EN

Case No COMP/M.1835 - MONSANTO / PHARMACIA & UPJOHN

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REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.03.2000

PUBLIC VERSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

MERGER PROCEDURE
6(1)b DECISION

To the notifying parties

Dear Sirs,

Subject: Case No IV/M. 1835 Monsanto/Pharmacia & Upjohn
Your notification of 16.2.2000 pursuant to Article 4 of Council Regulation No 4064/89[1]

1. On 16.2.2000**,** 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 Monsanto Company ("Monsanto") and Pharmacia Upjohn, Inc. (P&U) enter into a full merger within the meaning of Article 3(1)(a) of the Council 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.

[1] 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).

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I. THE PARTIES

3. Monsanto is a US company active in the world-wide manufacture and sale of products in the following main business areas:

   - Agricultural products: agricultural and industrial herbicides and other plant protection products, agricultural seeds and biotechnology.

   - Pharmaceuticals: anti-inflammatory, cardiovascular, central nervous system, gastrointestinal and women's health products.

   - Nutrition and consumer products: artificial sweeteners used primarily in beverages and food products (Monsanto is currently in the process of disposing that business).

   - Various industrial products such as cleaners, textile printing materials and oil and gas drilling applications.

4. Monsanto's merger with American Home Products that had been approved by the Commission on 28 September 1998[2] was not implemented because of major disagreements between the parties.

5. P&U is a US company, formed in November 1995 through the combination of Pharmacia Aktiebolag and the Upjohn Company[3]. P&U is engaged in the world-wide manufacture and sale of products in the following main business areas:

   – Pharmaceuticals: general therapeutics prescribed by primary care customers, speciality products (peptide hormones, ophtalmology and Parkinson's disease treatments), and hospital products (oncology and infectious disease products).

   - Consumer health: generic products of key pharmaceuticals (smoking cessation aid, hair loss treatment, vitamin, nasal spray and antifungal products).

   - Animal health: a broad range of pharmaceuticals and feed additives for livestock and pets.

   - Diagnostics: products allowing physicians to determine whether a patient suffers from allergy or asthma and an in vitro allergy test.

6. P&U sold the major portion of its nutrition business in late 1998 and the remaining part in Germany and China in 1999.

II. THE OPERATION

7. Pursuant to an Agreement and Plan of Merger dated December 19, 1999, the proposed concentration is a merger by way of a private agreement between Monsanto and P&U. This will be accomplished through a wholly-owned subsidiary of Monsanto which will be merged with P&U. The whole of both Monsanto and P&U will be subject to the concentration. The existing agricultural business of Monsanto will be transferred to a

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2 Case IV/M. 1229 – American Home Products/Monsanto, Commission decision of 28 September 1998

3 Case IV/M. 631 – Upjohn/Pharmacia, Commission decision of 29 September 1995

subsidiary of the resulting entity. It is expected that up to 19.9% of that business will be offered in an Initial Public Offering in 2000. It will become a separate legal entity, with a stand-alone board of directors and its own publicly traded stock upon completion of the intended IPO.

III. CONCENTRATION

8. Technically, each share of P&U common stock shall be converted into the right to receive 1.19 shares of the combined entity and each Monsanto share outstanding prior to the combined entity will represent one share in the resulting entity. Following the share exchange, the original Monsanto shareholders will hold 51% and P&U shareholders will hold 49% of the resulting entity. The operation is therefore a concentration since the operations described above will result in a full merger between Monsanto and Pharmacia Upjohn.

IV. COMMUNITY DIMENSION

9. Monsanto and P&U have a combined aggregate world-wide turnover in excess of EUR 5,000 million (in 1998 Monsanto: EUR 6,756.1 million, P&U: EUR 8,582.1 million). Each of them have a Community-wide turnover in excess of EUR 250 million (in 1998 Monsanto: EUR […] million, P&U: EUR […] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The operation does not qualify for co-operation with the EFTA surveillance authority pursuant to the EEA Agreement.

V. COMPETITIVE ASSESSMENT

A. Relevant product markets

10. The only area of overlap arising from the merger is in the research, development and production of prescription and over-the-counter (OTC) human pharmaceutical products. P&U has no material interests outside the field of human pharmaceuticals and consumer healthcare. However, some *[Deleted for publication ; business secret]* of Monsanto's 1999 turnover was accounted for by the manufacture and supply of agricultural products (agrochemicals, seeds and biotechnology). P&U has no activities which overlap with these businesses.

11. 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[4]. On the basis of these decisions, product markets in the pharmaceutical industry can be grouped into pharmaceutic specialities, active substances and future products.

1. Pharmaceutic specialities

[4] 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.

12. In its previous decisions, the Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" (ATC) classification, 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 third level of the ATC classification 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 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 pharmaceutic 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 pharmaceutic 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. Most medicines issued only on prescription are indeed reimbursed, whereas most of those, which may be sold over the counter, are not reimbursed. Prescription 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.

15. Within their broad pharmaceutical ranges, the parties have combined ATC-3 shares at the Member State level of 15% or over in respect of nine product areas: hepatic lipotropic (A5B), platelet aggregation inhibitors (B1C), diuretics (C3A), topical anti-acne preparations (D10A), trichomonacides (G1A), progestogens (G3D), plain corsticosteroids (H2A), anti-rheumatic non-steroid (M1A) and narcotic analgesics (N2A).

Hepatic lipotropic (A5B)

16. This ATC-3 category includes products used alone or in combination with others for the treatment of liver deficiency. The parties have submitted that this ATC-3 classification is appropriate to define the relevant market and have accordingly presented data on this basis. The Commission's investigation does not suggest otherwise.

