II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 17 July 1996

in a proceeding pursuant to Council Regulation (EEC) No 4064/89

(Case No IV/M.737 — Ciba-Geigy/Sandoz)

(Only the German text is authentic)

(Text with EEA relevance)

(97/469/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings (hereinafter referred to as 'the Merger Regulation') [1], and in particular Article 8 (2) thereof,

Having regard to the EEA Agreement, an in particular Article 57 thereof,

Having regard to the Commission decision of 2 May 1996 to initiate proceedings in this case,

Having regard to the opinion of the Advisory Committee on Concentrations [2],

Whereas:

1. The notification under consideration, which was made on 27 March 1996, concerns the proposed merger between Ciba-Geigy AG (Ciba) and Sandoz AG (Sandoz), both of Basle, to form a new single enterprise, Novartis AG (Novartis).

2. By decision of 18 April 1996, the Commission ordered the suspension of the notified merger, pursuant to Articles 7 (2) and 18 (2) of the Merger Regulation, until it had taken a final decision.

3. Having examined the notification, the Commission found that the project fell within the scope of the Merger Regulation and raised serious doubts as to its compatibility with the common market. By decision of 2 May 1996, the Commission accordingly initiated proceedings pursuant to Article 6 (1) (c) of the Merger Regulation.

4. The Advisory Committee discussed the draft of this Decision on 2 July 1996.

I. THE PARTIES

5. Ciba is a manufacturer of biological and chemical products in the health, agricultural and industrial sectors.

[1] OJ No L 395, 30. 12. 1989, p. 1; corrigendum: OJ No L 257, 21. 9. 1990, p. 13.
[2] OJ No C 230, 29. 7. 1997.

6. Sandoz is a manufacturer of biological and chemical products in the health, food, agricultural and building chemicals sectors.

II. THE CONCENTRATION

7. The parties' proposed concentration is a merger within the meaning of Article 3 (1) (a) of the Merger Regulation. Ciba and Sandoz are to be merged into a new single undertaking, Novartis. Under the exchange of shares which is to take place, Sandoz shareholders will receive 55 % of the shares in Novartis and Ciba shareholders 45 %.

8. The parties intend that the concentration should not include three sectors. Ciba's speciality chemicals business (industrial chemicals), consisting of the textile dyes, chemicals, additives, pigments and polymers divisions, is, after the merger as a single undertaking, to be accommodated in separate companies whose controlling company will be quoted on the stock exchange and will be transferred from Novartis to its shareholders. Following this transfer, according to the information provided by the parties, there will be no group link between Novartis and the new controlling company. According to the information provided by the parties, the Ciba division Mettler-Toledo was sold off to the American investor group AEA MT Inc. on 2 April 1996. The contract of sale is to be implemented once the necessary official approval has been given. The Sandoz building and environment division (building chemicals) is comprised within MBT Holding AG and is to be sold off before or after the merger. These three sectors are to be regarded as parts of the untertakings concerned, within the meaning of Article 1 (2), in so far as they are initially brought into Novartis.

III. COMMUNITY DIMENSION

9. The combined aggregate worldwide turnover of Ciba and Sandoz is more than ECU 5 billion. The aggregate worldwide turnover of Ciba is some ECU 13,1 billion and that of Sandoz some ECU 9,1 billion. Each of the two undertakings has an aggregate Community-wide turnover of more than ECU 250 million. The aggregate Community-wide turnover of Ciba is more than ECU 4 billion and that of Sandoz more than ECU 2,5 billion. Neither Ciba nor Sandoz achieves more than two thirds of its aggregate Community-wide turnover within one and the same Member State.

IV. APPRAISAL UNDER ARTICLE 2 OF THE MERGER REGULATION

10. Ciba and Sandoz have partly overlapping business activities in health-care products, crop protection products, animal health products and seeds.

11. According to the information provided by the parties, there are no overlaps in industrial chemicals, nutrition, building chemicals and weighing equipment. In these sectors, one of the parties has shares of more than 25 % on a number of markets, although the existing market positions will not be strengthened by the merger given the lack of overlaps.

A. HEALTH-CARE PRODUCTS

12. According to the information provided by the parties, the term 'health-care products' comprises pharmaceutical products, contact lenses and lens care products. The only overlaps in the activities of Ciba and Sandoz are in the case of pharmaceutical products.

13. According to the information provided by the parties, Ciba's market shares in the case of contact lenses and lens care products are below 25 % on a EEA-wide basis. At national level, Ciba has achieved market shares of between 25 % and 41 % in seven Member States in the case of contact lenses and in six Member States in the case of lens care products. In view of the lack of market share additions, and in the absence of other indications that the merger will strengthen Ciba's market position, there is no evidence to suggest that the merger will lead to the creation or reinforcement of a dominant market position.

14. However, the proposed merger will lead to market share additions on a large number of markets in pharmaceutical products. A close appraisal needs to be made only of the effects in the case of Rauwolfia, beta blockers, calcitonins, muscle relaxants and one aspect of HS-TK gene therapy. But even here the merger will not lead to the creation or reinforcement of a dominant market position.

1. *Definition of the product market*

15. 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 (see decisions of 10 June 1991, Sanofi/Sterling Drug; 29 April 1993 Procordia/Herbamond; 18 April 1994, Rhône-Poulenc/Cooper; 20 June 1993, La Roche/Syntex; 19 September 1994, AHP/Cyanamid; 28. February 1995, Glaxo/Wellcome; 3 April 1995, Behringwerke AG/Armour Pharmaceutical Co.; 22 June 1995, Hoechst/Marion Merrell Dow; 28 September 1995, Upjohn/Pharmacia).

(a) **Medicines**

16. Medicines may be subdivided into therapeutic classes by reference to the 'Anatomical Therapeutic Classification' (ATC), which is recognized and used by the World Health Organization. This classification, which was used by the Commission in earlier cases, allows medicines to be grouped together by reference to their composition and their therapeutic properties.

17. 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. However, it may be appropriate to carry out analyses at other levels of the ATC classification. For example, it might be necessary to combine certain groups. This would be the case where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease. On the other hand, it might also be appropriate to apply a narrower market definition where the medicines in question have clearly differing indications. Account should also be taken of the fact that the use of medicines may also vary nationally.

18. Medicines may, moreover, be 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. A further distinction is that between medicines whose costs are refunded in whole or in part by sickness insurance schemes and those whose costs are not reimbursed. These segments partly overlap. Most medicines issued only on prescription are reimbursed, whereas most of those which may be sold over the counter are not reimbursed. Furthermore, the allocation of a medicine to a particular segment is not permanent. It is based instead on decisions by the authorities, which may lead to changes between segments.

19. The parties agree with the Commission that in most cases it is appropriate to base the market definition on the third level of the ATC classification since the third level products generally serve the same treatment purpose and are not interchangeable with products from other classes. The parties also argue, however, that this definition does not always meet the need for functional substitutability from the viewpoint of the other side of the market. In the view of the parties, exceptions arise where the ATC classes are distinguished not according to therapeutic application areas but, at the very least, also according to pharmacological active principles and application formulae. The market definition could therefore be too narrow in some cases and too wide in others.

20. This view is confirmed in principle by the parties' competitors consulted by the Commission. In their view too, a definition of product markets based on the third level of the ATC classification is not appropriate in every individual case and may be either too narrow or too wide.

21. The interchangeability of products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption. In the case of medicines available on prescription only, therefore, these would be established medical practitioners. But the prescription practices of medical practitioners are regularly influenced by the objective scientific knowledge available to them concerning the active properties and similarities of medicines (see, for example, Bundesgerichtshof WuW/E BGH 1445, 1447 *et seq.*, Valium). Factors militating against any more far-reaching market definition include different degrees of tolerance of medicines by the patient and differences in price. In the case of medicines available on prescription only, therefore, the market definition cannot be based simply on whether different medicines are prescribed for the same illness (i. e. in the same indication group). The criterion is that prescription is based on fundamentally the same medical grounds. For such prescription practice, account can be taken of whether the medicines correspond to each other, for example in terms of active principle, tolerance, toxicity, and side effects.

22. Since, according to their information, appropriate data do not exist for the ATC classification, the parties have, in the market breakdown presented by them and in the corresponding data, made reference to a classification drawn up by the European Pharmaceuticals Manufacturers Association (EPHMRA), which underlies the IMS figures and, according to the parties, is very largely the same as the ATC classification. The

Commission's investigations have shown that the parties' competitors also consider the two to be very largely identical. For reasons of practicability, therefore, the Commission has used the breakdown and nomenclature employed by the parties.

