hoffman La Roche/Boehringer Mannheim; IV/M.1229 – American Home Products/Monsanto; IV/M. 1403 – Astra/Zeneca; IV/M.1397 – Sanofi / Synthélabo; IV/M.1378 – Hoechst/Rhône-Poulenc; COMP/M.1846 – Glaxo Wellcome/SmithKline Beecham.

therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

13. However, the Commission has in earlier decisions considered that the third level of the ATC is not in all cases an appropriate basis for the definition of products markets and that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceutical specialities. This would be the case where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease.
14. On the other hand, it may also be appropriate to apply a narrower market definition where the pharmaceutical specialities forming part of a certain ATC 3 class have clearly differing indications. In certain cases, pharmaceuticals may be further subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria. A possible distinction is that between medicines, which can be issued only on prescription and those, which can be sold over the counter (OTC). Most medicines issued only on prescription are reimbursed, whereas most of those, which may be sold over the counter, are not reimbursed. There are also other key considerations such as indications variances between prescription and OTC products, disease severity, demographic differences in consumers who refer to prescription as opposed to OTC products, driven by attitudinal differences and pricing factors. Prescription medicines and OTC products can belong to different markets, even if they are indicated in the same diseases because the customers, the legal background, the inherent risk, the marketing and distribution may be different. The allocation of a medicine to the prescription or the OTC segment is based on decisions by the authorities, which may lead to changes between segments according to the country concerned. There are different overlaps between the prescription and OTC market depending to a large degree on the reimbursement systems of a different Member State.
15. In this case, the parties have used the ATC 3 classification as a starting point in their analysis and accepted this as the market definition for most product markets. However, for some product markets which are further discussed below the parties have suggested alternative market definitions.
16. Within their broad pharmaceutical ranges, the parties have combined ATC 3 shares at the Member State level of 15% or over in respect of twelve product areas: antacids, antiflatulents, carminatives (A2A), intestinal anti-infective antidiarrhoeals (A7A), calcium antagonists, plain (C8A), cholesterol and triglyceride reduction preparations (C10A), macrolides and similar types (J1F), antidepressants (N6A), anti-Alzheimer products (N7D), anthelmintics, excluding schistosomicides (P1B), scabicides and ectoparasiticides (P1E), systemic nasal preparations (R1B), expectorants (R5C) and antitussives (R5D).

*a) Antacids, antiflatulents, carminatives (A2A)*

17. This ATC 3 category comprises products treating disorders of the gastro-intestinal tract. Pfizer's products are KOMPENSAN and ANTACIDUM, W-L produces and markets GELUSIL and SAB. All these products treat excess stomach acidity. The parties submit that the relevant product market is the ATC 3 level category A2A and have submitted data on this basis. This market definition has not been contested by third parties either.

*b) Intestinal anti-infective antidiarrhoeals (A7A)*

18. This product category includes all products containing one or more intestinal anti-infectives with or without other substances treating inflammations of the intestines, dysenteries and taeniasis. W-L markets two products, HUMATIN and HUMAGEL, and Pfizer is on the market with the drugs POLIMIXIN B and CUNTICINA. The parties have provided data on the basis of the ATC 3 class A7A. The market investigation does not suggest that any other market definition should be used.

*c) Calcium antagonists, plain (C8A)*

19. Calcium antagonists are primarily used for the treatment of high blood pressure and angina. They include dihydropyridines (DHPs) and non dihydropyridines (non-DHPs). Pfizer's product NORVASC belongs to the group of DHPs, W-L's DILZEM is a non-DHP. The parties argue that NORVASC and DILZEM are not fully substitutable. More particularly, the parties submit that DILZEM is primarily used for angina whereas NORVASC first and foremost treats hypertension, for which it is considered the superior drug
20. With regard to hypertension treatment, DHPs are, according to the parties, particularly recommended for patients with slow heart rate, atrial ventricular block, moderate to severe congestive heart failure, or aortic and mitral insufficiency. Non-DHPs are particularly recommended to patients with concomitant migraine or vascular headaches, asthma or chronic obstructive pulmonary disease and several types of fast heart-rate.
21. The parties submit that there are also important differences between DHPs and non-DHPs with respect to the treatment of angina. According to the parties, non-DHPs will typically be the preferred option in treatment of chronic angina because non-DHPs decrease heart-rate and contractility and should lower the oxygen demand of the heart. In contrast, the parties argue that DHPs can more safely be combined with beta-blockers for the management of angina, where there might be problems due to increased heart failure, bradycardia and A-V block
22. The parties submit that a market definition based on ATC 3 level C8A would be too narrow, mainly because calcium antagonists, which are prescribed against hypertension, are interchangeable with other drugs from other classes, grouped in different ATC 3 categories such as diuretics (C3A), beta-blockers (C7A/C7B), ACE inhibitors (C9A/C9B), alpha-blockers (C2A/C2B) and angiotensin II antagonists (C9C/C9D). The parties argue that all available drugs are suitable for the initiation and maintenance of anti-hypertensive therapy. They submit that the choice of drug depends on many factors, including socio-economic factors, cardiovascular risk factor profile of the individual patient, the presence of target-organ damage and of clinical cardiovascular disease and diabetes, the presence of other co-existing disorders, variation in individual patient responses to drugs from different classes, the possibility of interactions with drugs used for other conditions present in the patient and the strength of evidence for reduction of cardiovascular risk with the drug class in question.
23. The Commission's findings, however, do not support the parties' arguments. First, third parties have submitted that calcium antagonists are to a significant extent indicated for both hypertension and coronary heart diseases. The Commission's investigation shows that NORVASC and DILZEM have been approved and commonly

used for both indications for instance in Austria, where the operation has its strongest effects in this product category. The investigation also shows that “long acting” or “short acting” cannot be considered to constitute a criterion to distinguish between different classes of calcium antagonists. Differences resulting from different pharmacokinetic profiles can be modified by special galenic design, achieving slow release of shorter acting drugs to the effect of turning them into longer acting. Such galenic modifications enhance competition within the calcium antagonists. Thus DHPs and non-DHPs do largely compete with each other.

24. Second, as to the question whether the relevant product market should be enlarged to include also drugs grouped in diuretics (C3A), beta-blockers (C7A/C7B), ACE inhibitors (C9A/C9B), alpha-blockers (C2A/C2B) and angiotensin II antagonists (C9C/C9D), the Commission carried out a detailed investigation in this area in case *IV/M.1403 - Astra/Zeneca*. The Commission concluded that while the indications and contraindications for the four classes of hypertension medicines examined in that case partly overlap with one another, for a large proportion of hypertension patients the products in the various product classes are not substitutable. The Commission subsequently assessed the impact of the transaction separately for betablockers, calcium antagonists, ACE inhibitors and angiotensin inhibitors. The findings in this case do not suggest that the Commission should deviate from its conclusions in *IV/M.1403 - Astra/Zeneca*.
25. Therefore, on the basis of the foregoing and for the purposes of this decision, the relevant product market is considered to be limited to the ATC 3 level C8A.

*d) Cholesterol and triglyceride reduction preparations (C10A)*

26. This category comprises products relating to the cardiovascular system and includes all drugs reducing cholesterol and triglycerides only. Pfizer does not manufacture a cholesterol-lowering pharmaceutical product, but has entered into a co-promotion, co-marketing and distribution arrangement with W-L for ATORVASTATIN, a pharmaceutical compound with indications for lowering cholesterol levels. In countries, in which W-L does not have sufficient presence, Pfizer has been granted exclusive distribution rights.
27. The parties submit that ATC 3 level C10A is the appropriate market definition. Given that the market investigation has not suggested that any other market definition should be used, the assessment will be carried out at the ATC 3 level C10A.

*e) Macrolides and similar types (J1F)*

28. This product category comprises drugs against infectious diseases, in which the parties produce and market the pharmaceuticals ZITHROMAX (Pfizer) and ERYPAR (W-L). The parties have submitted data on the basis of the ATC 3 level classification J1F and this market definition has not been contested by third parties either. Therefore, the assessment will be based on J1F.

*f) Antidepressants (N6A)*

29. This category includes all substances used in the treatment of endogenous and exogenous depression. Pfizer's products in this class are ZOLOFT and SINEQUAN and W-L's products are LENTIZOL and NARDIL. The parties consider the ATC 3 class N6A to be the most appropriate market definition and have presented data on this basis. In their replies to the Commission's questionnaire, third parties have not indicated that another market definition should be used.

*g) Anti-Alzheimer products (N7D)*

30. Products within this segment are designed for the palliative treatment of Alzheimers's and/or relieving the symptoms of the disease. In this category, W-L markets the product COGNEX under licence since 1993. Pfizer has the exclusive right to co-promote the pharmaceutical ARICEPT. The drug was discovered and developed by the Japanese company Eisai Co., Ltd. Pfizer serves as Eisai's contract manufacturer, formulates the product from bulk sourced from Eisai and packages it.
31. The parties have provided data on the basis of the ATC 3 classification N7D. This market definition was not challenged by third parties. Therefore, the assessment will be based on the ATC 3 class N7D.