Platelet aggregation inhibitors (B1C)

17. Platelet aggregation inhibitors include products that reduce platelet adhesion and aggregation. They are most useful as a prophylactic measure to prevent clot formation in patients at risk of developing thromboembolism. Low dose acetylsalcylic acid (aspirin) preparations are the most common form of platelet aggregation inhibitor.

18. The Commission has considered in a previous case (Sanofi/Synthélabo[5]) that the B1C category comprised two distinct product segments: first line platelet aggregation inhibitors (AAS and dipyridamole) and second line platelet aggregation inhibitors (ticlopidine). The parties agree with this definition of the market for B1C products.

19. Monsanto's platelet aggregation inhibitors are made of ticlopidine and, as a result, belong to the second line segment of the market. P&U's platelet aggregation inhibitors are made of indobufen, which has characteristics similar to aspirin's and therefore belong to the first line product segment. The parties, accordingly, do not have overlapping sales in respect of platelet aggregation inhibitors. They do not hold strong positions on their respective segments either.

Diuretics (C3A)

20. The ATC-2 class C3 comprises a wide range of diuretics, plain and in combination with agents such as potassium, betablockers and calcium blockers. The ATC-3 class C3A includes products which share the characteristic of causing the body to lose water by urination and are most often used for the treatment of oedema and hypertension. The Commission has previously considered that this ATC-3 classification is appropriate for assessing diuretics[6]. The parties have accordingly presented data on this basis.

Topical anti-acne preparations (D10A)

21. The ATC-3 classification D10A comprises topical preparations (as opposed to preparations for systemic use) used specifically in the treatment of acne, including preparations with antibiotics, corticosteroids, sulphur, retinoids, etc. The parties consider that this ATC-3 classification is appropriate for assessing topical anti-acne preparations and have accordingly presented data on this basis. In their replies to the Commission's questionnaires, third parties have not indicated that another market definition should be used.

Trichomonacides (G1A)

22. The ATC-2 class G1 comprises a wide range of gynaecological anti-infective and antiseptic products that are mainly for local use. These products are indicated for the treatment of vaginal infections. Among them, the G1A trichomonacides are used specifically for the treatment of urethritis and vaginitis due to trichomonas vaginalis. All products in the G1A class have the same indication, although their active ingredient may be different (metronidazole, tinidazole, ornidazole, azanidazole, nifuratel, etc.). They exists in three formats: tablets, vaginal suppositories and cream. The parties consider that this ATC-3 classification is appropriate for assessing trichomonacides and the market investigation has not suggested otherwise.

Progestogens (G3D)

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5 Case IV/M.1397 – Sanofi/Synthélabo, Commission decision of 17 May 1999.

6 Case IV/M.1378 – Hoechst/Rhône-Poulenc, Commission decision of 9 August 1999; Case IV/M.632 – Rhône-Poulenc/Fisons, Commission decision of 21 September 1995; Case IV/M.587 – Hoechst/Marion Merrell Dow, Commission decision of 22 June 1995.

23. The ATC-2 class G3 comprises sex hormones and modulators of the genital system. The ATC-3 class G3D consists of progestogen replacement products use for the treatment of dysmenorrhea, menorrhagia, endometriosis, infertility, menopause, PMS, puerperal depression and breast cancer. Products in this category are usually sold at too high a dose to be used as contraceptives. The parties consider that this ATC-3 classification is appropriate for assessing progestogens and have accordingly presented data on this basis. This market definition has not been contested by third parties either.

Plain corticosteroids (H2A)

24. The ATC-2 class H2 comprises a wide range of corticosteroids based for systemic use (i.e. preparations that are intended to be absorbed by the entire human system as opposed to preparations for local use only). The active ingredients for all H2 products are synthetic derivatives of cortisone, whether natural or synthetic. Corticosteroids have a large number of different indications, the main ones being anti-inflammatory (lung disease, respiratory problems), anti-rheumatic and anti-allergic (e.g. asthma, Quincke oedema) indications.

25. Plain corticosteroid products (H2A) may exist in different forms: oral corticosteroids are mostly used for the treatment of small, moderate or chronic diseases and injections are used in more severe cases where treatment needs are quick, direct and in high doses. The parties consider that this ATC-3 classification is appropriate for assessing plain corticosteroids and have accordingly presented data on this basis. The results of the market investigation do not contest this definition.

Anti-rheumatic non-steroid (M1A)

26. This ATC-3 group consists of anti-inflammatory and anti-rheumatic preparations for systemic use. They are mostly used for the treatment of pain and inflammation associated with osteo and rheumatoid arthritis, low back pain and strains and sprains. The parties consider that this ATC-3 classification is appropriate for assessing anti-rheumatic non-steroid and have accordingly presented data on this basis. The Commission's investigation does not suggest otherwise.

Narcotic analgesics (N2A)

27. The ATC-3 class N2A comprises a wide range of opioid derived analgesics that are used in case of acute and chronic pain. It specifically comprises strong prescription analgesics that are used in cases of severe acute and chronic pain. N2A products have a number of different active ingredients including morphine, ketobemidone, fentanyl and methadone. They can be either immediate release formulations for the treatment of acute pain or slow release forms for the treatment of chronic pain. Although the same active ingredients are used in these two segments, they are supplied to hospitals and through pharmacies in different formulations and formats according to the segment targeted.

28. The parties do not consider this ATC-3 classification to be appropriate for assessing strong prescription analgesics. They believe that, for the purpose of measuring the competitive impact of this merger, a distinction must be made within this classification between immediate and slow-release analgesics, even though the same active ingredients are used in these two segments. They argue that immediate-release analgesics are used for the treatment of acute pain, whereas slow-release analgesics are

indicated for the treatment of chronic pain. Typical severe acute pain includes post-surgery pain and trauma. This segment requires analgesics that are immediately effective. Severe chronic pain mostly relates to a variety of cancer conditions. For chronic conditions, the most used opioids are in slow-release or retard formulations. The drug substance is released slowly into the system and relieves pain over a longer period of time (typically 12 to 24 hours). Such formulations are less suited to give immediate pain relief. Conversely, immediate-release forms are used for acute conditions where the time to onset of pain relief is essential. The parties argue that, in practice, almost none of the products sold in the severe pain segment are equally suited to treat both acute and chronic conditions.