23. With regard to the product markets relevant to the appraisal of the merger, the parties take the view that the definition based on the third level of the ATC classification is too narrow for certain medicines used in the treatment of high blood pressure (Rauwolfia, beta blockers) and osteoporosis (calcitonins), which, in terms of their main indications, are interchangeable and interchanged with other products from other ATC classes. In the case of muscle relaxants, by contrast it is too wide. In the opinion of the parties, the market definition based on the third level of the ATC classification is largely appropriate for the other medicines relevant to the appraisal of the merger. The Commission's investigations do not contradict this.

(1) *Rauwolfia and beta blockers*

24. Rauwolfia is a medicine used to reduce blood pressure. According to the information provided by the parties, C2D Rauwolfia and Comb. Diuretics are medicines which are typically made up of reserpine and a diuretic. Reserpine is a plant-derived active substance which has the disadvantage that it can sometimes induce depression when taken over a lengthy period. In the case of diuretics, a possible side effect is lack of potassium, particularly when taken in large doses over a lengthy period. Combinations of a number of active substances are used to attempt to reduce the side effects.

25. According to the information provided by the parties, Rauwolfia preparations are the oldest blood-pressure medicines on the market. According to the parties, there are various other substance classes used in the treatment of high blood pressure. These consist mainly of, in order of market entry, diuretics, centrally active anti-hypertensives, beta blockers, vasodilators (blood vessel — dilating agents), calcium antagonists and ACE inhibitors. According to the parties, in all EEA Member States these medicines are available on prescription only. Treatments are chosen according to the seriousness of the high blood pressure, accompanying complaints, previous treatment and the therapeutic experience of the medical practitioner in the case in question. There would normally be a number of possible ways of achieving the same treatment aim. A number of the parties' competitors have also cited various preparations of different third-level ATC classes used in the treatment of high blood pressure as exceptions to the basic suitability of the third level of the ATC classification for the market definition.

26. According to the information provided by the parties, Rauwolfia was one of the fastest-selling blood-pressure medicines between ten and fifteen years ago in a number of countries, including, for example, Germany, Austria and Italy. According to the parties, Rauwolfia preparations have been medically outdated for a number of years now. Many younger doctors no longer use these medicines but base their treatments exclusively on the high-blood-pressure-treatment table. The Commission's investigations have confirmed that Rauwolfia would appear no longer to be designated a first-choice blood-pressure treatment in relevant publications. According to the information provided by the parties, however, Rauwolfia preparations are still prescribed for the continued treatment of elderly patients in countries in which they were formerly used on a large scale. They are used predominantly for patients who have been well adjusted to these medicines for a long time. However, the proportion of Rauwolfia preparations used in the treatment of high blood pressure is steadily contracting. Even though the extent of this substitution varies in individual Member States, the Commission's investigations have not justified different national product market definitions for Rauwolfia.

27. Despite the abovementioned increasing substitution of Rauwolfia by other blood-pressure medicines, there are misgivings about the presumption that Rauwolfia preparations can be combined with the other high-blood-pressure-treatment medicines mentioned to form a single product market. There is, for example, the fact that the choice of medicine depends, among other things, on the age of the patient and the possible side-effects. The various medicines used in the treatment of high blood pressure sometimes have considerably different side-effects which are likely to rule out mutual substitutability for some patients. Furthermore, in Germany, for example, the Deutsche Liga zur Behandlung des hohen Blutdrucks e. V. has drawn up a table showing specific treatment levels of high blood pressure with different preparations. This too militates against the assumption of complete mutual interchangeability. In addition, there are the characteristic features of Rauwolfia products also reported by the parties. It would seem that these products are no longer recommended as first-choice medicines for the treatment of high blood pressure. This limits their interchangeability with such preparations as beta blockers and

diuretics. The further fact that demand for Rauwolfia preparations is steadily diminishing shows hat these preparations are nowadays prescribed predominantly for a particular category of patient only. The parties also point out that Rauwolfia is nowadays prescribed predominantly for elderly patients only. Given the substitution of Rauwolfia by other blood-pressure medicines, the relevant market is ultimately at any rat broader than C2D Rauwolfia.

28. Consideration might also be given to combining beta blockers and diuretics in a single market because, according to the Commission's investigations, both medicines are recognized first-choice means of treating high blood pressure. In view of the different ways in which these preparations work and their different side-effects, however, such a combination is highly questionable. According to the Commission's investigations, however, C7B Betablocker Comb. and C7A Betablocker plain can be combined as one market. Betablocker Comb. are combinations of beta blockers and other preparations predetermined by the manufacturer. This form of application is apparently in decline and can be replaced by a corresponding combined dosage of pure beta blockers and various other medicines. The preference for dosages made up of various medicines stems from the improved dosage options available to the physician in charge. The advantage of the combinations is, reportedly, that the patient has to take fewer tablets and does not himself have to adhere carefully to the correct dosage. The combination of pure beta blockers and beta blocker combination preparations also corresponds to the Rauwolfia and Comb. Diuretics class in the ATC classification. The division of pure beta blockers and beta blocker combinations into two markets would lead to an inappropriate subdivision of commercially connected products into two markets. For the purpose of this decision, no further examination of the question of the interchangeability of beta blockers with other blood-pressure medicines is necessary.

(2) *Calcitonins*

29. According to the information provided by the parties, calcitonin is a hormone which occurs naturally in the human body. It is used for bone formation and is normally in balance with the hormones which cause bone resorption. In old age, this balance sometimes shifts towards bone resorption. This then results in osteoporosis. H4A calcitonins are accordingly used primarily for the treatment of osteoporosis. According to the information provided by the parties, calcitonins are authorized in Sweden and the Netherlands only for the treatment of Paget's disease, a rare bone disease.

30. The parties argue that all the preparations used for the treatment of osteoporosis are substitutable for calcitonins. At any rate, they argue, this applies to the H4A calcitonins and to most of the preparations in the product class M5B Bone Calcium Regulators (diphosphonates), which, according to the information provided by the parties, can be obtained only on prescription. In addition, they argue, according to the German school, fluorides (A12C other mineral supplements) and calcitonins are to a limited extent substitutable for one another. The parties also see some substitutability in the mineral preparations (A12A calcium) used in particular in the prevention of osteoporosis. Lastly, in the view of the parties, hormone preparations (G3C Oestrogens and Comb.) offer moderate substitutability.

31. According to the information provided by the parties, there is from the doctor's point of view no clear-cut distinction between prevention and treatment when treating osteoporosis. The boundaries are fluid. The parties argue that there are as yet no internationally recognized, uniform and objective criteria on the question of when medication should begin. Cost considerations, the experience and training of the doctor, differences between national schools and the patient's symptoms are the key parameters determining the treatment chosen. However, the information provided by the parties also indicates that there are certain main types of uses to which the preparations are put.

32. The Commission's investigations have shown that, at any rate, calcitonins and most diphosponates may be regarded as predominantly substitutable one for another and may consequently be grouped within a single product market. Both are used mainly in the treatment rather than the prevention of osteoporosis. Both, according to the parties, increase bone density and, if used as intended, have few side-effects. According to the parties, the side-effects of calcitonins, rarely encountered, are a sensation of warmth, irritation of the nasal mucous membrane and nausea. Diphosphonates can, according to the parties, lead to heartburn and stomach complaints if not used as directed. More recent diphosponates, they say, are better tolerated. According to the parties, studies on both are being carried out to obtain evidence of a long-term decrease in the risk of bone fracture, a decrease in risk which is already recognized in the medium term. They are therefore, the parties argue, substitutable for one another, at any rate for the majority of patients. The parties submitted several publications showing similar use of diphosphonates and calcitonins.

33. The results of the Commission's investigations support this. The Swedish competition authority has also pointed out to the Commission that its enquiry to the Medical Products Agency confirmed that diphosphonates are in most cases substitutable for calcitonins. It also pointed out that this may apply to the other preparations referred to by the parties.