*h) Anthelmintics, excluding schistosomicides (PIB)*

32. Anthelmintics are drugs which destroy worms and larvae in the gastro-intestinal tract. Pfizer markets the product COMBANTRIN and W-L markets VANQUIN. The parties submit that the relevant product market is the ATC 3 category PIB and they have provided data on this basis. This market definition has not been contested by third parties either.

*i) Scabicides and ectoparasiticides (PIE)*

33. The ATC 3 class PIE comprises products which fall under the broad category of parasitology and include scabicides and products for the eradication of lice and fleas. The parties consider that this ATC 3 classification is appropriate for the assessment of the case and have accordingly presented data on this basis.
34. The parties nevertheless submit that their products do not overlap, as W-L's product LYCLEAR is a treatment to kill head lice and Pfizer's product RAPPEL is used to prevent the recurrence of head lice rather than kill them. The exact market definition can, however, be left open because in all alternative market definitions considered, the transaction would not raise serious doubts.

*j) Systemic nasal preparations (RIB)*

35. This category includes all preparations indicated primarily for rhinitis, allergic rhinitis, sinusitis, catarrh, nasal congestion and other similar conditions. Pfizer's product is RHINOPRONT, which treats rhinitis, and W-L's products are OLYNTH KOMBI and ACTIFED, treating acute rhinitis. The parties submit that ATC categorises nasal



preparations at level 3 by method of delivery: R1A topical in form of sprays or drops and R1B systemic as tablets, capsules and liquids. The parties submit that those products which are indicated for the same symptoms are often marketed under the same brand name and advertised as one product. Therefore, the parties argue that the relevant product market should include R1A and R1B.

36. Third parties, however, have submitted that the side effects of systemic and topical preparations are different. They argue that topical decongestants usually lack cardiovascular side effects, like hypertension or tachycardia. On the other hand, third parties have indicated that a continuous use of topical decongestants can cause atrophy of the nasal mucosa. Therefore, third parties have indicated that the method of delivery forms an important criterion for the choice of a drug.
37. It is not necessary, however, to reach a definite conclusion on the scope of the relevant product market, because regardless of the market definition used, competition concerns would not arise in this treatment area.

*k) Expectorants (R5C)*

38. The ATC 3 category R5C includes all cough preparations with expectorant as the main ingredient. It may also include antihistamines and bronchodilators but excludes combinations with antitussives and sucking tablets indicated for cough. The parties' products in this category are Pfizer's GALLOWAYS, LIQUFRUTA and BUTTERCUP and G-W's BENYLIN CHESTY COUGHS, all relieving symptoms of coughs, sore throats and/or other cold symptoms.
39. The parties submit that a market definition according to the ATC 3 level is too narrow. They argue that there is a high degree of demand-side and supply-side substitutability between several closely related R5 categories. More particularly, the parties argue that there is a substantial degree of interrelationship among the active ingredients used in these products. Cough and cold remedies contain according to the parties one or more of the four principal categories of active ingredients: nasal decongestants, antihistamines, antitussives and expectorants. The parties also contend that R5 pharmaceuticals face significant competition from alternative remedies, such as non-registered medicines (e.g. vitamin C) and homeopathic remedies, such as herbal products, which have become increasingly important in many Member States. Thus, the parties argue that, at a minimum, expectorants (R5C) and antitussives (R5D) should be regarded to belong to the same relevant product market but that probably also cold preparations (R5A) should also be included.
40. The Commission's investigation, however, shows that expectorants and antitussives are used to treat differing types of cough. Third parties have submitted that the two types of drugs have an opposite way of action: expectorants loosen the mucus and, by producing cough, are meant to allow better coughing up of mucus. In contrast, antitussives suppress cough and are indicated in the cases of bothersome cough, especially during night-time. Therefore, a dry, hacking cough would require an antitussive while a productive cough would require an expectorant. As for the question whether cold preparations (R5A) should be included in the relevant product market, several third parties have indicated that the direct substitutability between expectorants, antitussives and cold preparations is limited. It has been indicated that cold preparations comprise of various types of products, often combining several molecules or ingredients, mainly dedicated to treat symptoms of colds. Some cold preparations have antitussive effects

in addition to other actions. However, the investigation suggests that cold preparations are used to complement other products rather than as substitutes, as patients often use a wide range of products to treat cough symptoms.

41. Although there are indications that the substitutability between expectorants (R5C), antitussives (R5D) and cold preparations (R5C) is limited, the exact definition of the relevant product market can be left open, because regardless of the market definition used, competition concerns would not arise in this treatment area.

## 2. Future products

42. In the pharmaceuticals industry, a full assessment of the competitive situation requires examination of the products which are not yet on the market but which are at an advanced stage of development. As noted in the Ciba-Geigy/Sandoz decision<sup>3</sup>, R&D projects undergo three different phases of clinical testing: Phase I marks the start of clinical testing on humans, currently some eight to ten years before a product is marketed. Statistically, projects in phase I generally have no more than a 10% chance of being successful. Phase II, some four to five years before the product is marketed, involves working out the proper dose for the patient and defining the areas of application. The success of phase II is generally acknowledged to be approximately 30%. Phase III, starting three years before the product is marketed, involves establishing the product's effectiveness on larger groups of patients. The risk of failure in phase III is reported to be over 50%.
43. The potential for these products to enter into competition with other products which are either at the development stage or already on the market can be assessed by reference to their characteristics and intended therapeutic use. The Commission has to look at R&D potential in terms of its importance for existing markets, but also for future market situations.
44. In so far as research and development must be assessed in terms of its importance for future markets, the relevant product market can, in the nature of things, be defined in a less clear cut manner than in the case of existing markets. Market definition can be based either on the existing ATC classes or it can be guided primarily by the characteristics of future products as well as by the indications to which they are to be applied.

## **B. Relevant geographic markets**

### 1. Pharmaceutic specialities

45. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope, despite the trend towards standardisation at a European level. The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far reaching differences in terms of brand

---

<sup>3</sup> IV/M.737 – Ciba-Geigy/Sandoz, Commission decision of 4.2.1998

and pack-size strategies and in distribution systems. These differences lead to national market characteristics.

46. The market investigation in this case has confirmed that it is not possible to have uniform pricing at the same time as a supplier obtains an EEA marketing approval because various Member States have different ways of approving prices and reimbursement of pharmaceuticals. The markets for pharmaceutical specialities affected by the concentration will thus be regarded as national.

## 2. Future products

47. To the extent that products not yet on the market must be taken into account on the basis of research and development in particular areas, national restrictions do not have the same degree of effectiveness than for existing pharmaceuticals. Normally, a characteristic of such products is that they have not yet been registered. Because research and development is normally global, the consideration of future markets should therefore at least focus on the territory of the Community and possibly on world-wide markets.

## **C. Assessment**

### 1. Pharmaceutical specialities

48. The operation involves 12 product categories where the combined sales of Pfizer and W-L result in market shares of 15% or more.
49. In 11 national markets, the operation does not give rise to competition concerns because the aggregated market share of the parties remains below 25% and a certain number of competitors are present in the relevant markets. The markets concerned are antacids, antiflatulents, carminatives (A2A) in Austria and Germany, intestinal anti-infective antidiarrhoeals (A7A) in Germany and Spain, calcium antagonists, plain (C8A) in Spain, cholesterol and triglyceride reduction preparations (C10A) in Denmark, Greece, Italy and Spain, antidepressants (N6A) in Ireland, and macrolides and similar types (J1F) in the Netherlands.
50. In five other markets, the aggregated market share of the parties is between 25% and 35% while the increment is smaller than 5% (*Class 1 markets*). The markets concerned are antacids, antiflatulents, carminatives (A2A) in Portugal, calcium antagonists, plain (C8A) in Germany, anthelmintics, excluding schistosomicides (P1B) in Italy, scabicides and ectoparasitocides (P1E) in Ireland and antitussives (R5D) in the UK. In each market, there is at least one competitor with a market share which is almost as high as or even higher than the parties' aggregated market share. Moreover, there are several other competitors which, regardless of their lower market shares, have proven innovative potential in their pharmaceutical activities. Competition concerns are therefore unlikely to arise.
51. In one affected market, the parties' aggregated market share amounts to 25-35% while the market share increment is 5% or more (*Class 2 markets*). The market concerned is systemic nasal preparations (R1B) in Germany. Pfizer's market share with its product RHINOPRONT is [15-20] %. W-L holds [5-10] % of the market with the products OLYNTH KOMBI and ACTIFED, [...]. Considering that the parties' combined market share will not exceed [25-30] % and taking into account the fact that the parties are facing competition from Sanofi-Syntélabo ([10-15] %), Schwabe ([10-15] %), Hevert

([10–15] %), SmithKline Beecham ([5–10] %) and a number of other major pharmaceutical companies, the Commission concludes that competition concerns are unlikely to arise.

52. In five ATC 3 categories, the aggregated market share of the parties will exceed 35% (*Class 3 markets*). The 12 national markets concerned are calcium antagonists, plain (C8A) in Austria, anthelmintics, excluding schistomicides (P1B) in Austria and Germany, scabicides and ectoparasiticides (P1E) in the UK, expectorants (R5C) in the UK and anti-Alzheimer products (N7D) in Austria, Belgium, Finland, Greece, Luxembourg, Spain and Sweden. Class 3 markets will be assessed in more detail below.