29. The parties submit, however, that immediate and slow-release formulations can be used in combination in cases of patients with chronic pain suffering occasionally from a so-called "breakthrough" pain. In these cases, it is common to complement the slow-release medication with an immediate-release dose of the same molecule.

30. The market definition suggested by the parties regarding the existence of two different segments as well as their complementarity has been confirmed by the Commission's market investigation. Therefore, for the purposes of the present case, the immediate-release and the slow-release segments of the N2A ATC class will be considered to constitute two separate relevant markets and the assessment of the merger will be conducted at this level.

2. Active substances

31. The manufacturing process for pharmaceutical products includes two separate steps: the manufacturing of active substances, followed by the manufacturing of pharmaceutical products. Pharmaceutical products are produced by mixing the active substance with other substances and by presenting the result under a galenic form (pills, tablets). The Commission considers that active substances are separate and specific markets, which are upstream to the markets for pharmaceutic specialities. Active substances are produced from chemical and biological products and may be both manufactured for in-house purposes as well as traded. There are markets for active substances to the extent that such substances are the object of transactions between a producer and a buyer of these substances.

32. The parties have vertically overlapping activities in one active substance, that is, spironolactone. Spironolactone is a steroid that is used as a diuretic. The investigation shows that spironolactone can be substituted with a number of other active substances in diuretics, such as amiloride, triamterene, bumetadine and thiazides. Diuretics using all these different active substances fall under the same ATC-3 classification.

33. It is not, however, necessary to reach a definite conclusion on the exact scope of the relevant product market because the operation will not give rise to competition concerns even if the assessment was carried out by using the narrowest possible market definition.

3. Future products

34. 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[7], 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%.

35. 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.

36. 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.

37. The parties submit that the only broad primary research area in which they are both substantially active is oncology. In this area, there are three areas where there may be potential overlaps in their pipeline products: anti-angiogenesis, blood growth factors and colerectal cancer. The parties submit, nevertheless, that these products have different indications and therefore do not overlap. Third parties in their replies to the Commission's investigation have agreed with the parties' view. The parties submit further that there are no overlaps between their future products and current products on the market.

a) Anti-angiogenesis for oncology

Matrix metaloproteinase inhibitors

38. A potential overlap exists between Monsanto and P&U regarding the matrix metaloproteinase inhibitors (MMPI). According to the parties, MMPIs target specific molecules which are critical for tumour progression and metastasis. The parties submit that MMPIs are new products, none of which has yet reached the market. Replies to the Commission's questionnaires confirm this.

Alpha V Beta 3

39. According to the parties, Alpha V Beta 3 compounds are new products designed to target distinct molecules and may have an anti-angiogenic effect as well as applications in other areas. As with MMPIs, the parties argue that Alpha V Beta 3 treatments are new products. The investigation has confirmed this.

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7 IV/M.737 – Ciba-Geigy/Sandoz, Commission decision of 4.2.1998

Celecoxib/Anti-VEGF

40. Both parties have future products in this area. Monsanto's Celebrex is a COX-2 inhibitor and has been primarily developed for the treatment of arthritis. It also has a second line indication for the reduction of polyps in Familial Adenomatous Polyposis. P&U's anti-VEGF compound targets a broader range of molecules. The parties argue that there is no current competitive overlap between these two compounds because the first one has been approved for treatment of a very specific and rare type of tumour and is designed to target pre-cancerous growths rather than cancer itself. The investigation has confirmed the parties' submission.

b) Blood growth factors for oncology

41. According to the parties, blood growth factors are intended to treat the side effects of chemotherapy by restoring blood cells. Both parties have future products in this area. They argue that these compounds have two different molecular targets and two distinct therapeutic outcomes: P&U's product is indicated for the treatment of chemotherapy induced thrombocytopenia and is directed at producing platelets. Monsanto's compound is intended to prevent chemotherapy induced neutropenia and is primarily directed towards producing neutrophils, although it may also stimulate the production of platelets. The parties submit that the broader effect of the second compound may create some overlaps with the first one but that, in both instances, the compounds face other products which are more direct competitors. The investigation has shown that competitors consider products affecting different blood cells as belonging to different markets.

c) Colorectal cancer

42. Monsanto's Celebrex is not a cancer treatment but is rather designed to prevent the development of polyps which lead to cancer. P&U's Campostar is a treatment of advanced colorectal cancer. The parties argue that the products are not competitors and would not be used for the same indication at the same time. The investigation has confirmed this.

B. Relevant geographic market(s)

1. Pharmaceutic specialities

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

44. The market test 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 on pharmaceuticals.

The markets for pharmaceutic specialities affected by the concentration will thus be regarded as national.

2. Active substances

45. In previous decisions, the Commission has established that the upstream markets for active substances are at least EEA-wide[8]. The parties agree with this geographic market definition.

3. Future Products

46. 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, the said 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

47. There has been a global move to consolidation within the pharmaceuticals industry in recent years in response to a rapidly changing business environment characterised by efforts to react to health-care costs containment, increasing R&D costs, new therapies, and the desire to achieve both synergies and economics of scale. Notwithstanding the ongoing consolidation in the global pharmaceutical industry, the industry remains largely fragmented with no single pharmaceutical company accounting for more than 6% of the 1999 world market. The human pharmaceuticals market exhibits a relatively low degree of concentration also at the European level: in 1999, the top five companies (AstraZeneca, Merck, Glaxo Wellcome, Pfizer and Bristol-Myers Squib) accounted for only around 21% of total sales in Europe.