34. It is true that the fact that the preparations contain different active principles may argue against any substitutability of calcitonins and diphosphonates. The bones which the preparations help to form are also reported to be somewhat differently structured. Calcitonins are reported by the parties to have an additional analgesic effect. However, this aspect is irrelevant since osteoporosis does not in general cause pain. In view of the lack of proper knowledge of the causes of osteoporosis, however, neither of the two active principles seems at present *a priori* to be any more or less suitable for patients. According to the information provided by the parties, calcitonin can at present be administered only nasally or by injection, while the diphosphonates authorized in osteoporosis are administered orally. However, the parties point out that a British firm has announced that is has successfully tested an oral administration form and will apply for authorization by the end of this year. In addition, an Italian firm is reported to have successfully developed a calcitonin to be administered orally. Any difference that still exists in the form of application cannot be regarded as relevant as far as patients receiving caltitonins are concerned. The oral administration of diphosphonates does not at any rate represent any disadvantage for the patient in this respect and does not therefore affect substitutability. Furthermore, in individual ATC classes, differing forms of administration are grouped together in a product market, so that this difference cannot in general be adduced as a decisive argument. However, not all diphosphonates can be included in a single market. Ciba's diphosphonate (Aredia brand) covers only a limited range of application and is not authorized and not suitable for the treatment of osteoporosis. It is available only as a solution for infusion, whereas, according to the information provided by the parties, all other modern diphosphonates are available in oral form.

35. All in all, diphosphonates which are authorized for the treatment of osteoporosis are, at any rate for merger control purposes, to be regarded as substitutable for calcitonins. Since it is not possible to pursue separate price strategies *vis-à-vis* a minority of purchasers for whom calcitonins are not interchangeable with other preparations, the competitive room for manoeuvre of the suppliers of calcitonins *vis-à-vis* all purchasers is limited by the suppliers of diphosphonates used for the treatment of osteoporosis. Calcitonins are moreover also replaceable by diphosphonates in the case of Paget's disease.

(3) *Muscle relaxants*

36. The muscle relaxants included in the third level of the ATC comprise, in the parties' opinion, different indications which are distinguished only at the fourth level and, in such distinction, are once again interchangeable with pharmaceuticals from other classes.

37. M3B muscle relaxants are, according to the parties, in all Member States of the EEA available on prescription only. According to the parties, the relevant preparations of Ciba (Lioresal) and Sandoz (Sirdalud) have areas of use which overlap to only an insignificant extent. The differences in their indications justify the assumption of separate markets. According to the parties, a distinction may be made between severe muscle spasms in the case of multiple sclerosis, etc. and harmless muscle spasms caused by strain resulting in lumbago or similar spasm conditions. Lioresal is reported to be used almost exclusively in the first area and Sirdalud almost exclusively in the second.

38. The Ciba preparation is authorized only for spasticity in the case of diseases of the central nervous system, and the Sandoz preparation for spasticity in diseases of the central nervous system and muscle spasms. The marketing of the Sandoz product is, according to the parties, oriented entirely towards muscle spasms. According to the parties, the prescription panels for Europe show the following average indications: for Lioresal, [...] [3] spasticity in diseases of the central nervous system, [...] [3] spasticity in diseases of the central nervous system, [...] [3] muscle spasms and [...] [3] other, for Sirdalud [...] [3] muscle spasms, [...] [3] spasticity in diseases of the central nervous system and [...] [3] other. 'Other' includes a large number of sub-indications both in the central nervous system and in the spasm area, which, according to the parties, account for under [...] [3], and illegible data or data which for other

[3] Omitted for reasons of business secrecy.

reasons cannot be properly classified. The higher proportion of 'other' uses in the case of Lioresal may, according to the information provided by the parties, be due to the fact that there are many rare disease syndromes of differing names which are associated with spasticity and which should really come under the heading of spasticity in diseases of the central nervous system.

39. With a breakdown of M3B muscle relaxants into two relevant product markets, there are, according to the parties, substitutabilities in the case of both indications with N5C tranquillizers, and in the case of spasticity with N2B analgesics, C4A cerebro-peripheral vasodilators, N3A antiepileptics and G4B urologics, and in the case of harmless spasms with N2B analgesics and M1A antirheumatics. For the purposes of this Decision, however, it is not necessary to decide on any further market definition.

40. In conclusion, therefore, it is clear that the third level of the ATC classification M3B muscle relaxants is to be broken down into two separate product markets one of which comprises the corresponding medical products for the treatment of spasticity in diseases of the central nervous system and the other medicinal products for the treatment of simple muscle spasms, with these then once again being substitutable with individual products of other ATC classes.

(b) **Active substances**

41. The manufacture of pharmaceutical products generally takes place in two separate processes: manufacture of the active substances and manufacture of the pharmaceuticals. Manufacture of the pharmaceuticals means the mixing of the active substance with other substances and the manufacture of the galenic form such as capsules or tablets. Active substances are both manufactured for in-house purposes and also traded. There are therefore separate markets for active substances which are upstream from the markets for pharmaceuticals.

(c) **Future markets**

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 (normally after extremely large sums of money have been invested). 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 only by reference to their characteristics and intended therapeutic use. In so doing, it must be borne in mind that research and development cannot as a rule be traded between pharmaceutical companies, but are rather intended primarily for the development of a company's own active substances and products. On the other hand, cooperation takes place in the research field between pharmaceutical companies and public and private research institutes and small biotechnology undertakings which, although they have the relevant know-how, do not themselves have the resources and facilities for the clinical testing that must be carried out prior to market authorization and for the manufacture of the pharmaceuticals. The Commission has to look at R & D potential in terms of its importance for existing markets, but also for future markets.

43. Some of the parties' competitors surveyed by the Commission point out that there is a trend towards commissioning firms to carry out research and development. Some do not see research and development as a separate market. This is evidently based essentially on the fact that research and development, at least by pharmaceutical undertakings engaging in research, is still carried out predominantly for in-house purposes.

44. In so far as research and development must be assessed in terms of its importance for future markets, the relevant product market must, by its very nature, be defined in a less clear-cut manner than in the case of existing markets. Market definition can be based on the existing ATC classes only if existing products are to be replaced. Otherwise it must be guided primarily by the indications to which the future products are to be applied. Here, fundamentally different modes of action must be taken into account. The merger in question calls for closer examination of the parties' research activities in the field of HS-TK gene therapy for the treatment of brain tumours and other tumours. HS-TK gene therapy, according to the parties, does not involve the healing of a genetically conditioned disease, but a method of applying a therapeutic substance to the appropriate place. HS-TK gene therapy is, according to the parties, a process of suicide gene therapy in which an enzyme gene is fed through a vector system into diseased cells. A prodrug is then administered which is activated by the enzyme gene. Prodrug means a drug pre-stage which, in conjunction with the enzyme gene, has the effect of killing the cell. In this way, the diseased cells are killed off. The healthy cells, the

parties claim, are not affected. The parties argue that HS-TK gene therapy is in direct competition with other gene therapies and with other processes such a chemotherapy, immunotherapy and radiation.

45. The parties can be agreed with only in so far as there are other therapies being pursued for the treatment of tumours. However, these clearly differ in their mode of action from HS-TK gene therapy. As also in the case of the market definition for medicinal products, reference cannot be made solely to a common treatment objective. Rather, account must also be taken of different active principles which lead to different degrees of effectiveness and tolerance. In the same way as the market definition for medicinal products, HS-TK gene therapy for the treatment of brain tumours and other tumours could be regarded as a separate future product market. However, for the purposes of this Decision, it is not necessary to take any final decision on the inclusion of other therapies.

46. Research work being carried out by an American subsidiary of Sandoz, GTI, in the HS-TK gene therapy area is currently at R & D phases II/III. This means that GTI has already achieved substantial progress in this area and that market entry seems possible within the next three to five years. The parties point out that, despite GTI's advances, it is still very uncertain whether this form of therapy will ever be used. The market interest in this area noted by the Commission indicates that it is by no means an area that has as yet no business relevance. Rather, the Commission has established that large amounts of financial expenditure have already been incurred and that the market is already giving consideration to the marketing of HS-TK gene therapy.

2. *Geographic market*

(a) **Manufacture of medicinal products**

47. The markets for pharmaceutical products have been defined as national markets in the decisions hitherto adopted by the Commission. The inquiries in this procedure have shown that there is no reason to depart from the decision-making practice so far. The results of the Commission's investigations among competitors of the parties bear this out.

48. There are, however, efforts at European standardization. The harmonization of technical provisions within the Community and the entry into force of new registration procedures for medicines represent the completion of the programme for the common market in terms of the scientific and technical requirements applying to medicines. Since the beginning of 1995, pharmaceutical companies have had the option (and indeed, in the case of biotechnology products, the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products, which then issues a recommendation to the Commission, whose decision is binding on all Member States. At present, medicines can be registered in different Member States for different indications.

49. The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the 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 mean that markets are national in character.