*a) Calcium antagonists, plain (C8A)*

53. Following the operation, the parties would attain a very strong position in Austria in the C8A category. The new entity's combined market share would be by value [50–55] % (Pfizer [40–45] % and W-L: [5–10] %) while competitors would be far smaller. Most importantly, Bayer has [15–20] % of the market, BASF [10–15] % and AstraZeneca [5–10] %.
54. The parties argue that the operation would not lead to adverse competition effects in Austria. More particularly, the parties argue that the active ingredient of DILZEM, *diltiazem*, is off patent and hence subject to generic competition. On the Austrian market, Genericon, Ratiopharm and Corazem are authorised to offer generic versions of DILZEM in various dosage forms. The parties further submit that the price of DILZEM has been decreasing continuously due to the entry of generic products. At the same time, the parties argue, NOVARSC is under increasing price pressure due to generic competition from other antihypertensive drugs.
55. The parties arguments do not, however, remove serious concerns on the C8A market in Austria. Pfizer and W-L are the number one and four suppliers on the Austrian market, and the largest competitor, Bayer, would have not much more than one third of the aggregated market share of the parties. Moreover, Pfizer has increased its market share considerably from [30–35] % to [40–45] % within the last three years and is the clear market leader. At the same time, most competitors have lost market share. Therefore, the Commission considers that the existing competitors are not able to offset the market power of the new entity and the addition of [5 – 10] % market share therefore has to be considered to be sufficient to lead to serious doubts on this market.
56. The investigation shows further that competition for DILZEM from generics is weak in Austria. Whilst generics might be relatively strong in other Member States, they do not have an important role in Austria where DILZEM still accounted for more than 90% of the *diltiazem* demand in 1999. The weak position of generic products is further evidenced by Pfizer's positive market share evolution.
57. Moreover, as for the parties' argument that new competition arises from pipeline products such as VANLEV from Bristol-Myers Squibb, ZESTRIC from AstraZeneca and PRINVIL from Merck, the Commission does not consider that potential competition is sufficient to counterbalance the parties' position on the market. First, the Commission notes that only Bristol-Myers Squibb's VANLEV is in Phase III of development. The Commission notes, however, that this compound is not a calcium antagonist. It is therefore not clear to what extent this product would be in direct

competition with the parties' products. Second, the market leader Pfizer has two pipeline products in this area: the first concerns the use of NOVARSC for congestive heart failure and has concluded Phase [X]. The second compound involves the adaptation of NOVARSC for paediatric hypertension indications and is in Phase [X] of development. Therefore, given Pfizer's already strong presence in the market and the fact that it has two compounds in Phase [X], it is reasonable to assume that Bristol-Myers Squibb's pipeline would not be sufficient to counterbalance the new entity's position on the market, in particular in view of the fact that Bristol-Myers Squibb's product is not a calcium antagonist and Bristol-Myers Squibb is not currently present on the market with existing products.

58. On the basis of the foregoing, serious doubts as to the compatibility of the operation with the common market exist in calcium antagonists, plain (C8A) in Austria.

*b) Anthelmintics, excluding schistosomicides (PIB)*

59. With regard to anthelmintics, the only markets affected are Germany and Austria. In Germany, the parties will have a combined market share of [40-45] % (Pfizer [20-25] % and W-L [25-30] %). In Austria, the parties account together for [45-50] % of the total sales (Pfizer [30-35] % and W-L [15-20] %).
60. However, the parties submit that their market shares have been declining in recent years and that the market is shrinking due to modern food hygiene standards. In Austria, in 1999 the total market represented approximately US \$ [300.000-350.000] (down from US \$ [350.000-400.000] in 1995) and in Germany US \$ [4,5-5,0] million (compared to US \$ [4.5-5,0] in 1995). The parties claim that given the low value of the market and the negligible sales that both parties derive from it, the new entity will have no incentive to take advantage of its combined market share on either of the affected markets.
61. The parties also claim that their market share is declining. In Germany, Pfizer's market share went down from 1995 to 1999 within the range of [20-25] %, and W-L's share declined within the range of [25-30] %. In Austria, the parties' combined market share declined from [50-55] % in 1995 to [45-50] % in 1999. Furthermore, the parties argue that they will continue to face competition, particularly from the market leader in Europe, Johnson & Johnson, who has an EEA-wide market share of [45-50] %. More specifically, in Germany, major competitors include Johnson & Johnson ([20-25] %), SmithKline Beecham ([10-15] %) and Krewel ([5-10] %). In Austria the parties face competition from Johnson & Johnson ([25-30] %) and SmithKline Beecham ([20-25] %).
62. The parties further submit that their products COMBANTRIN and VANQUIN are old products, which have been off-patent for more than ten years and are relatively low priced. They argue that even after the concentration they would not have the market power to increase prices or in any other way take advantage of their combined market share. The parties argue that if there were a significant price increase on the market, generic products would immediately enter the market. The parties also contend that there is potential competition from all other major pharmaceutical companies, who market alternative compounds and have already set up distribution networks in Germany and Austria.

63. The Commission, however, considers that serious doubts exist on both markets. More particularly, the Commission notes that the parties' market shares are stagnant rather than directly declining, as the market shares move in the range of a few percentage points in either direction from one year to another. The same applies for the total value of the market, which has been slightly increasing and decreasing from one year to another but, in general terms, remained stagnant. Under these conditions, where the new entity would account for some [45–55] % of the market, the Commission considers that actual competition is not sufficiently strong to offset the market power of the new entity. Nor are the present market conditions likely to attract new entry. The fact that the markets are small and mature with a number of established players must be considered to constitute a powerful barrier to entry, because the cost of entry (for instance to develop and market a new drug) would most likely exceed the potential revenues which can be generated on such markets. This is first and foremost evidenced by the total absence of generic products despite the fact that, for instance, the parties' products have long been off patent. The Commission also notes that there has been no new product launch for more than 10 years and no new products have been reported to be currently under development either.
64. On the basis of the foregoing, the Commission considers that the operation raises serious doubts as to its compatibility with the common market in the market for anthelmintics, excluding schistosomicides (P1B), in Austria and Germany.

*c) Scabicides and ectoparasiticides (P1E) in the UK*

65. If, as suggested by the parties, the market for scabicides and ectoparasiticides (P1E) in the UK are separate product markets, the transaction will not lead to any overlap. Under the hypothesis that the products are substitutable, the combined market share of the parties would be [35–40] %. W-L currently accounts for [35–40] % of the market while Pfizer only has a *de minimis* presence on the market with less than [5] %.
66. The Commission considers that competition concerns are unlikely to arise on this market given first and foremost the fact that the parties would face competition from the market leader SSL International who has [50–55] % of the UK market and that Pfizer was not a significant competitor in this market. Other competitors include Kestrel Healthcare ([5–10] % market share) and Block Drug ([0–5] % market share). Furthermore, the market investigation shows that the parties' products, LYCLEAR and RAPELL, are long off-patent and are sold over-the-counter. There are no barriers to entry, such as high development costs or time consuming and cost intensive registration procedures, and potential competitors could therefore enter the market.
67. On the basis of the foregoing, the Commission does not have serious doubts as to the compatibility of the operation with the common market in the market of scabicides and ectoparasiticides (P1E) in the UK.

*d) Expectorants (R5C)*

68. As to the market for expectorants (R5C), no overlap between the parties occurs except for the market in the UK. With regard to the market definition of the combined R5A, R5C and R5D classes as submitted by the parties, the combined market share of the new entity would be [30–35] %, with an increment of [0–5] %. Considering the ATC 3 category R5C as the most narrow product market definition possible, the market share of the parties would amount to [40–45] %, with an increment of [0–5] %. Pfizer's market share in the R5C market has stagnated below 5 % from 1995 onwards while W-L's market share declined between 1995 and 1999 within the range of [40–45] %. The whole market for expectorants has expanded from US \$ [7.500.000–8.000.000] in 1995 to US \$ [10.500.000–11.000.000] in 1999.
69. The parties claim that the new entity will face strong competition from Roche ([25–30] %), SSL International ([5–10] %), AHP ([0–5] %) and 13 other suppliers of expectorants, including the largest European supplier Boehringer Ingelheim, as well as other large multinationals (GlaxoWellcome, SmithKline Beecham, Novartis, Aventis and Merck). The parties further argue that a number of leading European suppliers, who already have well-established distribution and marketing systems, are potential entrants to the market. The parties also claim that powerful and sophisticated customers in the UK distribution channels for OTC health care products could easily take advantage of low barriers to expansion and a high degree of supply-side flexibility.
70. The Commission considers it unlikely that the transaction would lead to adverse competition effects on the UK market for expectorants. In particular, if assessing the transaction on the basis of the narrowest market definition possible, the fact that Roche holds a market share of close to [25–30] % in the segment for R5C has led the Commission to conclude that the parties would face strong competition from Roche. The Commission also notes that while the parties' market share has either been stagnant or declining, Roche has been able to increase its market share from [25–30] % in 1995 to the present [25–30] %. Furthermore, in view of the fact that the increment of market share - regardless of the market definition considered - is small and does not exceed [0–5] %, the Commission considers that the operation does not raise serious doubts as to its compatibility with the Common market in the market for expectorants (R5C) in the UK.