48. Size is nevertheless an increasingly important competitive factor in the pharmaceutical industry. It allows firms to leverage increasing R&D costs across a broader range of products and to spread the risk inherent in every new research project over a large capital base. The greater resources of a larger company can be used to fund additional R&D projects, to devote more resources to long term projects and to increase spending on already advanced projects to accelerate the development process.

49. Monsanto and P&U are both major players in the research and development, manufacture and supply of human pharmaceuticals. Their merger will unite the world's 20th and 17th pharmaceutical companies and creates the 10th largest pharmaceutical company in the world, the 7th largest in Europe and the 12th largest in the United States. However, on world-wide basis, the new entity will remain subject to strong competition from numerous multinational companies. In 1999, the market leader Novartis achieved a turnover of approximately *[Deleted for publication ; business secret]* from pharmaceutical products against *[Deleted for publication ; business secret]* achieved by P&U and Monsanto together.

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8 For example IV/M.737 – Ciba-Geigy/Sandoz, Commission decision of 4.2.1998; IV/M.1229 – American Home Products/Monsanto, Commission decision of 14.8.1998.

1. Pharmaceutic specialities

50. The operation involves 10 horizontally affected pharmaceutic specialities markets where the combined sales of Monsanto and P&U result in market shares of 15% or more.

51. In 2 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 topical anti-acne preparations (D10A) in Italy and antirheumatic non-steroid (M1A) in Sweden.

52. In 2 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 hepatic lipotropic (A5B) in Italy and diuretics (C3A) in Sweden. 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.

53. 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 progestogens (G3D) in the United Kingdom.

54. In 5 affected markets, the aggregated market share of the parties will exceed 35% (*Class 3 markets*). The markets concerned are trichomonacides (G1A) in Italy, diuretics (C3A) in France, plain corticosteroids (H2A) in Belgium and narcotic analgesics (N2A) in Denmark and Sweden.

a) Class 2 market

Progestogens (G3D)

55. In the market for progestogens (G3D) in the United Kingdom, the combined market share of the parties amounted to [25-35] % by value and [25-35] % by volume in 1999. Monsanto held [0-10] % of the market in 1999 ([0-10] % in 1998 and [0-10] % in 1997) in the United Kingdom with its *Utovlan* product, which is a synthetic norethisterone. *Utovlan* is used, in low doses, for the treatment of dysmenorrhea, menorrhagia and endometriosis and, in high doses, for breast cancer. Monsanto also supplies norethiserone to generic producers of progestogen products that are sold in the United Kingdom in competition with *Utovlan*. P&U held [15-25] % of the market in 1999 ([10-20] % in 1998 and [10-20] % in 1997) in the United Kingdom with a medroxyprogesterone based product, *Provera*, which has indications similar to *Utovlan's* and, in addition, is used for the treatment of infertility. Both products are oral formulations only available on prescription.

56. The new entity will thus acquire a strong position and the leadership on this market but will face a number of major pharmaceutical manufacturers which also supply branded G3D products in the UK. Among these competitors Solvay (product *Duphaston*) was the previous market leader with [15-25] % share by value and [10-20] % by volume in 1999 ([20-30] % in 1998 and [20-30] % in 1997). Shire Holdings held [10-20] % of the UK market by value and [20-30] % by volume with its product *Cyclogest Hoe* ([10-

20] % in 1998 and [10-20] % in 1997) and Schering AG [0-10] % by value and [10-20] % by volume ([5-15] % in 1998 and [5-15] % in 1997).

57. The parties will also face strong competition from generic and own branded producers including Boots, the leading UK chemist, since *Utovlan* and *Provera* have for many years ceased to be protected by patents. Generic substitutes are available mostly in the form of norethisterone, an oral formulation with indications similar to *Utovlan's*. Producers of generic norethisterone, including Boots and Lagap (who is supplied by Monsanto and accounted for [10-20] % of its sales of norethisterone) have, according to IMS, a [10-20] % share of the sales of G3D products in the UK in value terms and [20-30] % by volume. The parties argue that since Boots does not publish or supply their sales to any third party, IMS data tends to underestimate the importance of generic sales in the UK. Monsanto has estimated that Boots alone accounts for approximately [5-15] % share of G3D product sales in the UK. The data show that the market share of generic products has been gradually increasing during the past three years from [5-15] % in 1997 to [10-20] % in 1999.

58. Moreover, the parties argue that there are other strong players in this product area who are far stronger than the parties at the EEA level. While P&U accounts for [0-10] % of the total EEA sales of progestogens and Monsanto [less than 1] %, the corresponding market share of Aventis is [15-25] %, that of Theramex [10-20] % and Solvay [10-20] %. The parties argue that these companies would be able to develop their position in the UK market either by launching new products or promoting existing products. It is indeed not excluded that any of the large and resourceful companies could enter the UK market, should they deem this strategically justified.

59. On the basis of the foregoing, and in particular in view of the large number of competitors on the market, the Commission draws the conclusion that the operation does not raise serious doubts as to its compatibility with the common market in the market for progestogens (G3D) in the UK.

b) Class 3 markets

Trichomonacides (G1A) in Italy

60. In this market, the combined market share of the parties amounted to [30-40] % by value and [35-45] % by volume in 1999. Monsanto held [20-30] % of the market in Italy in 1999 ([20-30] in 1998 and [20-30] in 1997) where it markets trichomonacides under the *Macmiror* and *Macmiror Complex* brands. They are nifuratel based products and exist in oral, suppository and vaginal cream formulations. P&U held [0-10] % of the market in Italy in 1999 ([0-10] % in 1998 and [0-10] % in 1997) with the *Flagyl* brand, a trichomonacide product containing metronidazole, in both tablets and vaginal suppository formats. This brand belongs to Aventis and was licensed to P&U by Rhône Poulenc Rorer in 1982 together with the know-how necessary to manufacture the product. *[Deleted for publication ; duration of the license]*.