(b) **Manufacture of active substances**

50. The markets for active substances, which are situated upstream from the pharmaceuticals markets, are, by contrast, international markets that have to be examined at least at Community level. In view of the lack of customs barriers and the frequent mutual recognition of product licences between the United States and the European Economic Area, consideration may also be given to a wider market definition. The parties' competitors questioned by the Commission incline to the assumption of worldwide markets.

(c) **Future markets**

51. To the extent that future product markets can be considered on the basis of research and development in particular areas, the said national restrictions do not have the same impact. A characteristic of future markets is that no

products have yet been registered. Because research and development is normally global, the consideration of future markets should therefore focus on the territory of the Community at least, and possibly on worldwide markets. This view is for the most part confirmed by the competitors questioned. Reference is sometimes also made to the fact that, depending on the relevant project, the market definition could differ in individual cases. The geographic coverage of patents may also be relevant for the geographic definition of future markets. In the case of HS-TK gene therapy, patents are separately applied for and granted in the United States and Europe. The patent situation has considerable influence on the marketing opportunities of the competitors of patent holders. Patent differences may in future lend themselves to different competitive situations inside and outside the Community. At any rate for the purposes of this Decision, it can be assumed that the Community is the relevant geographic market.

3. *Competitive assessment*

52. The setting-up of Novartis will create the second largest supplier of pharmaceutical products in the world after Glaxo Wellcome. Next come a number of other large suppliers such as Hoechst Marion Roussel, Merck & Co., Bristol Myers Squibb, American Home Products, Johnson & Johnson, Pfizer, Rhône-Poulenc Rorer and Smith Kline Beecham. The share of Novartis in worldwide sales of pharmaceutical products will probably be under 5 %.

53. Ciba and Sandoz are involved in the research, development and production of active chemical substances and in the production and marketing of pharmaceutical products. According to the information provided by the parties, Novartis will be active mainly in seven medicinal fields, namely immunology/inflammation, diseases of the central nervous system, cardiovascular diseases, hormonal and metabolic diseases, cancer, dermatology and asthma.

(a) **Medicinal products**

(1) *General market conditions*

54. Drug manufacturers distribute their products, possibly through their national distribution companies. to wholesalers, which in turn sell to pharmacies, clinics and other large customers. Sometimes the manufacturer or its national distribution company sells direct to large customers. The distribution systems differ in each of the Member States. Pharmaceutical wholesalers, as the major purchasers, generally distribute all the pharmaceutical products supplied in the country concerned. They carry comprehensive stocks and have little influence on the selection and quantity of the pharmaceutical products they purchase. In general they simply pass on the decisions of doctors and pharmacists.

55. The prices of most medicinal products are regulated directly or indirectly by national laws. Differences in the systems for reimbursing prices and costs lead to wide differences in the prices of medicinal products in the Member States.

56. A general characteristic of the markets for pharmaceutical products is that products are introduced onto the market after completion of their development and testing before undergoing — though with considerable time differences from product to product — a phase of expansion during which, depending on the patent situation, other competitors also enter the market. Depending on the product's success on the market, additional competitors enter the market once patent protection has ended and supply the same medicinal products in the form of generic products.

57. According to the statements made by the pharmaceutical companies questioned, the main barriers to market entry are the length of time needed for research and development and the heavy expenditure involved in marketing these products, which is partly the result of the need for national registrations.

58. Future market entry is possible for companies which currently have products undergoing research and development. The parties draw a distinction between various phases of development. Phase I marks the start of clinical testing on humans (some 8 to 12 years before the product is marketed). Projects in phase I are claimed to have no more than a 10 % chance of being successful. As a rule, phase I activities are not publicized by the undertakings concerned. Phase II (some 6 to 7 years before the product is marketed) involves working out the proper dose for the patient and defining the areas of application. Here the success rate is said to be 30 %. Phase III (starting 3 to 4 years before the product is marketed) involves establishing the product's effectiveness on larger groups of patients. In phase III, the risks of failure may still amount to over 50 %. Once the clinical testing has been completed, there is the registration phase

which as a rules takes at least 1 to 2 years. After registration has been obtained, it takes 6 to 12 months, depending on the Member State, until the price is established and approved and cost reimbursements by social security worked out, whereupon the product can finally be placed on the market [4].

59. On e patent protection has expired, market entry is, the parties state, less costly for a competitor already active in pharmaceuticals manufacture. So long as the active substance for a medicinal product is covered by patent protection, market entry costs are, according to the information provided by the parties, high. A competitor would have to acquire a licence or invent another active ingredient that worked in the same or a similar way without infringing the original patent. Such a parallel product would then have to go through the entire preclinical and clinical development process, which, according to the parties, could take up to 10 years and cost up to ECU 300 million.

60. According to the parties, if a group's medicinal product is registered for only one indication, it can generally be assumed that it will also actually be used only for that indication. All types of advertising or sales promotion for an unregistered indication are prohibited. If a doctor were to prescribe for an unregistered indication, he would also incur specific liability risks. With regard to cost reimbursement, systems differ from country to country, the parties state. In some cases, costs can be reimbursed even when the medicinal product is used outside the indication area for which it is registered, on condition that the doctor provides specific justification for this. On the whole, the parties argue, the use of medicinal products for indications other than those for which they are registered is not quantitatively significant.

61. The special features of the production of medicines affect the significance of market shares when appraising the market situation, at any rate when generic products are able to compete on the affected market and other competitors are active on the market with original preparations. The competition provided by such products remaining on or entering the market should normally be given more weight in the pharmaceutical industry than in other industries, mainly because it is much easier for a manufacturer to extend capacity: this restricts the competitive scope of leading suppliers deriving from market share to a much greater extent than on markets on which competitors can extend capacity only by utilizing substantial resources and frequently only after a considerable delay. The competitive scope arising from such a delay largely disappears in the case of suppliers of medicines inasmuch as a supplier already present on the market can generally extend its capacity relatively quickly, either by using its own production capacities or, particularly in the case of medicines not protected by patent, by contracting-out production to a third party. According to the information provided by the parties, the capacity utilization of manufacturers of active substances and pharmaceutical preparations is estimated at some 50 % industry-wide. However, in the case of new preparations protected by patent, which, if production is contracted out, may give rise to problems to do with the protection of business secrets, this mechanism is not fully operative.

(2) *Effects of the merger*

62. The parties are active on a variety of pharmaceutical product markets and achieve substantial market shares on a large number of national markets. If the product markets are broken down in accordance with the third level of the World Health Organization ATC classification, the proposed merger will not lead to additional market shares on many national markets, even if one of the parties is often in a very strong position on those markets.

63. In the notification the parties name 48 national markets which are affected markets within the meaning of the implementing Regulation and invole a total of 23 different product groups (A4A Antinauseants, C1E Nitrites, C2D Rauwolfia & Comb. & Diuretics, C5C Variocose therapie. syst., C7A Betablocker plain, C7B Betablocker Comb., D4A Topical Antipuritics, G3C Estrogens, G3F Estrogen & Progesteron Comb., H4A Calcitonins, LA4 Immunosuppressive Agents, M1A Antirheumatic, nonsteroidal, M3B Muscle Relaxants, central, N2C Antimigraines, N7B Antismoking Products, R2A Throat Preps., S1X Other Ophthalmological, A12B Potassium, A12C other mineral supplements, H2B Corticosteroids Comb., R1B Syst. Nasal preparations, R3C N-Steroidal Resp., R5D Antitussives).

[4] These differences in cost reimbursements by social security systems still play a role even after the introduction of central European registration.

64. The parties' combined market shares on many of the affected markets are small. Furthermore, patent protection for the medicines they manufacture has often expired and generic products exist. Market entry by generic products seems, however, to take place primarily on the larger markets. This may be due to the fact that, for a generic-product producer, market entry costs, which derive from national requirements for the registration of medicines, still represent a substantial barrier to market entry on markets where turnover is small, so that the expiry of patent protection does not on its own necessarily entail a change in supply on such markets. The costs involved in obtaining a national registration comprise the registration costs themselves and the costs of preparing the necessary dossier, although a dossier produced for registration in one Member State can also be used at least in part for applications in other Member States.

65. On a further 13 national markets involving 7 different products (C1C, C2C, C5B, D1A, D6A, J1H, N4A), one of the parties achieves a market share of over 25 %. Although both parties are active here on individual product markets in the EEA, this does not lead to combined market shares on national markets. Nor is there any sign that in this respect the parties are in an — at least potential — competitive relationship with each other. The markets are generally small and the parties' activities throughout the Community tend to be insignificant. There are no discernible incentives for the parties to enter the market.