*e) Anti-Alzheimer products (N7D)*

71. The parties have combined market shares exceeding 35 % in anti-Alzheimer products in Austria, Belgium, Finland, Greece, Luxembourg Spain and Sweden. In four of these countries, the increment in market share is less than 5%. In Austria, the parties will have a combined market share of [60–65] % (Pfizer [55–60] % and W-L [0–5] %); in Finland the aggregated market share will be [80–85] % (Pfizer [75–80] % and W-L [0–5] %); in Luxembourg the parties account for [95–100] % of the sales (Pfizer [90–95] % and W-L [0–5] %) and in Sweden the combined sales will amount to [80–85] % (Pfizer [80–85] % and W-L [0–5] %). The parties, however, submit that W-L's COGNEX was withdrawn from the market in both Finland and Sweden at the end of February 2000. Therefore, there will be no overlap in these Member States. In other three countries, the increment in market share will be more than 5%. In Belgium, the parties jointly account for [95–100] % of the market (Pfizer [85–90] % and W-L [5–10] %).

); in Greece the combined market share will be [90- 95] % (Pfizer [70–75] % and W-L [15–20] %) and in Spain the parties will have sales of [80–85] % (Pfizer [75–80] % and W-L [5–10] %). The markets are characterised by a sharp decline of W-L's product COGNEX from up to 100% in many national markets in 1997 and, simultaneously, a rapid increase in market share of Pfizer's product ARICEPT, which was introduced on the European market only recently.

72. Although the increment of market share is below 5% in a number of countries and, in general terms, less than 10% in all countries except for Greece (15 – 20 %), the increment has to be considered sufficient to lead to serious doubts given the already very high market shares of Pfizer, ranging from 55 – 60 % in Austria to 90 – 95 % in Luxembourg. The largest competitor, Novartis, with its product EXELON, has market shares in the above mentioned countries ranging between 0 – 5 % in Luxembourg and 25 – 30 % in Austria, where Novartis achieves its strongest position. However, in all other Member States discussed above, the new entity's market share will be more than eight times higher than that of Novartis.
73. The parties submit that the situation is changing rapidly due to the fact that several major pharmaceutical companies are developing products for the treatment of Alzheimer's disease. By way of example, the parties submit that Novartis launched a new product, EXELON, on national European markets starting in June 1998. The parties argue that the market share of EXELON is expected to grow continuously. In some Member States, however, EXELON up until now accounts only for negligible sales (0 – 5 % in Luxembourg; 0 – 5 % in Belgium). Therefore, it is uncertain that the product will develop to be a viable competitor within the near future in particular in view of the fact that Pfizer's product ARICEPT is currently regarded as the gold standard in this category.
74. With regard to potential competitors, Intelligen/Johnson & Johnson/Shire have recently started to market REMINYL in Austria, Germany and Sweden and pipeline products are in different stages of development. The parties submit that HYPERZINE A of Joyson has been registered in Asia and is undergoing clinical trials in the US. TAK-147 of Takeda is in phase III, and QUILOSTIGMINE of AstraZeneca is in phase II.
75. The investigation shows that Alzheimer's disease is an attractive market for future Research and Development. However, it remains uncertain whether the pipeline products which are currently under development will be able to be viable competitors. With regard to those compounds which are in Phase III of development, the Commission takes under consideration that even phase III clinical trials take three years until the product will be launched on the market and that even at this stage the risk of failure is approximately 50%. The Commission notes further that the only pipeline product currently in Phase III is that of Takeda's, who has no existing products in the EEA market in this category. Therefore, given the very high market shares the new entity would achieve, the Commission considers that potential competition is not sufficient to eliminate competition concerns in this treatment area.
76. On the basis of the foregoing, serious doubts as to the compatibility of the operation with the Common market exist in anti-Alzheimer products (N7D) in a number of Member States.

## 2. Future products



77. The parties submit that the only broad primary research area in which they are both substantially active is in the field of oncology. Both parties have pipeline products in Phase [X], which are expected to fall into ATC 3 category L1X. Pfizer has two compounds at Phase [X] development, relating to sporadic adenomatous polyps and colon cancer respectively, and one Phase [X] compound for lung cancer. W-L has two compounds at Phase [X] [business secrets ...] stages of development.
78. The parties argue that there is a potential overlap between their future products only in relation to Pfizer's [pipeline product] X and W-L's pipeline [business secrets ...]. The parties argue, however, that the mode of action of W-L's [pipeline product Y] remains at present unknown. The parties submit further that Pfizer's [pipeline product X] is an EGFR TK inhibitor, whereas W-L's [pipeline product Y] is an angiogenesis inhibitor and that, therefore, the discoveries do not overlap. The parties claim further that there are a number of pipeline products in the same category as W-L's Phase [X] [pipeline product Y], and that there are many angiogenesis compounds currently being tested in human trials. The parties have submitted that a number of competitors have pipeline products in this area in Phase III development, including Aeterna, British Biotech, Sytran and Merck.
79. The market investigation has largely confirmed that Pfizer's pipeline product X and W-L's pipeline product Y have different mechanisms of action and, as a result, attack cancers differently. The investigation has also shown that a number of competing compounds are under development in Phase III and II. Third parties have confirmed that competition is vigorous in the field of oncology and that the merger would not lead to any adverse competition effects in this field.
80. On the basis of the foregoing and, in particular, given that Pfizer does not currently market or sell any cancer drugs and W-L has minimal sales in the EEA, that a number of existing competitors are on the market and that there are numerous pipeline products in Phase III and II of development, the Commission does not consider that the parties' pipeline products would raise serious doubts in the field of oncology.

### 3. Vertical relationships

81. W-L, through its subsidiary Capsugel, produces and sells hard gelatine capsules as a commodity product in the upstream market of oral dosage forms in which a pharmaceutical product can be delivered. Pfizer does not manufacture or supply hard gelatine capsules, but purchases approximately [85–95] % of its requirements from W-L in the EEA.
82. Hard gelatine capsules have been used in the pharmaceutical industry for over 100 years. They are produced on the basis of animal gelatine as raw material, using well-known technology and readily available equipment. Patents and proprietary technology play a minor role in this segment. The parties submit that suppliers of hard gelatine capsules face intense competition from alternative dosage methods, such as soft gelatine capsules, tablets, powder, powder and liquid. The parties argue that, with very few exceptions, there are no pharmaceutical drugs for which hard gelatine capsules are the sole or preferred method of oral dosage, or for which hard gelatine capsules would offer significant performance advantages over alternative dosage forms. Because of the high degree of demand-side substitutability, the parties submit that oral dosage forms, combining hard and soft gelatine capsules and tablets, constitute the relevant product market.

83. The parties submit that all major suppliers operate on a world-wide basis. The parties argue that transport costs play only a minor role and that country-specific barriers to entry do not exist. Therefore, the parties submit that the relevant geographic market is world-wide.
84. According to the broader market definition suggested by the parties, W-L would have a world-wide market share of [5–10] % of a total market of [1500-2000] billion capsules and an EEA-wide share of [5–10] % of a total European market of [400-500] billion capsules. On the world-wide market of hard gelatine capsules of approximately [250-260] billion capsules, W-L has a market share of [45–50] %. Other leading suppliers include Shionogi Qualicaps ([5–10] % of the market), RP Scherer ([5–10] %) and Su Hueng ([0–5] %). In the EEA, W-L's market share amounts to [60–65] % of a total market of [60-70] billion capsules. In Europe, W-L faces competition most importantly from Shionogi Qualicaps ([10–15] % of the market) and RP Scherer ([5-10] %).
85. The Commissions considers that the market definition submitted by the parties appears to be too broad in its scope. In order to switch from one dosage form to another, particularly from a capsule to a tablet or vice versa, a pharmaceutical company will have to re-formulate the drug. On the basis of the information provided by the parties, this would take approximately from 12 to 18 months. Also, every different dosage form has to be registered separately. There are some indications, however, that at least hard and soft gelatine capsules could be considered as a close oral dosage substitute. This regards the technical aspect of delivery as well as the spectrum of performance. On the basis of this market definition, W-L would hold a world-wide market share of [30–35] %, producing [100-150] billion capsules of a total market of [300-400] billion. In Europe, W-L would account for sales of [45–50] % or [30-50] billion capsules of a total market of [80-90] billion capsules.
86. The exact definition of the relevant product market can, however, be left open. On the basis of its market investigation, the Commission has come to the conclusion that even under the narrowest market definition possible, effective competition will not be adversely affected as a result of Pfizer becoming vertically integrated with the leading upstream supplier of hard gelatine capsules and the operation is unlikely to lead to the foreclosure of the market for the supply of hard gelatine capsules. In many cases, the registration of a pharmaceutical product is not specific as to the supplier of the capsules used in the product and in those cases, where the registration is specific, pharmaceutical companies very frequently register their product with two or more suppliers of capsules. Know-how of production technology and the supply of raw material do not form market entry barriers. Therefore, a purchaser could shift its sourcing to any of the alternative hard gelatine capsules suppliers if W-L attempted to foreclose the market or increase prices. Existing competitors could increase their production and new competitors could enter the market.
87. On the basis of the foregoing, the Commission has concluded that no serious doubts exist as to the compatibility of the operation with the common market in hard gelatine capsules in the EEA.