61. The parties submit that they face strong competition from the market leader, Farmigea, whose G1A products, *Vagilen* and *Meclon*, have a share of [40-50] % by value and [40-50] % by volume. Farmigea's share has been increasing for the past three years. Pfizer also sells trichomonacides in Italy under the brand *Fasigin* and has a market share of [0-10] % by value and [0-10] % by volume ([0-10] in 1997 and [0-10] in 1998). There are also a number of other competing brands with smaller market shares: *Deflamon*

(SPA), *Tiberal* (Roche), *Trimonase* (Tosi) and *Triclose* (ICT). The parties submit that trichonomacides are old products whose prices are low (most of them were first marketed in Italy in the late 60's and have long lost patent protection) and sales are stable. The parties therefore argue that any increment of prices by one of the suppliers is not likely because there are many other suppliers able to produce full substitutes at a low price.

62. In view of the fact that the parties will face competition from the market leader, that P&U's market share has declined over time and that there are also a number of other competitors on the market, the Commission considers that the operation does not raise serious doubts as to its compatibility with the common market in the market for trichomonacides (G1A) in Italy.

Diuretics (C3A) in France

63. In this market, the combined market share of the parties amounted to [35-45] % by value and [25-35] % by volume in 1999. Monsanto held a strong position with [30-40] % of the market where it supplies several diuretics: *Aldactone*, *Aldactazine*, *Aldalix*, *Practon*, *Practazin* and *Soludactone*. These are oral formulation (tablets) that are mostly used for the treatment of hypertension and, incidentally, cardiac insufficiency. In 1999, P&U held [0-5] % of the market in France with its product *Logirène* which is an oral formulation that is only indicated in case of cardiac insufficiency. *Logirène* is manufactured by Aventis and supplied to P&U, who markets it under its own trademark as a result of an exclusive distribution agreement entered into in 1989 with Rhône Poulenc Rorer. *[Deleted for publication ; duration of the distribution agreement]*.

64. P&U's sales in France account for [0-5] % in value and [0-5] % in volume on this market. P&U's sales have been relatively stable and P&U has not promoted this product for several years. Monsanto's market share has been slightly decreasing during the past three years from [35-45] % in 1998 to [30-40] % in 1999.

65. The parties will face strong competition from major pharmaceutical manufacturers who market diuretics very similar to the parties' on the French market: Aventis whose products include *Lasilix*, *Eurelix* and *Cycloteriam* has a [20-30] % share of sales by value and [35-45] % by volume (the difference between value and volume is due to the fact that Aventis also distributes generic products). Servier holds [5-15] % of the market in terms of value and [0-10] % in volume with its product *Fudex*. In addition, several generic products competing with the parties' branded diuretics are supplied by Merck, Bayer, Aventis and Servier.

66. The parties submit that sales of diuretics have been steadily declining over the last few years. The parties further submit that diuretics are old products, most of which were first put on the French market in the 1960's and early 70's. According to the parties there has not been any major innovation since then. The parties also submit that in the treatment of hypertension, which is the main indication of diuretics, diuretics are being replaced by other drugs, such as betablockers (ATC7), calcium blockers (ATC 8) and angiotensin antagonists (ATC 9).

67. Monsanto's product *Aldactone 25*, which is a paediatric formulation of Monsanto's classic *Aldactone* product, is covered by a patent until 2007. It accounted for [0-5] % of Monsanto's C3A sales in value and less than 1 % in volume in 1999 in France. Aventis

has a similar product, *Lasilix paediatric*, whose sales in 1999 exceed those of *Aldactone 25*. P&U does not have any product of this kind.

68. Considering the fact that the small increment of market share comes from an old P&U product whose market share is declining and which is no more promoted and that there are other competitors on the market, notably Aventis, serious doubts as to the compatibility of the operation with the common market do not arise on the market for C3A in France.

Plain Corticosteroids (H2A) in Belgium

69. In this market, the combined market share of the parties amounted to [70-80] % by value and [50-60] % by volume in 1999. P&U held [70-80] % ([70-80] % in 1998 and [70-80] % in 1997) of that market in Belgium where it sells oral corticosteroids under the trademark *Medrol* and injectable corticosteroids under the trademarks *Solu-Cortef*, *Solu-Medrol* and *Depo-Medrol*. In 1999, Monsanto held [less than 1] % of the market in Belgium with its oral corticosteroids products *Cortisone*, *Prednicort* and *Prednicortelone*. Monsanto's market share has not changed for the past three years.

70. P&U is a very significant player on the H2A Belgian market and also at the EEA level with a [10-20] % share of sales. The market share in value added by Monsanto's sales in Belgium will be of [less than 1 %] by value and [less than 2] % in volume. The parties submit that Monsanto's products have not been promoted in Belgium for a number of years and have lost patent protection (as have P&U products). In addition, Monsanto has hardly any sales of plain corticosteroids outside Belgium either.

71. On the basis of the foregoing and given in particular the *de minimis* overlap and the fact that Monsanto's position has remained stable over time, the Commission considers that the operation does not raise serious doubts as to its compatibility with the common market in the market for plain corticosteroids (H2A) in Belgium.

Narcotic analgesics (N2A) in Denmark and Sweden

a) General

72. Monsanto supplies several narcotic analgesics (same brands and formulations) in oral, injectable and suppository form both in Denmark and in Sweden. These products include *Ketogan* and *Ketogan/Novum*, which are immediate release ketobemidone based products used for the treatment of the most acute form of pain, and *Ketodur*, which is a slow release ketobemidone based product used to relieve severe chronic pain such as cancer pain.