66. On a further 137 national product markets involving 37 different products, for which in each case only one of the parties achieves sales in the EEA, one of the parties has market shares of at least 25 %. On these markets the proposed concentration cannot be expected to create or strengthen a dominant position. Since activities do not overlap, the concentration does not lead to any reduction in actual competition. Even if the parties as suppliers of pharmaceutical products were both to be regarded as potential competitors in principle, this would also hold good for the other large suppliers of pharmaceutical products. For this reason, no relevant restriction of potential competition would result here either.

67. Even for products eligible for a market definition other than the third level of the ATC classification, a broader market definition gives rise neither to additional overlapping in the parties' activities nor to larger market shares on the markets on which there are market share additions.

68. Where the parties have research and development projects in phases II and III, these too do not give rise to any further overlapping on markets on which one of the parties already has a strong market position.

69. When evaluating the effects of the concentration on the product markets, a number of general market conditions can basically be taken into account:

— Prices are often regulated by the national authorities, and this restricts the supplier's scope for competitive behaviour,

— General pressure exists to reduce health-care costs, which increases the price pressure on suppliers,

— The suppliers of pharmaceutical products present on the market generally find it much simpler to extend capacity than suppliers in a number of other economic areas experiencing equivalent success on the market. The greater flexibility with which competitors can react reduces the significance of high market shares.

(a) Rauwolfia & Comb. Diuretics

70. Taking the area of blood-pressure products as a whole, the parties' share is a relatively small one. According to the information provided by a competitor, the parties achieve on a correspondingly broadly defined market a Community-wide share of some 6,2 %, which is tending to fall slightly. This overall position of the parties puts into perspective from the outset the market shares they achieve on individual products markets.

71. The parties will have no scope for competitive behaviour — typical of a company in a dominant position — in the case of Rauwolfia even after the concentration because of the competition from other suppliers of Rauwolfia preparations and other blood-pressure products.

72. Taking the sales of Rauwolfia alone, the parties would achieve a higher share. But it can also be seen that other Rauwolfia suppliers are present on all affected markets.

Germany

	Volume (ECU million)	C	S	C + S	(Boehringer)	(Bayer)	(P & G)
1993	34,0	4,3 %	66,4 %	70,7 %	15,7 %	5,2 %	2,6 %
1994	32,5	3,8 %	68,9 %	72,7 %	14,7 %	4,9 %	2,3 %
1995	30,8	4,1 %	69,8 %	73,9 %	13,7 %	4,7 %	2,3 %

Italy

	Volume (ECU million)	C	S	C + S	(Abbott)	(SKB)
1993	1,4	45,9 %	46,3 %	92,2 %	5 %	1,1 %
1994	1,2	49,0 %	45,9 %	94,9 %	4,2 %	0,9 %
1995	1,0	51,3 %	44,0 %	95,3 %	4,3 %	0,5 %

Austria

	Volume (ECU million)	C	S	C + S	(Boehringer)	(P & G)
1993	1,5	4,5 %	49,8 %	54,3 %	34,2 %	9,6 %
1994	1,2	4,5 %	49,2 %	53,7 %	34,6 %	9,8 %
1995	1,1	5,5 %	48,7 %	54,2 %	33,9 %	10,0 %

Spain

	Volume (ECU million)	C	S	C + S	(Lacer)	(Altana)	(Gross)
1993	1,1	3,8 %	45,0 %	48,8 %	36,7 %	7,3 %	7,3 %
1994	0,8	3,8 %	45,1 %	48,9 %	35,7 %	7,7 %	7,7 %
1995	0,7	3,7 %	45,0 %	48,7 %	35,7 %	7,8 %	7,8 %

EEA

	Volume (ECU million)	C	S	C + S	(Boehringer)	(Bayer)	(P & G)
1993	40,1	7,2 %	63,2 %	70,4 %	14,9 %	4,5 %	2,6 %
1994	36,6	6,8 %	65,6 %	72,4 %	14,1 %	4,3 %	2,4 %
1995	34,3	6,7 %	66,6 %	73,3 %	13,3 %	4,2 %	2,4 %

73. It should also be borne in mind that sales of C2D Rauwolfia & Comb. & Diuretics are falling sharply. The parties' sales in absolute terms have also fallen. According to the information they provide, their medicines are also no longer protected by patent. Their basic patents for two active substances expired between 1976 and 1979.

74. According to the information provided by the parties, the prices in Germany of Ciba products rose by over 10 % between 1993 and 1995 and those of Sandoz products by over 5 %. These price increases are, however, barely above the general rate of inflation which occurred in this period, so that they cannot in general be regarded as a sign of scope for dominant behaviour. This is particularly true of the markedly smaller price increases of Sandoz, which indicate that even Sandoz, by far the largest supplier on the German market, had no more scope for setting prices than its competitors.

75. Finally, scope for competitive behaviour typical of dominant companies is ruled out in the case of Rauwolfia by the considerable pressure of competition from other high-blood-pressure products. If betablockers alone are taken into consideration, the parties' combined share in 1995 falls to some 11 % in Germany, some 18 % in Italy, some 7 % in Austria, some 5 % in Spain and under 9 % in the EEA. The proposed concentration cannot therefore be expected to lead to the creation of a dominant position.

(b) Betablockers

76. In the case of C7B Betablockers Comb. the parties' products basically no longer have any patent protection. There are generic products on the market. Ciba still has a patent for specific fractionable sustained-release tablets containing, for example, Logroton; this patent will expire in the year 2000.

77. France is the only country where the parties achieve high combined shares for C7B Betablocker Comb. In 1995 these, it is said, amounted to around 55,1 % for Ciba and to around 11,6 % for Sandoz, or a combined total of some 66,7 %. According to the information provided by the parties, the only large supplier of these products was Merck Sharp and Dohm at around 33,3 % The total turnover achieved for these products in France was, however, only ECU 3,6 million. While sales of Betablocker Comb. are shrinking in France and throughout the EEA, sales of Betablocker plain are in each case showing a marked rise. The parties' combined market shares in France on the market for betablockers including Betablocker plain were some 7,8 % in 1993, some 6,8 % in 1994 and some 6 % in 1995. According to the information provided by the parties, Zeneca is the leading supplier of betablockers throughout the EEA. The parties are not expected to acquire a dominant position as a result of the concentration.

(c) Calcitonins and diphosphonates

78. The parties as a rule do not have high market shares on the markets for calcitonins and disphosphonates for the treatment of osteoporosis or Paget's disease. Their competitive strength on this product market is based solely on their calcitonin activities. They are not involved in disphosphonates for the treatment of Paget's disease and osteoporosis.

79. The strengths of the parties vary as regards calcitonins. Sandoz is the first supplier to have brought calcitonin onto the market as a nasal spray. The advantages over injection led to a considerable increase in the Sandoz sales figures. But, according to the information provided by the parties, nasal sprays are also supplied in Italy by Rhône-Poulenc, Procter & Gamble and generics manufacturers. The registration of nasal sprays can also be expected in other countries. On the other hand, Ciba has been unsuccessful in trying to develop a nasal spray. According to the information provided by the parties, it is a fact that the human calcitonin used by Ciba can only be injected and is unsuitable for administration in the form of a nasal spray or an oral preparation. This is why Ciba has in the meantime largely ceased its efforts to compete with calcitonin.

80. According to the information provided by the parties, their basic patents for calcitonins have expired in all the EEA countries. Ciba still has two patents: Stable Solutions Containing Human Calcitonin (patent protection until December 2011) and Fibrillated Human Calcitonin (patent protection until April 2012). In the case of Miacalcin (salmcalcitonin), Sandoz only has process protection in Austria until 1997 and a patent for a nasal spray formulation until 2003. Miacalcin is reported to be one of the parties' most successful products. The parties say that they have other products under development in this area which could come onto the market in the next few years. Two developments of Sandoz for calcitonin are in research phase III and so, according to the information provided by the parties, could be brought onto the market in three or four years' time. They relate to a special form

of osteoporosis caused by taking cortisone preparations over a long period.

81. Exact sales figures exist only for the calcitonins product group, but not for the relevant market. The following information on market shares is therefore based on estimates provided by the parties. Because of the market structures, the proposed concentration cannot be expected to lead to the creation or strengthening of a dominant position for the parties in any Member State on the markets for calcitonins an diphosphonates registered for the treatment of osteoporosis and Paget's disease.

— *Belgium*

82. The parties achieve a combined market share of some 21 % (Sandoz around 21 %, Ciba around 0 %). The parties assume that Ciba will be forced out of the Belgian market in the next few years.