## **VI. MODIFICATIONS TO THE PROPOSED OPERATION**

88. In order to remove serious doubts resulting from the proposed transaction, the parties offered the Commission undertakings. The detailed text of these undertakings is

annexed to this decision. The full text of the annexed undertakings forms an integral part to this decision.

89. In the market for anti-Alzheimer's (N7D), the parties have proposed to divest all assets relating to W-L's COGNEX to a viable and independent third party. The parties have already entered into an unconditional asset purchase agreement with First Horizon Pharmaceutical Corporation, a US based company. The proposed undertaking removes the entire overlap between Pfizer and W-L in this market.
90. In the market for calcium antagonists (C8A), the parties have proposed to outlicense W-L's DILZEM in Austria. The proposed undertaking removes the entire overlap between the parties in this market.
91. In order to remove the competition concerns arising in anthelmintics, excluding schistosomicides (PIB) in Germany and Austria, the parties have committed themselves to transfer all assets relating to either the product HELMEX/COMBANTRIN (Pfizer) or VANQUIN (W-L) to an unassociated third party in those countries. The proposed undertaking removes the entire overlap between Pfizer and W-L in these markets.
92. The Commission considers that the undertakings are sufficient to eliminate serious doubts as to the compatibility of the transaction with the common market. These commitments will solve competition concerns both by eliminating the overlap between the parties in this market and facilitating new entry to the market. The undertakings have also been supported by third parties in their replies to the Commission's market test.

## **VII. CONCLUSION**

93. The Commission concludes that the undertakings submitted by the parties are sufficient to address the competition concerns raised by this concentration. Accordingly, subject to the full compliance with the commitment submitted by the notifying parties, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(2) of Council Regulation (EEC) No 4064/89.

For the Commission,

## ANNEX

### *Anthelmintics Commitment*

Pfizer Inc. and Warner-Lambert Company hereby give the commitments set forth below to the European Commission of the European Communities pursuant to Article 6(2) of Council Regulation (EEC) No 4064/89 of 21 December 1989 as amended (the "Merger Regulation") in the context of the proposed concentration between Pfizer Inc. and Warner-Lambert Company, to be known as Pfizer Inc., in order to alleviate any competition concerns in the supply of anthelmintics for the treatment of worm-related diseases in Germany and Austria. These commitments shall take effect on receipt of the European Commission's decision declaring the proposed concentration between Pfizer Inc. and Warner-Lambert Company compatible with the Common Market pursuant to Article 6(1)(b) of the Merger Regulation.

#### **I. Definitions**

"Closing Date" means the first business day after the satisfaction or waiver of the conditions set forth in Article VI of the Agreement and Plan of Merger dated 6 February 2000 among Pfizer Inc, Seminole Acquisition Sub Corp. and Warner-Lambert Company which will bring about the Merger.

"Commission" means the Commission of the European Communities.

"Confidential information" means all information concerning the research, development, marketing, distribution cost, pricing, sale and commercialisation of the Product in the Territory.

"Divestiture Assets" means all assets relating to the Product in the Territory, including, but not limited to, Know-how, advertisements, promotional materials, marketing plans and strategies, minutes, agendas, reports, and materials, regulatory information, pricing and discount strategies, price lists, pricing and discount plans and objectives, market contracts, proposals and contracting templates, sales forecasts, trademarks, labelling materials, recalls or other corrective action information, supply forecasts, manufacturing information and capacity materials, distribution information, purchase orders, receivables, medical inquiries and product complaints, detail plans and reports, payment information, and any and all materials that are related to the marketing, sale or use of the Product in the Territory.

"Helmex/Combantrin" means the pharmaceutical product containing pyrantel pamoate manufactured by Pfizer in its plant Heinrich Mack Nachf. GmbH Co. KG, at Illerstissen, Germany, in tablets and suspension form and sold in the Territory for use in the treatment of ancylostoma duodenale, ascaris lumbricoides (roundworm), enterobius vermicularis (pinworm), necator americanus, trichostrongylus colubriformis et orientalis, and all rights relating to the manufacture and sale of Helmex/Combantrin in the Territory.

"Know-how" means all technological, technical, scientific, chemical, biological pharmacological, toxicological, regulatory, marketing and other information relating to the Product, including without limitation all formulae, trade secrets, inventions, techniques, patents, patent applications, discoveries, compounds, compositions of matter, assays, reagents, and biological materials, trademarks, research data, technical data and information,

statistical analysis, analytical data, manufacturing data and information, regulatory submissions, and any other information and experience.

“Merger” means the proposed concentration between Pfizer and Warner-Lambert as notified to the Commission on 31 March 2000.

“Parties” means Pfizer and Warner-Lambert.

“Pfizer” means Pfizer Inc., its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Pfizer, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

“Product” means Helmex/Combantrin or Vanquin to be determined by the Parties at their discretion.

“Territory” means Austria and Germany.

“Vanquin/Molevac” means the pharmaceutical product containing the active ingredient pyrvinium embonate sold by Warner-Lambert in tablet and suspension form in the Territory for use in the treatment of oxyuriasis.

“Warner-Lambert” means Warner-Lambert Company, its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Warner-Lambert, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

## **II. Object of the undertaking**

Pfizer and Warner-Lambert undertake the following:

At the latest within six (6) months following the Closing Date,

- (a) to transfer or assign to a third party purchaser approved by the Commission the Divestiture Assets;
- (b) to transfer or assign to the same third party purchaser all Know-how, information and other materials that have been received or generated by the Parties relating to the promotion, manufacture or sale of the Product in the Territory;
- (c) to transfer or assign to the same third party the existing national marketing authorisations for the Product issued by the competent national authorities in the Territory and to grant the technical support necessary for the transfer of such authorisations;
- (d) to assign or grant to the same third party an irrevocable license to use the Parties’ trademarks relating to the Product for the marketing, sale and distribution of the Product in the Territory; and
- (e) to grant to the same third party an irrevocable license of the formulae used by the Parties for the manufacture of the Product for sale in the Territory, subject to appropriate confidentiality commitments.

At the request of the third party purchaser, in case the third party purchaser does not have production facilities of its own, Pfizer and Warner-Lambert shall enter into an agreement for

adequate remuneration and under reasonable terms and conditions for the supply of the Product in quantities sufficient to meet the third party's requirements for the sale of the Product in the Territory, for a period of up to two years from the date of the divestiture or such shorter period as may be elected by the third party purchaser.

The divestiture shall be made to a viable and independent third party purchaser, and shall be subject to the prior approval of the Commission.

Pending divestiture of the Product Pfizer and Warner-Lambert shall:

(a) take such actions as are necessary to maintain the viability and marketability of the Product; and

(b) introduce internal communication arrangements to ensure that no Confidential information directly relating to and necessary to a full and proper exploitation of the Product in the Territory from Pfizer or Warner-Lambert employees hitherto involved with the Product or otherwise involved in the performance of the transfer of the Divestiture Assets is supplied to any other Pfizer or Warner-Lambert employee or any unauthorised third party other than Pfizer or Warner-Lambert employees who strictly need to know the same, as agreed with the third party purchaser.

5. Nothing provided in this undertaking shall limit any right of the Parties to develop, manufacture, distribute or sell the Product outside the Territory or to participate in the development, manufacture, distribution or sale of the Product outside the Territory, or to manufacture the Product in the Territory for any of the above purposes or to supply the third party purchaser for a reasonable period pursuant to Section II.2. In addition, nothing provided in this undertaking shall prevent the Parties from maintaining all rights in respect of the Product outside the Territory and to manufacture the Product for sale outside the Territory.

6. The Parties reserve their rights under Community law to request the Commission to review the whole or any part of this commitment.

### **III. Appointment of a Trustee**

Within seven (7) working days after the Closing Date, the Parties will propose to the Commission two trustees, who are independent of the Parties ("Proposed Trustees"). The appointment of the Proposed Trustees is subject to approval of the Commission. If the Commission does not reject the Proposed Trustees by notice in writing to the Parties within ten (10) Commission working days of the proposal, the Proposed Trustees shall be deemed to have been approved. If only one of the Proposed Trustees has been approved, then that trustee shall be appointed. If both Proposed Trustees have been approved, then the Parties shall, at their own discretion, appoint one of them.

If the Proposed Trustees are rejected, the Parties will propose the name of a new trustee ("New Trustee") within seven (7) working days of being informed of the rejection. If the Commission does not reject the New Trustee by notice in writing to the Parties within ten (10) Commission working days of the new proposal, the New Trustee shall be deemed to have been approved. If the New Trustee is rejected by the Commission, the Commission shall nominate a suitable Trustee ("the Commission Trustee") which the Parties will appoint or cause to be appointed. The Commission Trustee shall be an expert in the negotiation of licensing agreements and shall have substantial experience in the industry.