73. P&U also sells several narcotic analgesics in oral and injectable form both in Denmark and in Sweden. These products include *Morfin, Dolcontin, Contalgin, Dolcontin/Unotard* (*Contalgin Uno), Pethidine* and *Metadone*. *Morfin* is an immediate release morphine based product. *Dolcontin* (marketed in Sweden), *Contalgin* (marketed in Denmark) and *Dolcontin/Unotard* (*Contalgin Uno*) are slow release morphine based products used to relieve severe chronic pain. *Pethidine* is an immediate release morphine based product used in injections and *Metadone* an immediate release methadone based product used for the treatment of chronic pain. P&U distributes *Dolcontin* (*Contalgin*) and *Dolcontin/Unotard* (*Contalgin Uno*) under an exclusive

trademark and marketing agreement with Mundipharma. *[Deleted for publication ; duration of the agreement]*.

b) Denmark

74. In Denmark, the parties' N2A businesses are broadly complementary. P&U is exclusively active in the slow release segment of the market and the transaction has thus a neutral effect on the immediate release segment which accounts for the bulk of Monsanto's sales in Denmark.

75. In the slow release segment in Denmark, Monsanto is a small player with a declining [0-10] % market share in value in 1999 ([0-10] % in 1998 and [0-10] % in 1997). P&U is a stronger player with [30-40] % in 1999 but its market share is also declining: [40-50] % in 1997 and [35-45] % in 1998. The parties submit that both Monsanto and P&U sell products that have lost patent protection and have been on the market for many years.

76. The parties argue that the newly launched products of Johnson & Johnson (a patch which releases a strong analgesic on a constant basis) and Mundipharma (new molecules derived from morphine which are not subject to the exclusive trademark and distribution agreement mentioned in paragraph 71) grow at the expense of P&U's and Monsanto's. Johnson & Johnson is the current market leader in this segment in Denmark with a [35-45] % market share in 1999. This market share has been growing relatively rapidly from [20-30] % in 1997. The share of Mundipharma increased from [less than 2] % in 1997 to [0-10] % in 1999.

77. The parties argue that barriers to entry are low in particular for commodity morphine-based analgesics that would compete directly with P&U's product *Contalgin*. The parties argue that companies like AstraZeneca and Nycomed/Amersham which have substantial pharmaceutical businesses in Scandinavia and already have analgesic products and sell generics could easily and quickly (within a few months) launch additional N2A commodity morphine products in Denmark. In addition, the parties argue that manufacturers of such products who would be able to supply the relevant active ingredients are numerous.

78. The parties further argue that existing competition exerts pressure on the prices of slow-release analgesics, as does the prospect of more active marketing of their product by Norpharma, Nycomed and other pharmaceutical companies which have a strong local presence. A number of companies have products that compete directly with *Ketodur*, *Contalgin* and *Contalgin/Uno* registered in Denmark, including *Repriadol* of Nycomed and *Malfin* of Nettopharma, that have not so far been actively promoted.

79. The Commission's investigation has shown that, despite the distribution link of P&U with the new entrant Mundipharma, it is unlikely that, after the operation, the parties would be in a position to act independently from their competitors. This is particularly due to the fact that the parties' respective market shares are declining in favour of Johnson & Johnson, which is the current market leader. Moreover, the parties' products have lost patent protection and barriers to entry in this market appear to be low. Therefore, the Commission concludes that the operation is unlikely to lead to any competition concerns in the slow release segment of the N2A market in Denmark.

c) Sweden

80. In Sweden, the parties' products overlap on both segments, in immediate-release analgesics used for acute pain (*Ketogan*, *Ketogan/Novum* and *Morfin*) and slow-release analgesics used for chronic pain (*Ketodur*, *Dolcontin* and *Dolcontin/Unotard*).

81. In the immediate-release analgesics used for acute pain segment, the parties will achieve a combined share of [80-90] %. The market share of P&U has been decreasing in value for the last three years ([50-60] % in 1997, [40-50] % in 1998 and [40-50] % in 1999) but Monsanto's market share has been increasing within the same period ([20-30] % in 1997, [35-45] % in 1998 and [35-45] % in 1999). As a result, the aggregated market share of the parties has been stable and around [80-90] % for the last three years. The competitors, whose market shares are considerably lower than those of the parties, are AstraZeneca ([0-10] % in 1999), Abigo ([0-5] % in 1999) and Knoll ([0-5] % in 1999). Two new entrants, Mundipharma and Boehringer Ingelheim, introduced a new product on the market in 1998 and 1999 respectively.

82. The parties argue that all P&U's products in this segment are generic products which are effectively sold on a non-branded basis (morfin and pethidin being effectively the names of the relevant active ingredients). The parties argue that these products are sold at low prices and at low margins to hospitals and other outlets. They submit that their market share is highly contestable by any generic producer who wishes to promote more actively their generic equivalent. The parties further argue that any attempt by the Monsanto/P&U group to increase prices post merger is likely to attract more active competition by other established players who have directly competing products already being sold in the market. According to the parties, by such active promotion, companies such as AstraZeneca and Nycomed/Amersham can be expected to increase their market share.

83. The parties also maintain that, the market for analgesics in Sweden is likely to be fertile ground for new product launches. They argue that competition has increased the last year with the introduction of *Oxynorm* from Mundipharma and *Oramorph*. As stated above in relation to the N2A market in Denmark, the competitive assessment must nevertheless take into account that there is a structural link between P&U and Mundipharma, since P&U has an exclusive trademark and marketing agreement with Mundipharma for the distribution of slow release analgesics in Denmark and Sweden.

84. The arguments of the parties cannot be accepted because the market shares do not show any evolution in favour of generic products or new products. Furthermore, the concerns arising from the strong position of the parties in the immediate release segment are strengthened by the fact that the parties have and will have a link with one of the competitor which has recently entered successfully the market. The operation therefore raises competitive concerns on the N2A segment for immediate release analgesics used for acute pain in Sweden.