— *Germany*

83. According to the information provided by the parties, Sandoz had a dominant market position in Germany until 1990. Since 1991 a number of new manufacturers have entered the market. At the same time sales have fallen. This has considerably intensified competition, as can also be seen from the market successes of the new entrants. If diphosphonates are included, the parties' market share, on the basis of their own estimates, falls to around 51 % (Sandoz some 34 %, Ciba some 17 %). This market share will tend to fall further since disphosphonates have only just been introduced into Germany for the treatment of osteoporosis. According to the information provided by the parties, Boehringer Mannheim is by far the leading supplier of diphosphonates, and Medac, Procter & Gamble and Gehe are also active in Germany.

84. The parties have submitted a calculation of shares for calcitonin for Germany on the basis of pack units which shows up clearly the market success of generics manufacturers. The calculation also shows that, on the basis of pack units, the share of the Sandoz preparation Karil fell from 95,12 % in 1986 to 22,23 % in 1995. The share of Cibalcalcin between 1989, when it entered the market, and 1994 rose to 18,83 % and in 1995 fell to 15,87 %. According to the information provided by the parties, Ciba's market success, which peaked in 1994, is connected with the strong publicity devoted to human calcitonin. In comparison, Calci, made by Hexal, entered the market in 1992 and, although its shares rose only slightly after 1993, it was the leading preparation in 1995 at 25,34 %, and Calcitonin, made by Ratiopharm, entered the market in 1994 and had already reached 10 % in 1995. Ostostabil, made by Jenapharm, achieved a share of 1,69 % in 1995. Other suppliers include Rhône-Poulenc Rorer, Azupharma, Tosse, Durachemie and Pharmacia Upjohn. In the view of the parties, the fact that in the long run calcitonin, which can only be injected, has no market prospects can be clearly ascertained from the trend characterizing the market share of Rhône-Poulenc Rorer's Calsynar, which can also only be injected and which peaked at 16,92 % in 1991 but reached only 4,49 % in 1995.

— *France*

85. In France the parties' combined market shares have been falling since 1991. Sandoz is expecting to be able to bring the nasal spray onto the French market around 1998. It is assumed that at that time other manufacturers will also introduce the nasal or oral form of preparation. Diphosphonate, which is interchangeable with calcitonin for the treatment of osteoporosis, has achieved the same large market volume as calcitonin. On the basis of the parties' estimates, if disphosphonates are included, their combined market share is only some 21 % (Sandoz some 6 %, Ciba some 15 %).

— *Greece and Portugal*

86. The calcitonin markets in Greece and Portugal have grown considerably in recent years. Sandoz market shares have fallen markedly since 1993, while Ciba market shares have fallen to under 2 % and 3 % respectively. At the same time, new competitors, such as Rhône-Poulenc Rorer, have entered the market and have achieved an appreciable market share. On the basis of the estimates submitted by the parties, if disphosphonates are included, the combined market share in Greece is some 54 % (Sandoz some 54 %, Ciba some 1 %). Since disphosphonates have just been introduced in Greece, this market share can be expected to fall substantially. On the basis of the estimates submitted by the parties, if disphosphonates are

included, the combined market share in Portugal is some 66 % (Sandoz some 63 %, Ciba some 3 %). Disphosphonates are just being introduced into Portugal and, according to the information provided by the parties, will largely replace calcitonins for the treatment of osteoporosis, partly because this use of calcitonin is to be restricted by government measures. For this reason it is possible that the market will contract in the same way as it did in Italy.

— *Italy*

87. In 1990 Italy was by far the largest market for calcitonin with a market volume of some ECU 350 million. According to the information provided by the parties, the high expenditure on calcitonin in Italy led to a situation in which the health authorities wished to limit its prescription and refused to reimburse the cost of calcitonin. Since 1994 the market has shrunk by 85 %. Competition has intensified. In the view of the parties, Ciba will not be able to continue there much longer. According to the estimates submitted by the parties, if disphosphonates are included, the parties' combined market share is still only some 11 % (Sandoz some 11 %, Ciba some 0 %).

— *Austria*

88. In Austria Ciba market shares have been falling sharply. The competing product, Elcimen, made by Nycomed, the Norwegian manufacturer, has a considerable market position. According to the estimates submitted by the parties, if disphosphonates are included, the parties will have a combined market share of only 24 % or so (Sandoz some 21 %, Ciba some 3 %).

— *Sweden and Netherlands*

89. In Sweden and the Netherlands calcitonin is not registered for the treatment of osteoporosis, but only for Paget's disease. Market volume is therefore very small in these countries. Osteoporosis is predominantly treated with hormonal preparations and the new disphosphonates. If calcitonin were to be registered for the treatment of osteoporosis, market volume would increase substantially. This would provide an incentive for other suppliers to enter the market. According to the communication from the Swedish competition authorities, six disphosphonates interchangeable with calcitonins are registered in Sweden the suppliers of which include Astra, Roche and Boehringer Mannheim. They also say that all patents have expired in Sweden so that it seems possible that competitors active in other Member States would enter the market if the parties were to raise their prices.

(d) Muscle relaxants

90. For M3B Muscle relaxants, the parties' combined market shares will be insignificant. The parties' products are basically to be found on other markets. Even taking all M3B Muscle Relaxants together, the concentration cannot be expected to give rise to the creation or strengthening of a dominant position because of whole range of competing preparations.

91. It is difficult to calculate actual market shares because of the different uses of the medicines and the fact that they can be partially replaced by other preparations. According to the information provided by the parties, severe spasticity occurs as a symptom of various illnesses.

92. In the case of harmless muscle tension, the combined market shares will not be appreciable. Only the Sandoz preparation is registered for this indication. Admittedly, according to the information in the prescription panel, use of the Ciba preparation for simple muscle tension stands at 3 %, although it is not registered for this condition. Because of the inevitable simplifications in this kind of statistical evaluation and the insignificant share of sales, the Ciba preparation cannot be regarded as a competing product with the Sandoz preparation in this area. Even assuming a slight strengthening effect, this would not lead to the creation or strengthening of a dominant position. According to the information provided by the parties, Sandoz has substance protection for Sirdalud only until 1998 in Belgium and procedure protection for it only until 1997 in Spain. Otherwise, patent protection no longer exists. There are a large number of generics and competing products.

93. The parties' activities will not overlap significantly on the markets for medicines for the treatment of spasticity in the case of diseases of the central nervous system. While both products are registered for this indication, the marketing of the Sandoz product is geared only to its use in the case of simple muscle tension. Sales on prescriptions for the spasticity indication are only 8 % of the total in the case of the Sandoz product. Since the Sandoz product is also registered for this indication, the parties' activities

do overlap to a certain extent. But this is very slight and does not lead to the creation or strengthening of a dominant position. First, according to the information provided by the parties, the patent protection for the Ciba preparation has expired. According to the information provided by the parties, a number of generics have existed for Lioresal since the expiry of patent protection. In addition, according to the information provided by the parties, the scope for competitive behaviour is limited by a number of other products for the treatment of severe spasticity, e.g. by preparations of the benzodiazepine group.

(b) **Active substances**

94. According to the information provided by Ciba and Sandoz, their activities on the markets for the manufacture of active substances are marginal. They manufacture active substances almost exclusively for their own purposes. The concentration cannot therefore be expected to lead to the creation or strengthening of a dominant position.

(c) **Future markets**

95. The market strength of the undertakings in research and development is difficult to estimate since success in R & D can usually be assessed only after the R & D has been completed. Nevertheless, the undertakings' existing R & D potential cannot be ignored in the competitive assessment since their future competitive strength is bases precisely on such potential.

96. The parties are particularly strong in the biotechnology and genetic engineering fields. Their strength is based primarily on a number of cooperation agreements with and stakes in US undertakings and research establishments. Through these holdings and cooperative arrangements, the parties also have access to patents in this field. This calls for closer examination in the area of genetic engineering research on the treatment of brain tumours and other types of tumour. Of particular importance in this connection are Sandoz's stake in GTI and Ciba's 49,9 % stake (which can be increased) in Chiron.

97. GTI's research on HS-TK gene therapy is now at phase II/III. Patents in the EC have been applied for. According to the information provided by the parties, Viagen, a subsidiary of Chiron, has research work at the preclinical stage, i.e. before phase I. Little can be said with certainty about the time required to achieve results in this area. Since the diseases to be treated are as a rule ones which hitherto could not be adequately treated, authorization of developed processes can possibly be given much more quickly than in the case of traditional medicinal products which merely replace ones that are already available and effective.