Pfizer and Warner-Lambert shall consent to the following terms and conditions regarding the powers, duties, authorities and responsibilities of a Proposed Trustee, the New Trustee or the Commission Trustee as approved or deemed to be approved in accordance with the above provisions (the "Trustee"). The Trustee shall have the power and authority to monitor the compliance of Pfizer and Warner-Lambert with the terms of this undertaking and shall exercise such power and authority and carry out the duties and responsibilities of the Trustee in a manner consistent with the purposes of this undertaking and in consultation with the Commission on the basis of written monthly reports.

Within seven (7) days after appointment of the Trustee, the Parties shall execute a trust agreement that, subject to the prior approval of the Commission confers on the Trustee the rights and powers necessary to permit the Trustee to monitor their compliance with the terms of this undertaking and in a manner consistent with the purposes of this undertaking.

Insofar as this information pertains to the Territory the Trustee shall have full and complete access to Pfizer's and Warner-Lambert's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of the Product or to any other relevant information, as the Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of the Product and all materials and information relating to government or regulatory approvals. Pfizer and Warner-Lambert shall cooperate with any reasonable request of the Trustee. Pfizer and Warner-Lambert shall take no action to interfere with or impede the Trustee's ability to monitor Pfizer's and Warner-Lambert's compliance with Section II.

If, after six (6) months have elapsed following the Closing Date (as extended by the Commission as may be necessary or appropriate to accomplish the purpose of this undertaking), Pfizer and Warner-Lambert have not entered into a binding agreement for the obligations set forth in Section II, the Trustee's mandate shall be extended to carry out the additional functions set out hereunder.

Subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to accomplish the arrangements provided in Section II at a fair market price.

Within seven (7) days after any extension of the Trustee's mandate, Pfizer and Warner-Lambert shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Trustee all rights and powers necessary to permit the Trustee to effect the arrangements provided in Section II.

The Trustee shall have three (3) months from the date the Commission approves the trust agreement to accomplish the arrangements provided in Section II, which shall be subject to the prior approval of the Commission. If at the end of the three month period, the Trustee has submitted a plan to accomplish the arrangements provided in Section II or believes that such arrangements can be achieved within a reasonable time, the three (3) month period may be extended by the Commission for an additional three (3) months.

Pfizer and Warner-Lambert shall develop such information as the Trustee may request and shall cooperate with the Trustee. Pfizer and Warner-Lambert shall take no action to interfere with or impede the Trustee's accomplishment of the arrangements provided in Section II.

The Trustee shall use his or her best efforts to negotiate the most favourable price and terms available in each contract that is submitted to the Commission, subject to Pfizer's and Warner-Lambert's absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to an acquirer as set forth in Section II; provided, however, if the Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Trustee shall divest to the acquiring entity selected by Pfizer and Warner-Lambert from among those approved by the Commission, subject to the condition that Pfizer and Warner-Lambert shall select such entity within ten business days of receiving notification of the Commission's approval.

The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the arrangements provided in Section II.

The Trustee shall have no obligation or authority to operate or maintain the Product business or assets in the Territory.

Notwithstanding the Trustee's overall responsibility to discharge its functions and in particular notwithstanding the Trustee's position as an independent unrelated third party, the Trustee shall have due regard to the commercial interests of Pfizer and Warner-Lambert.

15. The Trustee shall serve until the divestiture of the Divestiture Assets; provided, however, that the Commission may extend this period as may be necessary or appropriate to accomplish the purposes of this undertaking.

16. The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this undertaking.

17. The Trustee shall report in writing to Pfizer and Warner-Lambert and the Commission on a monthly basis concerning the Trustee's efforts to accomplish the arrangements provided in Section II.

### **Cognex Commitment**

Pfizer Inc. and Warner-Lambert Company hereby give the commitments set forth below to the European Commission of the European Communities pursuant to Article 6(2) of Council Regulation (EEC) No 4064/89 of 21 December 1989 as amended (the "Merger Regulation") in the context of the proposed concentration between Pfizer Inc. and Warner-Lambert Company, to be known as Pfizer Inc., in order to alleviate any competition concerns in the supply of Alzheimer's disease treatments in the EEA. These commitments shall take effect on receipt of the European Commission's decision declaring the proposed concentration between Pfizer Inc. and Warner-Lambert Company compatible with the Common Market pursuant to Art. 6(1)(b) of the Merger Regulation.

#### **I. Definitions**

1. "Closing Date" means the first business day after the satisfaction or waiver of the conditions set forth in Article VI of the Agreement and Plan of Merger



dated 6 February 2000 among Pfizer Inc, Seminole Acquisition Sub Corp. and Warner-Lambert Company which will bring about the Merger.

2. "Commission" means the European Commission of the European Communities.
3. "Cognex" means any pharmaceutical preparation containing the drug substance tacrine hydrochloride, any of its constituent elements, active ingredients or intermediaries, and all rights held by Warner-Lambert relating to the research, development, manufacture and sale of Cognex.
4. "Cognex Divestiture Assets" means all assets relating to Cognex, including, but not limited to, samples, field aids, training materials, advertisements, promotional materials, tokens, marketing plans and strategies; minutes, agendas, reports, and materials; prescriber information, FDA and other regulatory information, pricing and discount strategies, price lists, pricing and discount plans and objectives; managed care, pharmaceutical benefit manager, hospital, long-term care, governmental and all other specialty market contracts, proposals and contracting templates; notes, minutes and other documents relating to speaker programs, and meetings with medical advisers to Warner-Lambert, including plans for future programs and meetings, market research data and proposals relating to Cognex, sales forecasts, including forecasts of sample distribution, clinical study plans and protocols relating to Phase IV studies, information relating to Cognex development, including line extensions, formulation development and development of metabolites or isomers of Cognex, physician targeting data and physician call notes, professional affairs letters and templates used for responding to physician inquiries, trademarks, labelling materials, recalls or other corrective action information, supply forecasts, manufacturing information and capacity materials, distribution information, purchase orders, receivables, medical inquiries and product complaints, detail plans and reports, internal call reporting data, promotional amount reporting, co-promotion fee and payment information, and any and all contracts that are related to the research, development, marketing, sale or use of Cognex.
5. "Cognex Divestiture Agreement" means the agreement between Warner-Lambert and First Horizon, a third party purchaser unrelated to Warner-Lambert or Pfizer, relating to the sale of the Cognex Divestiture Assets, dated 14 April 2000.
6. "Cognex Know-how" means all confidential business information and know-how presently in the possession or control of Warner-Lambert that relates in whole or in part to Cognex, including without limitation information and documents stored on management information systems; proprietary software used in connection with Cognex; all data, contractual rights, materials, documents and information relating to obtaining government or regulatory approvals for Cognex; and any other information, documents and experience

relating to Cognex. Cognex Know-how shall be deemed to include all information included in the Cognex Divestiture Assets.

7. “First Horizon” means First Horizon Pharmaceutical Corporation, a Delaware corporation, with its office and principal place of business located at 660 Hembree Parkway, Suite 106, Roswell, GA 30076, United States, and includes its directors, officers, employees, agents and representatives, predecessors, successors, and assigns, licensees, the subsidiaries, divisions, groups and affiliates controlled by First Horizon, and the respective directors, officers, employees, agents and representatives, successors and assigns of each.
8. “Merger” means the proposed concentration between Pfizer and Warner-Lambert as notified to the Commission of the European Communities on 31 March 2000.
9. “Pfizer” means Pfizer Inc., its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Pfizer, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.
10. “Warner-Lambert” means Warner-Lambert Company, its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Warner-Lambert, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

## II. Object of the undertaking

Pfizer and Warner-Lambert undertake to carry out the following steps:

1. Prior to, or at the latest, within six (6) months following the Closing Date, Warner-Lambert shall divest the Cognex Divestiture Assets, absolutely and in good faith and at no minimum price, in accordance with the Cognex Divestiture Agreement. The divestiture shall be made to a viable and independent third party purchaser, and shall be subject to the prior approval of the Commission. The Cognex Divestiture Agreement is incorporated by reference into this undertaking and made part hereof as **Confidential Appendix 1**.
2. Pfizer and Warner-Lambert shall contract manufacture and deliver to the third party purchaser, in a timely manner and under reasonable terms and conditions, a supply of Cognex at direct cost excluding corporate overhead (or such other price specified in the Cognex Divestiture Agreement with the approval of the Commission) for a period of time up to three (3) years from

the date of the divestiture or such shorter period as may be elected by the third party purchaser.

3. Upon reasonable notice and request from the third party purchaser, Pfizer and Warner-Lambert shall use all reasonable efforts to provide in a timely manner assistance and advice to enable the third party purchaser (or designees thereof) to obtain all necessary European regulatory approvals to manufacture and sell Cognex.
4. In order to ensure an orderly transfer of Cognex to the third party purchaser, Warner-Lambert also undertakes to:
  1. conclude, prior to, or at the latest, within six (6) months following the Closing Date, with the third party purchaser arrangements for distribution and marketing support of Cognex for a period ending on 30 November 2000.
  2. pending divestiture of Cognex introduce internal communication arrangements to ensure that no Confidential Business Information directly relating to and necessary to a full and proper exploitation of Cognex in the Territory from those Warner-Lambert employees hitherto involved with Cognex or providing the support referred to in Section II.B and II.D.1 above or otherwise involved in the performance of the transitional arrangements described above is supplied to any other Pfizer or Warner-Lambert employee or any unauthorised third party other than those Warner-Lambert employees who strictly need to know the same, as agreed with the third party purchaser.