85. In the segment for slow release analgesics used for acute pain, the parties achieve combined sales of [30-40] %. The market share of P&U has been decreasing in value for the last three years ([35-45] % in 1997, [25-35] % in 1998 and [25-35] % in 1999). Monsanto's market share has been slightly increasing then stagnating within the same period ([0-10] % in 1997, [0-10] % in 1998 and [0-10] % in 1999). As a result, the aggregated market share of the parties has decreased by ten percentage points in the last three years. The main competitor of the new entity is also the market leader Janssen-Cilag whose market share has been increasing for the last three years from [40-50] % in 1997 to [55-65] % in 1999.

86. Based on the information supplied by the parties, Janssen-Cilag has a successful product in the segment, *Durogesic*, that is growing rapidly and is expected to continue growing for the next two to four years. Moreover the parties argue that the situation with regard to barriers to entry is similar to that prevailing in Denmark. The parties submit that Nycomed/Amersham, who currently accounts for [less than 2] % of the market and Mundipharma, whose market share in Sweden is [less than 2] %, can be expected to increase the promotion of existing products if any market opportunity presented itself.

87. Despite the fact that after the operation there will be two leading players on this segment, namely the new entity with [30-40] % and Janssen-Cilag with [50-60] % of the market, serious doubts do not arise concerning duopolistic dominance because of the above-described different evolution of the new entity's and Janssen-Cilag's market shares and the possible entry of competitors.

88. In conclusion, the operation raises competitive concerns regarding the creation of a dominant position in the immediate-release segment of the N2A market in Sweden.

2. Active substances

89. Both parties are active in the production of active ingredients for use in their own pharmaceutical products. To the exception of Monsanto's active ingredient spironolactone, neither party is active to a material extent in the manufacture of active ingredients for resale to third parties within the EEA.

90. Monsanto produces spironolactone, and both Monsanto and P&U use it. Therefore, there is no aggregation of market share in the manufacture of sprionolactone but only a vertical link between the parties. Monsanto uses spironolactone as the active ingredient for the bulk of its diuretic products in Europe and elsewhere. P&U has not traditionally used spironolactone for its diuretic products in Europe but its main range of diuretics are based on thiazides, such as bendroflumethiazide. P&U has only one spironolactone-based diuretic, a branded generic product *Spironolakton NM Pharma*, which is sold exclusively on the Swedish market.

91. While Monsanto is the largest producer of spironolactone in Europe, there are at least four other manufacturers of spironolactone in Europe: Aventis, Dipharma, Gideon Richter and Searle. Based on the information submitted by the parties, Monsanto, Aventis and Dipharma produced *[Deleted for publication ; amount of production]* of spironolactone in 1999. Monsanto accounted for [60-70] % of the third party sales, Aventis [20-30] % and Dipharma for the remaining [0-10] %. Despite the fact that Monsanto accounts for the largest part of the sales of spironolactone to third parties, the Commission does not consider that the operation would lead to any adverse competition effects in the supply of this active substance. Most importantly, given that P&U uses mainly other active ingredients in the manufacture of diuretics in the EEA, the concentration is unlikely to lead to the foreclosure of the market. In addition, as for the supplies to third parties, there are a number of alternative suppliers on the EEA market. Moreover, given the absence of barriers to expansion and the fact that manufacturers of diuretics may use also other active ingredients, the operation is unlikely to lead to the creation or strengthening of a dominant position in spironolactone in the EEA. Third parties have not raised any concerns in this respect either.

3. Future Products

92. Research and development is an important element in competition among pharmaceutical companies. The global pharmaceutical market is characterised by a significant number of players undertaking significant R&D. Manufacturers meet this challenge by focusing on innovation. Frequently this research is carried out in-house by the pharmaceutical companies themselves, but important R&D also occurs through numerous academic and commercial laboratories. Because the investments required for pharmaceutical R&D can be financed only if a company is able to generate the necessary cash flow during the relevant period of patent protection of the product development, the pharmaceutical companies consider that it is essential to launch the products on the markets of large industrialised countries as quickly as possible. The survival of large pharmaceutical companies depends on the profitability of a small number of products and also on the regular renewal of a portfolio of patents on new pharmaceutical products.

93. The parties have a number of pharmaceutical projects at phase II and III of the pharmaceutical development process. The parties claim that the merger is expected to speed innovation and improve the effectiveness of the R&D of the two companies. In 1999, Monsanto spent *[Deleted for publication ; business secret]* % of its pharmaceutical turnover on research and development. At the same time, P&U's research and development expenditures were about *[Deleted for publication ; business secret]* or about *[Deleted for publication ; business secret]* % of its total turnover. Of this amount, more than *[Deleted for publication ; business secret]* was accounted for pharmaceuticals and biotechnology. Pharmaceutical manufacturers typically spend 10-12% of turnover on research and development.

94. The investigation has confirmed the parties' submission that their current product development in the field of oncology overlaps only to a minor extent. Although it may be noted that the parties' products are only at the clinical stage or Phase I and their indications could change to some extent, there is no evidence that the parties' current research and development activities would lead to adverse competition effects. It may also be noted that a number of other companies are active in future products in the field of oncology. For instance, Merck is engaged in R&D in the area of colorectal cancer and anti-angiogenesis for oncology with respect to Alpha V Beta 3, COX-2 inhibitors and anti-VEGF and Pfizer is active in future products in colorectal cancer and in COX-2 inhibitors. A number of companies (British Biotech, Augouron, Aeterna) have MMPIs in Phase III of the development. Third parties have not raised concerns over the parties activities in research and development. Therefore, the Commission concludes that the operation as notified would not lead to the creation or strengthening of a dominant position in the future products.