98. The Commission has established in the curse of its investigations that the parties could, as a result of these holdings, have exclusive access to a combination of broadly defined patents covering retroviral HS-TK (herpes simplex thymidine kinase) constructs, retroviral vectors and methods for the treatment of brain tumours and other tumours using such retroviral vectors. Sandoz in particular seems to be in a strong position in this area through its subsidiary GTI, which is endeavouring to develop gene therapy for brain tumours in the United States. Viagen has patent applications in related areas that could be useful for the development of successful gene therapy for brain tumours. The patent applications cover such a wide spectrum of patent claims that, if the patents are issued with the coverage applied for or with similar coverage, their combination as a result of the merger could mean that other competitors were largely excluded from parts of this field of research (gene therapy for brain tumours and other tumours).

99. Patent rights may pose considerable entry barriers to competitors on future markets. When R & D results are marketed, a number of patents held by other undertakings must often be taken into account. Undertakings must then either find ways of marketing their R & D results without infringing other patent rights or acquire the relevant licences. The more patents exist in a particular area of research and the wider the coverage of such patents, the more difficult the situation may be in individual cases. Particular problems may arise where individual suppliers have a combination of patents that make it difficult or indeed impossible for other suppliers to gain market access without infringing such patents. Where a merger leads to the holding of such a combination of patents, market foreclosure can result.

100. The parties argue that some at least of the patent applications, in particular those attributable to Chiron, are so broadly formulated that it is highly improbable that they will be granted without a more detailed specification. Furthermore, they argue, the patents attributable to Chiron, as currently specified, do not cover the treatment of brain tumours and other tumours. They therefore take the view that, even if the relevant patents are granted, the proposed merger will not lead to any combining of patents that might result in market foreclosure. Lastly, the parties object that they do not have any exclusive access to the patents attributable to Chiron.

101. According to information deriving from the market, any combining of the future patent rights of GTI and Viagen could block the development of gene therapies for tumours or other treatment methods by other undertakings. It is still uncertain whether this situation will actually apply. At any rate, the merger may place competitors in a substantially worse negotiating position for obtaining a licence from GTI or Chiron after the merger. Whether this worsening of competitors' negotiating positions might actually result in market dominance depends essentially on three conditions:

(1) It is not certain that gene therapy will ultimately prove to be a successful method of treatment;

(2) Other research results may open up ways of circumventing any obstacle created by the combining of patents;

(3) The patent situation is very unclear. The parties have as yet submitted only patent applications. Patents have still to be granted.

102. If these three conditions become reality, the proposed merger may lead to a structural danger of foreclosure of the future market for HS-TK gene therapies for tumours. The parties would then have power over other competitors' market access through the issue of licences.

103. The first condition is one which applies in any examination of future markets. What it ultimately amounts to is that the market must be created before any problem can arise. As stated above, GTI's research projects are already at phase II/III. Even if it cannot yet be predicted whether this new method for treating tumours will actually be applied, there is nevertheless, in view of the progress being made in research, sufficient probability to warrant protecting the market in terms of competition.

104. The second condition is difficult to assess in current terms. In so far as the parties' competitors may in future be prevented from marketing their products as a result of patents, they will, in view of the large amounts of expenditure incurred on research, try to find a way of circumventing this difficulty if they cannot obtain any licences. There is not enough information available to be able to say whether such a way will be found. Although any such endeavour may require additional time and money, the possibility can by no means be ruled out that competitors might seek and find such ways.

105. A key question regarding the creation of any competition problem is whether the parties will obtain patents that may have a blocking effect. This applies primarily to the blocking effect which patent applications attributable to Chiron may create for competitors of GTI in their pursuit of a competing product. The Commission's investigations have identified substantial market fears in this respect. The granting of such patents depends on two preconditions. First, the parties must assert their patent claims on the basis of a specification that includes areas of HS-TK gene therapy for tumours. This precondition is solely in the hands of the parties. To this extent, the proposed merger may pose an increased structural danger of market foreclosure. The second precondition is the actual granting of such patents, and this is not in the hands of the parties. The patent applications could of course exert some disruptive effect. Undertakings wishing to market a HS-TK gene therapy for tumours would have to bear in mind that patents having a broad specification might possibly be granted. They are therefore confronted with the question of whether they should carry out investment in this area at all and whether they would have seek a way of getting round any patent. Viewed in abstract terms, this could pose an obstacle to competitors wishing to gain market access. However, this alone is not sufficient to conclude that the parties would have a dominant position on this market.

106. It cannot therefore ultimately be said with sufficient probability that the merger will on any future market lead to the creation or strengthening of a dominant position.

107. The Commission notes that, in the course of these merger-control proceedings, the parties made the following statement: 'Both undertakings hereby

make the following binding statement on behalf of Novartis AG: Novartis will exercise the potential legal and contractual influence which it has as a result of its holding in Chiron Corporation, Emeryville, California, United States of America and through the Board Members appointed by it in such a way as to ensure that the Chiron subsidiary Viagene issues to interested firms on the terms and conditions customary in trade and industry non-exclusive licences for each European patent and for national patents derived therefrom that are based on the international patent applications Nos WO 89/09271 and WO 90/07936 for HSTK (Herpes simplex Thymidine Kinase) gene therapy for tumours. This obligation is subject to the proviso that the conduct of Novartis and of the Board Members appointed by it must in accordance with US law be in the best interests of Chiron and its shareholders. The obligation will apply for 10 years following the issue of the European patents.'

B. PLANT PROTECTION

1. *Relevant product market*

108. In the plant protection area, a distinction is usually made between the following:

— herbicides for weed control,

— fungicides for disease control,

— insecticides for insect control,

— seed treatment for the protection of seeds and subsequent plants against disease and insects,

— trace elements to overcome deficiency symptoms, e.g. iron deficiency,

— growth regulators.

(a) **Herbicides**

109. On the demand front, the type of plant to be protected by the relevant herbicide is one of the main factors determining substitutability. Other factors such as the type of weed, the active ingredient and the time of application of the plant protection product also influence the substitutability of different herbicides.

110. There are herbicides that can treat weeds affecting different types of plants, e.g. maize and cereals. In many cases, however, herbicides for the protection of different plants are not substitutable one for another. There is, for example, only limited substitutability between herbicides for the protection of cereals, fruit and sugar beet. Consequently, herbicides which protect different types of plants constitute separate relevant product markets (see IV/M.392 Hoechst/Schering, points 16 *et seq.*, and IV/M.354 American Cyanamid/Shell, points 11 *et seq.*). In assessing competitive relationships, however, it must be borne in mind that a large number of herbicides have a very wide spectrum of activity.

111. A breakdown of herbicides in terms of the weed which they are intended to treat is also conceivable (see IV/M.354 American Cyanamid/Shell, point 12). However, a specific type of plant is mostly affected by a mixed 'weed population' comprising grasses and broadleaved weeds. Herbicides are therefore made up in such a way that an entire population of weeds can be treated with them. However, the make-up of any such weed population is seasonally variable. There are therefore herbicides which are more suitable for treating grasses and herbicides which are better suited to treating broadleaved weeds. According to the Commission's investigations, farmers usually purchase a whole series of herbicides with specific selectivities and mix these in accordance with the types of weeds that appear, or they purchase a ready-made product containing the desired mixture. In principle, therefore, there is substitutability between products with a narrower spectrum of activity and those with a broader spectrum. In addition, the dividing lines between the two product groups are fluid, making it impossible to draw up a hard-and-fast classification.

112. A breakdown based on the time at which the herbicide is applied must also be disregarded since pre-sowing, pre-emergence and post-emergence herbicides ([5]) are all used to treat the same types of weeds and display the same degree of effectiveness. Before sowing at least, therefore, the herbicides in the groups specified are, as far as the farmer is concerned, substitutable for one another.

(b) **Fungicides**

113. Fungicides are used to prevent the deterioration of plants and plant products through fungi and moulds prior to and after harvesting. Fungicides having the same chemical compositions may be

([5]) Pre-sowing herbicides are applied to the soil immediately before the seed is sown. In pre-emergence treatment, the herbicides are applied immediately before germination, i.e. about eight days after sowing. Post-emergence herbicides are applied to the soil or the plants after germination (see OJ No L 272, 4. 11. 1993, p. 30).

used against fungi and moulds in a number of different types of plants. Thus, the same fungicide may be used for the protection of fruit, cereals, potatoes and sugar beet. For the purchaser, therefore, the key question determining which product he purchases is the harmful organism which the relevant fungicide treats, i.e. not the type of plant to be protected (see IV/M.392 Hoechst/Schering, points 18 *et seq.*).