For the work relating to the maintenance of the Cognex business in the ordinary course of business Warner-Lambert shall receive no compensation.

5. Pending divestiture of the Cognex Divestiture Assets, Pfizer and Warner-Lambert shall take such actions as are necessary to maintain the viability and marketability of the Cognex Divestiture Assets and to prevent the destruction, removal, wasting, deterioration or impairment of any of the Cognex Divestiture Assets except for ordinary wear and tear.
6. Pfizer and Warner-Lambert reserve their rights under Community law to request the Commission to review the whole or any part of this commitment.

### III. Appointment of a Trustee

1. Within seven (7) working days after the Closing Date, Pfizer and Warner-Lambert will propose to the Commission two trustees, who are independent of Pfizer and Warner-Lambert ("Proposed Trustees"). The appointment of the Proposed Trustees is subject to approval of the Commission. If the Commission does not reject the Proposed Trustees by notice in writing to the Parties within ten (10) Commission working days of the proposal, the Proposed Trustees shall be deemed to have been approved. If only one of the Proposed Trustees has been approved, then that trustee shall be appointed. If both Proposed Trustees have been approved, then the Parties shall, at their own discretion, appoint one of them.
2. If the Proposed Trustees are rejected, the Parties will propose the name of a new trustee ("New Trustee") within seven (7) working days of being informed of the rejection. If the Commission does not reject the New Trustee by notice in writing to the Parties within ten (10) Commission working days of the new proposal, the New Trustee shall be deemed to have been approved. If the New Trustee is rejected by the Commission, the Commission shall nominate a suitable Trustee (the "Commission Trustee") which the Parties will appoint or cause to be appointed. The Commission Trustee shall be an expert in the negotiation of licensing agreements and shall have substantial experience in the industry.
3. Pfizer and Warner-Lambert shall consent to the following terms and conditions regarding the powers, duties, authorities and responsibilities of a Proposed Trustee, the New Trustee or the Commission Trustee as approved or deemed to be approved in accordance with the above provisions (the "Trustee"). The Trustee shall have the power and authority to monitor the compliance of Pfizer and Warner-Lambert with the terms of this undertaking and shall exercise such power and authority and carry out the duties and responsibilities of the Trustee in a manner consistent with the purposes of this undertaking and in consultation with the Commission on the basis of written monthly reports.
4. Within seven (7) days after appointment of the Trustee, Pfizer and Warner-Lambert shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Trustee the rights and powers necessary to permit the Trustee to monitor their compliance with the terms of this undertaking and in a manner consistent with the purposes of this undertaking.
5. The Trustee shall have full and complete access to Pfizer's and Warner-Lambert's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of Cognex, or to any other relevant information, as the Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Cognex and all materials and information relating to the FDA and other government or regulatory approvals. Pfizer and Warner-Lambert shall cooperate with any reasonable request of the Trustee. Pfizer and

Warner-Lambert shall take no action to interfere with or impede the Trustee's ability to monitor Pfizer's and Warner-Lambert's compliance with Section II.

6. The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this undertaking.
7. If, after six (6) months have elapsed following the Closing Date (as extended by the Commission as may be necessary or appropriate to accomplish the purpose of this undertaking), Pfizer and W-L have not entered into a binding agreement for the obligations set forth in Section II, the Trustee's mandate shall be extended to carry out the additional functions set out hereunder.
8. Subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to divest all of the Cognex Divestiture Assets.
9. Within seven (7) days after any extension of the Trustee's mandate pursuant to Section III.G, Pfizer and Warner-Lambert shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Trustee all rights and powers necessary to permit the Trustee to effect the divestiture required by Section II.
10. The Trustee shall have three (3) months from the date the Commission approves the trust agreement to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If at the end of this period, the Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission for an additional (3) months.
11. Pfizer and Warner-Lambert shall develop such financial or other information as the Trustee may request and shall cooperate with the Trustee. Pfizer and Warner-Lambert shall take no action to interfere with or impede the Trustee's accomplishment of the divestiture.
12. The Trustee shall use his or her best efforts to negotiate the most favourable price and terms available in each contract that is submitted to the Commission, subject to Pfizer's and Warner-Lambert's absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to an acquirer as set out in Section II; provided, however, if the Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Trustee shall divest to the acquiring entity selected by Pfizer and Warner-Lambert from among those approved by the Commission; provided further, however, that Pfizer and Warner-Lambert

shall select such entity within five (5) business days of receiving notification of the Commission's approval.

13. The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by Section II.
14. The Trustee shall have no obligation or authority to operate or maintain the Cognex Divestiture Assets.
- N1. Notwithstanding the Trustee's overall responsibility to discharge its functions and in particular notwithstanding the Trustee's position as an independent unrelated third party, the Trustee shall have due regard to the commercial interests of Pfizer and Warner-Lambert.
15. The Trustee shall report in writing to Pfizer and Warner-Lambert and the Commission on a monthly basis concerning the Trustee's efforts to accomplish the divestiture.

### **Dilzem Commitment**

Pfizer Inc. and Warner-Lambert Company hereby give the commitments set forth below to the European Commission of the European Communities pursuant to Article 6(2) of Council Regulation (EEC) No 4064/89 of 21 December 1989 as amended (the "Merger Regulation") in the context of the proposed concentration between Pfizer Inc. and Warner-Lambert Company, to be known as Pfizer Inc., in order to alleviate any competition concerns in the C8A (calcium antagonist plain) market in Austria. These commitments shall take effect on receipt of the European Commission's decision declaring the proposed concentration between Pfizer Inc. and Warner-Lambert Company compatible with the Common Market pursuant to Art. 6(1)(b) of the Merger Regulation.

#### **I. Definitions**

- A. "Closing Date" means the first business day after the satisfaction or waiver of the conditions set forth in Article VI of the Agreement and Plan of Merger dated 6 February 2000 among Pfizer Inc, Seminole Acquisition Sub Corp. and Warner-Lambert Company which will bring about the Merger.
- B. "Commission" means the European Commission of the European Communities.
- C. "Confidential Business Information" means all information concerning the research, development, marketing, distribution, cost, pricing, sale and commercialisation of Dilzem in the Territory.
- D. "Diltiazem Supply Agreement" means the Supply Agreement dated 1 July 1996 between Tanabe and Gödecke AG (an indirect subsidiary of Warner-Lambert), as amended.

- E. "Dilzem" means the corresponding product, diltiazem hydrochloride, that is the subject of the Diltiazem Supply Agreement, and all rights relating to the research, development, manufacture, use, existing product and marketing registration, and sale of Dilzem in the Territory.
- F. "Dilzem Know-How" means all Confidential Business Information and Know-How presently owned by Warner-Lambert which relates to and is necessary for a full and proper exploitation of Dilzem in the Territory, including without limitation information stored on management information systems, proprietary software used in connection with Warner-Lambert's Dilzem, and all data, contractual rights, materials and information relating to obtaining necessary registrations for the sale of Warner-Lambert's Dilzem in the Territory, and any other information and experience relating directly and necessary to a full and proper exploitation of Dilzem with regard to the Territory.
- G. "Dilzem Patent Rights" means any and all patents and patent applications owned, licensed or controlled by Warner-Lambert related directly to and necessary for a full and proper exploitation of Dilzem in the Territory, and any and all reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations or divisions of or to any of the aforesaid patents.
- H. "Elan" means Elan Corporation plc, an Irish corporation, with its office and principal place of business located at Monksland, Athlone, Co. Westmeath, Ireland, and includes its directors, officers, employees, agents and representatives, predecessors, successors, and assigns, licensees, the subsidiaries, divisions, groups and affiliates controlled by Elan, and the respective directors, officers, employees, agents and representatives, successors and assigns of each.
- I. "Elan Agreement" means the Agreement dated 18 October 1995, between Elan and Gödecke AG (an indirect subsidiary of Warner-Lambert), as amended.
- J. "Know-How" means all technological, technical, scientific, chemical, biological, pharmacological, toxicological, regulatory, marketing and other information, including without limitation all formulae, trade secrets, inventions, techniques, patents, patent applications, discoveries, compounds, compositions of matter, assays, reagents, and biological materials, trademarks, research data, technical data and information, testing data, preclinical and clinical data, toxicological and pharmacological data, statistical analysis, analytical data, clinical protocols, specifications, designs, drawings, processes, testing and quality assurance/quality control data, manufacturing data and information, regulatory submissions, and any other information and experience.
- K. "Merger" means the proposed concentration between Pfizer and Warner-Lambert as notified to the Commission on 31 March 2000.