VI. MODIFICATIONS TO THE PROPOSED OPERATION

95. In order to remove the serious doubts resulting from the proposed transaction in the immediate-release analgesics used for acute pain segment in Sweden, the parties have offered the Commission an undertaking. The detailed text of this undertaking is annexed to this decision. The full text of the annexed undertaking forms an integral part to this decision.

96. In order to remove the competition concerns in the immediate-release analgesics used for acute pain segment in Sweden, the parties have committed to licensing to a viable and independent third party approved by the Commission *Morfin*, *Morfin Skopolamin*, *Morfin Epidural* and *Petidin* in Sweden. These P&U products all belong to the immediate-release analgesics market. Since these products represent the whole market share of P&U in this market, the Commission considers that the undertaking is sufficient to avoid the creation of a dominant position in this market in Sweden. This commitment will indeed solve competition concerns both by eliminating the overlap between the parties in this market and facilitating new entry to the market. This undertaking has also been supported by third parties in their replies to the Commission's market test.

VII. CONCLUSION

97. The Commission concludes that the undertaking submitted by the parties is 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 decides 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(1)(b) of Council Regulation (EEC) No 4064/89.

For the Commission,
Mario Monti
Member of the Commission

ANNEX

UNDERTAKING

Case IV/COMP.1835 Monsanto/Pharmacia & Upjohn

Whereas, on 16 February 2000, Pharmacia & Upjohn, Inc. ("PNU") and Monsanto Company ("Monsanto") (together the "Parties") notified the proposed merger between the Parties (the "Operation") to the European Commission (the "Commission") pursuant to Council Regulation 4064/89 (the "Merger Regulation").

Whereas, the Parties wish to submit commitments pursuant to Article 6(2) of the Merger Regulation to form the basis of a decision pursuant to Article 6(1)(b) of the Merger Regulation.

Therefore, the Parties offer the following commitments on the basis that the Commission approves the Operation pursuant to Article 6(1)(b) of the Merger Regulation.

I. Divestiture of Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden

1. The Parties shall transfer, or cause to be transferred, to a third party to be approved by the Commission, the following tangible and intangible rights and assets in connection with Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden:

   (i) the Parties shall sell, or cause to be sold, to such third party the marketing authorisations obtained by PNU for Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden; and

   (ii) the Parties shall transfer, or cause to be transferred, to the purchaser of the marketing authorisations for Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden, the economic benefits of all their manufacturing and/or supply agreements in connection with Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden.

2. To assist the Commission in determining whether any proposed third party purchaser is suitable, the independent trustee appointed under paragraph II shall confirm in a report to the Commission that: (i) the Parties do not own a material direct or indirect interest in any proposed purchaser; and (ii) the conditions for the sale of the marketing authorisations and trademark and related agreements are such to allow the third party purchaser effectively to compete on the relevant market.

3. If, within […] following receipt of a fully documented proposal for a prospective purchaser, the Commission has not expressed in writing its disagreement, negotiations with such purchaser shall be free to proceed. In the event that the Commission has to request additional information on the prospective purchaser, the receipt of such information shall constitute the starting point of the […] period referred to above. Provided that the procedure for approval of potential purchasers by the Commission has been complied with, the Parties shall be free to accept any offer they consider best in the event of a plurality of offers for the interests or assets to be divested.

4. The arrangement will be entered into as soon as practicable following completion of the Operation and, in any event, not before the independent trustee has been appointed under

paragraph II and within […] of the date of the Commission's decision under Article 6(1)(b). The Parties will report bi-monthly to the Commission on progress of the negotiations. If, at the end of the period of […] (or such extension to that period as may be agreed with the Commission), no suitable arrangement has been concluded, the Parties will grant to a trustee an irrevocable mandate to negotiate and conclude the sale of the marketing authorisations and trademark and related agreements described in paragraph 1 above at no minimum price.

II. Trustee

1. Within […] from adoption by the Commission of a decision under Article 6(1)(b), the Parties shall appoint an independent trustee to assist the Commission in accordance with paragraph I.2 above and, if necessary pursuant to paragraph I.4 above, to negotiate and conclude the agreements described in paragraph I.1 above.

2. The appointment of the trustee is subject to the approval of the Commission, such approval not to be unreasonably withheld. The Parties shall consent to the following terms and conditions regarding the powers, duties, authorities and responsibilities of the trustee. The trustee shall preferably be a person with experience and expertise in acquisitions and divestitures in the pharmaceutical industry.

3. The trustee shall have the power and authority to monitor the Parties' compliance with the terms of the Undertaking, and shall exercise such power and authority and carry out the duties and responsibilities of the trustee in a manner consistent with the terms and purposes of the Undertaking and in consultation with the Commission on the basis of written monthly reports.

4. Within […] from the appointment of the trustee, the Parties shall execute a trust agreement that, subject to prior approval of the Commission, confers on the trustee all the rights and powers necessary to monitor their compliance with the terms of the Undertaking and in a manner consistent with the purposes of the Undertaking.

5. The trustee shall serve until Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden have been divested in accordance with the terms and purposes of the undertaking. The Commission may, however, extend this period as may be necessary or appropriate to accomplish the purposes of the Undertaking.

6. The trustee shall have full access to the Parties' personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of Morfin, Morfin Skopolamin, Morfin Epidural and Petidin in Sweden, or to any other relevant information as the trustee may reasonably request.

7. 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 the Undertaking.

III. Review Clause

1. The Parties may request the Commission at any time a review and adjustment of this Undertaking in the light of substantial changes in market conditions or other significant

changes of circumstances. IN WITNESS THEREOF, the undersigned have caused this Undertaking to be executed as of March 27, 2000

For Monsanto	For PNU
By: Rufus Yerxa Chief Counsel Europe/Africa	By: Frederik Berg VP General Counsel Europe & Int.