- L. "Pfizer" means Pfizer Inc., its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Pfizer, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.
- M. "Tanabe" means Tanabe Seiyaku Co., Ltd., a Japanese corporation, with its office and principal place of business located at 2-10 Dosho-machi, 3-Chome, Chou-Ku, Osaka, Japan, and includes its directors, officers, employees, agents and representatives, predecessors, successors, and assigns, licensees, the subsidiaries, divisions, groups and affiliates controlled by Tanabe, and the respective directors, officers, employees, agents and representatives, successors and assigns of each.
- N. "Territory" means Austria.
- O. "Warner-Lambert" means Warner-Lambert Company, its directors, officers, employees, agents, subsidiaries, divisions, groups and affiliates controlled by Warner-Lambert, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

## **II. Object of the undertaking**

Pfizer and Warner-Lambert undertake to carry out the following steps:

- A. At the latest within six (6) months following the Closing Date, Warner-Lambert undertakes:
  - 1. to transfer or assign to a Commission-approved third party purchaser all Dilzem Know-How and Dilzem Patent Rights, information and other materials that have been received or generated by Warner-Lambert relating to the actual or proposed development, promotion, manufacture or sale of Dilzem in the Territory pursuant to the Diltiazem Supply Agreement;
  - 2. to transfer or assign to the same third party purchaser all authorizations provided by the Public Authorities concerning Dilzem with respect to the Territory and to grant the technical support necessary for the transfer of such authorizations;
  - 3. to assign or grant to the same third party purchaser an irrevocable exclusive license to use Warner-Lambert's trademark "Dilzem" for the marketing, sale and distribution of Dilzem in the Territory;
  - 4. to grant to the same third party purchaser an irrevocable exclusive license of the formulae used by Warner-Lambert for the manufacture of Dilzem (injectable, 60mg and 90 mg dosage forms) subject to the thus manufactured Dilzem being sold in the Territory and subject to appropriate confidentiality commitments;



5. not to extend the Diltiazem Supply Agreement when its current term expires as of 31 December 2000 (or to terminate the Agreement sooner) insofar as the Agreement pertains to the Territory, and to use their best efforts to cause Tanabe to supply the same third party purchaser with diltiazem hydro-chloride as of 1 January 2001 (or the termination date), whichever is earlier; and
  6. to grant, subject to approval of Elan, for the term of the Elan Agreement, an irrevocable sub-license to prepare, use and sell DSDF, as defined in the Elan Agreement, in the Territory, and to use their best efforts to cause Elan to grant such approval.
- B. At the request of the third party purchaser in case the third party purchaser does not have production facilities of its own, Pfizer and Warner-Lambert shall enter into an agreement for adequate remuneration and under reasonable terms and conditions for the supply of Dilzem in quantities sufficient to meet the third party's requirements for the sale of Dilzem in the Territory, for a period of up to two (2) years from the date of the divestiture or such shorter period as may be elected by the third party purchaser. Such supply obligation is subject to the third party purchaser supplying Warner-Lambert in a timely manner with the requisite diltiazem hydrochloride, the Product as defined in the Elan Agreement, and any other necessary excipients.
- C. The divestiture shall be made to a viable and independent third party purchaser, and shall be subject to the prior approval of the Commission.
- D. Pending divestiture of Dilzem, Pfizer and Warner-Lambert shall:
1. take such actions as are necessary to maintain the viability and marketability of Dilzem; and
  2. introduce internal communication arrangements to ensure that no Confidential Business Information directly relating to and necessary to a full and proper exploitation of Dilzem in the Territory from those Warner-Lambert employees hitherto involved with Dilzem or providing the support referred to in Sections II.B and II.D.1 above or otherwise involved in the performance of the transfer arrangements above is supplied to any other Pfizer or Warner-Lambert employee or any unauthorised third party other than those Warner-Lambert employees who strictly need to know the same, as agreed with the third party purchaser; and
  3. refrain (and insure that their affiliates and subsidiaries will refrain), other than for the fulfillment of its obligations under Section II.B.1 above, from using or disclosing any Confidential Business Information directly relating to and necessary to a full and proper exploitation of Dilzem in the Territory;
- E. Nothing provided in this undertaking shall limit any right of Warner-Lambert to develop, manufacture, distribute or sell Dilzem outside the Territory or to participate in the development, manufacture, distribution or sale of Dilzem

outside the Territory, or to manufacture Dilzem in the Territory for any of the above purposes. In addition, nothing provided in this undertaking shall prevent Warner-Lambert from maintaining all rights in respect of Dilzem outside the Territory and to manufacture Dilzem for sale outside the Territory.

- F. Pfizer and Warner-Lambert reserve their rights under Community law to request the Commission to review the whole or any part of this commitment.

### **III. Appointment of a Trustee**

- A. Within seven (7) working days after the Closing Date, Pfizer and Warner-Lambert will propose to the Commission two trustees, who are independent of Pfizer and Warner-Lambert ("Proposed Trustees"). The appointment of the Proposed Trustees is subject to approval of the Commission. If the Commission does not reject the Proposed Trustees by notice in writing to the Parties within ten (10) Commission working days of the proposal, the Proposed Trustees shall be deemed to have been approved. If only one of the Proposed Trustees has been approved, then that trustee shall be appointed. If both Proposed Trustees have been approved, then the Parties shall, at their own discretion, appoint one of them.
- B. If the Proposed Trustees are rejected, the Parties will propose the name of a new trustee ("New Trustee") within seven (7) working days of being informed of the rejection. If the Commission does not reject the New Trustee by notice in writing to the Parties within ten (10) Commission working days of the new proposal, the New Trustee shall be deemed to have been approved. If the New Trustee is rejected by the Commission, the Commission shall nominate a suitable Trustee (the "Commission Trustee") which the Parties will appoint or cause to be appointed. The Commission Trustee shall be an expert in the negotiation of licensing agreements and shall have substantial experience in the industry.
- C. Pfizer and Warner-Lambert shall consent to the following terms and conditions regarding the powers, duties, authorities and responsibilities of a Proposed Trustee, the New Trustee or the Commission Trustee as approved or deemed to be approved in accordance with the above provisions (the "Trustee"). The Trustee shall have the power and authority to monitor the compliance of Pfizer and Warner-Lambert with the terms of this undertaking and shall exercise such power and authority and carry out the duties and responsibilities of the Trustee in a manner consistent with the purposes of this undertaking and in consultation with the Commission on the basis of written monthly reports.
- D. Within seven (7) days after appointment of the Trustee, Pfizer and Warner-Lambert shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Trustee the rights and powers necessary to permit the Trustee to monitor their compliance with the terms of this undertaking and in a manner consistent with the purposes of this undertaking.

- E. Insofar as this information pertains to the Territory the Trustee shall have full and complete access to Pfizer's and Warner-Lambert's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of Dilzem or to any other relevant information, as the Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of Dilzem and all materials and information relating to government or regulatory approvals. Pfizer and Warner-Lambert shall cooperate with any reasonable request of the Trustee. Pfizer and Warner-Lambert shall take no action to interfere with or impede the Trustee's ability to monitor Pfizer's and Warner-Lambert's compliance with Section II.
- F. The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this undertaking.
- G. If, after six (6) months have elapsed following the Closing Date (as extended by the Commission as may be necessary or appropriate to accomplish the purpose of this undertaking), Pfizer and Warner-Lambert have not entered into a binding agreement for the obligations set forth in Section II, the Trustee's mandate shall be extended to carry out the additional functions set out hereunder.
- H. Subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to accomplish the arrangements provided in Section II.
- I. Within seven (7) days after any extension of the Trustee's mandate pursuant to Section III.G, Pfizer and Warner-Lambert shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Trustee all rights and powers necessary to permit the Trustee to effect the arrangements provided in Section II.
- J. The Trustee shall have three (3) months from the date the Commission approves the trust agreement to accomplish the arrangements provided in Section II, which shall be subject to the prior approval of the Commission. If at the end of this period, the Trustee has submitted a plan to accomplish the arrangements provided in Section II or believes that such arrangements can be achieved within a reasonable time, the period may be extended by the Commission for an additional (3) months. The Trustee shall serve until the divestiture or other alternative arrangement relating to the Dilzem business in the Territory has been completed.
- K. The Trustee shall continue to have full and complete access to information relating to the Dilzem business in the Territory, as provided in Section III.E above. Pfizer and Warner-Lambert shall develop such information as the Trustee may request and shall cooperate with the Trustee. Pfizer and Warner-Lambert shall take no action to interfere with or impede the Trustee's accomplishment of the arrangements provided in Section II.

- L. The Trustee shall use his or her best efforts to negotiate the most favourable price and terms available in each contract that is submitted to the Commission, subject to Pfizer's and Warner-Lambert's absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to an acquirer as set out in Section II; provided, however, if the Trustee receives bona fide offers from more than one viable and independent third party, and if the Commission determines to approve more than one such entity, the Trustee shall divest to the acquiring entity selected by Pfizer and Warner-Lambert from among those approved by the Commission, subject to the condition that Pfizer and Warner-Lambert shall select such entity within five business days of receiving notification of the Commission's approval.
- M. The Commission may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the arrangements provided in Section II.
- N. The Trustee shall have no obligation or authority to operate or maintain the Dilzem business or assets relating to the Territory.
- O. Notwithstanding the Trustee's overall responsibility to discharge its functions and in particular notwithstanding the Trustee's position as an independent unrelated third party, the Trustee shall have due regard to the commercial interests of Pfizer and Warner-Lambert.
- P. The Trustee shall report in writing to Pfizer and Warner-Lambert and the Commission on a monthly basis concerning the Trustee's efforts to accomplish the arrangements provided in Section II.