114. Fungicides are, as a rule, used not to combat individual harmful organisms, but to combat (often preventively) entire complexes of harmful organisms. Examples include the typical cereal diseases rust, powdery mildew, eyespot, septoria and fusarium. In the case of sugar beet, the four main types of disease which occur are powdery mildew, rust, cercospora and ramularia, and combinations of them. Potatoes, on the other hand, are affected almost exclusively by late blight. Since the various plants display differing (albeit partly overlapping) disease patterns, a breakdown of fungicides by type of plant is appropriate.

115. There is, in the Commission's view, no need for an additional breakdown of fungicide markets. Although, for example, potato fungicides can be subdivided into contact products, penetrant products and systemic products, such products are all used to combat the same disease, can be used partly preventively and partly curatively, vary in the duration of their effectiveness and are in some cases already mixed together in the products or are mixed by growers in order to achieve optimum effectiveness for specific circumstances. A further breakdown into the product groups specified is therefore not appropriate and would in any case lead to double and triple counting, since the breakdown by type of plant already contains a partial subdivision by broad and narrow selectivity. A breakdown into products with a broad spectrum and those with a narrow spectrum can also be disregarded since, in the case of some plants, only a single harmful organism has to be controlled (e.g. late blight in the case of potatoes), while with other plants an entire complex of harmful organisms occurs. Consequently, fungicides predominantly have a broad spectrum, or a broad spectrum with a simultaneous particular effectiveness against a particular type of harmful organism. For the rest, the comments made in respect of herbicide markets (see above) apply. Similarly, a breakdown of fungicides in terms of their use at differing stages of development of the plant is not appropriate since, in some cases, no such fungicides exist or, if they combat specific harmful organisms in the early, middle or late development stage of the cultivated plant, may also be used or are effective during other development stages (see also the comments on the treatment of seeds below).

(c) **Insecticides**

116. Insecticides are products used to control insects that damage cultivated plants. Here, as in the case of fungicides, the same insecticide may be used to control a specific type of insect, irrespective of the type of plant affected. Since not all plants are attacked by the same insects and since there are no plant-specific insects, a breakdown of insecticides by type of plant is appropriate. In assessing competitive relationships, it will have to be borne in mind here too that a large number of insecticides may be used to treat different plants.

117. Farmers and growers generally purchase products that combat the groups of harmful insects whose composition varies by type of plant. Consequently, they purchase either products with a broad spectrum of activity, combination products (broad spectrum with specific selectivity) or insecticides with a narrow spectrum, which they themselves mix. From the farmers' point of view, therefore, insecticides with a broad spectrum and a combination of insecticides with a narrow spectrum are basically substitutable. In addition, the breakdown of markets by type of plant already contains a breakdown of insecticides by spectrum, so that any additional breakdown in terms of broad or narrow spectrum is, for this reason as well, not appropriate.

(d) **Seed treatment**

118. Seed treatment with plant protection products is intended to protect seeds and the subsequent plant against disease and insects. Since the treatment of seeds must be based on a prediction of what diseases and what insects the seed and the subsequent plant might be affected by, the corresponding products (fungicides and insecticides for use on seeds) are basically plant-specific in their composition. There is therefore only slight substitutability between products for the treatment of seeds of different plants. The relevant product markets should therefore be defined by type of plant.

119. The parties argued in their notification that the treatment of seeds constitutes a separate product group in the plant protection area, but they left open the question of whether what was involved

here was actually a separate market. Similarly in the publication 'Novartis, Backgrounder' attached to the notification, the product group 'seed treatment' is identified on page 17 as being separate from fungicides and insecticides.

120. In two later submissions, the parties took the view that seed treatment is not a separate market. This was essentially for the following reasons:

The final purchaser (farmer) can purchase ready-treated seed or can treat the seed himself. As far as insecticides are concerned, the farmer can, instead of treated seed, apply granulated insecticide into the seed row during sowing or can carry out blanket or row spraying with a liquid preparation. In addition to these prophylactic procedures, the farmer has also the possibility of deferring treatment until the first signs of infestation occur. One of the charts attached to the submission sows that the time of application, the duration of effectiveness, the duration of application and the effectiveness profile of seed treatment involving, on the one hand, soil treatment with granulates and, on the other, the blanket treatment of the soil with liquid preparations prior to sowing overlap.

The same essentially applies in the case of fungicides. The following diseases can occur in beans and peas: damping-off of seedlings, downy mildew, ascochyta leaf blight and botrytis. Seedling diseases are controlled either by seed treatment products, which allow only protection of the seed, or by seed protection products, which control both seedling diseases and also downy mildew and leaf blight. Downy mildew and leaf blight are controllable both by means of seed treatment and through spray treatments. Botrytis can be controlled only by means of spray treatment, and products which are effective against botrytis can also be used against leaf blight. Seed treatment is therefore a particular type of application of insecticides and fungicides, but serves the same purpose as products which are applied to the soil or sprayed.

121. In seed treatment, the seed grains are dressed. Ciba and Sandoz do not dress the seed grains themselves but supply the seed treatment products to other firms which have the appropriate dressing plants. However, in the Commission's view, this fact cannot be taken as a justification for identifying a separate market for seed treatment but, at most, a market for the dressing of seeds. As noted above, treated seed is form the farmer's point of view ultimately substitutable for fungicides and insecticides applied to the soil or sprayed. The Commission has therefore concluded that there are no separate markets for seed treatment.

(e) **Trace elements**

122. Trace elements are used to treat deficiency symptoms such as iron deficiency. Here too, a breakdown by type of plant may be regarded as appropriate since a given type of plant suffers predominantly from the same nutrient deficiency.

(f) **Growth regulators**

123. Growth regulators for individual plant types form separate relevant markets. On such markets, the merger will not create any market share additions since Sandoz neither markets nor produces growth regulators.

(g) **Active substances**

124. The manufacture of plant protection products takes place in three stages: the manufacture of the active substances, the manufacture of the formulations (formulated products) from the active substances, and the packaging of such formulations. Ciba and Sandoz manufacture the active substances for plant protection in central factories. The manufacture of the formulation and its packaging, by contrast, are carried out in several plants. Ciba, Sandoz and other competitors also sell or exchange active substances to or with other firms. There are therefore markets for active plant-protection substances.

125. Each active substance has unique properties and, where appropriate, is patented. Upon registration, i.e. authorization of a particular plant protection product, information must be given on the active substance(s) contained in the product. If the manufacturer uses another active substance, this gives rise to anther product for which, though it may have a similar effect to the first product, authorization must once again be sought. According to the Commission's investigations, it takes between six months and three years for such authorization to be obtained. In addition, the manufacturer will have to formulate the product anew and test the new product's effectiveness before applying for authorization, and this once again will take some time. For these reasons, active substances are basically not substitutable for one another.

2. *Relevant geographic market*

126. In the parties' view, the relevant markets for plant protection products are Community-wide markets. This market definition is supported by the following: the existence of a large number of major multinational groups, central production plants, low transport costs as a proportion of total costs and, in most cases, Community-wide patent protection for individual plant protection products. In addition, the marketing of plant protection products in the Community has been harmonized by Council Directive 91/414/EEC [6].

127. On the other hand, plant protection products, including the active substances and the formulations, must be registered in a Member State before they may be marketed. Between six months and three years are required from the time of the application until the authorization of the product, depending on the Member State and the product involved (generics, new active substance and/or formulation). Price differences between Member States for one and the same product are substantial; there are no signs of any tendency for alignment of prices. Furthermore, customers (agricultural cooperatives, other wholesalers) purchase the relevant products at national level, i.e. not on a Europe-wide basis. The suppliers therefore in most cases have national sales organizations or distribute their products via the sales organization of another manufacturer operating in the relevant Member State. The distribution of market shares in the Member States also differs quite widely, and this similarly suggests national differences in competitive relationships. In addition, there are differences as regards the composition of the individual products and also in the methods of use, depending on the different conditions existing in the individual Member States as regards agriculture, plant health, the environment, climate, soil properties and topography (see IV/M.392 Hoechst/Schering, points 20 *et seq.*, and IV/M.354 American Cyanamid/Shell, points 17 *et seq.*).

128. The definition of the relevant geographic market may, however, be left open as far as the herbicide, insecticide and trace element markets are concerned since, even applying the narrowest (national) market definition and any other market definitions, the merger will not create or strengthen a dominant position.

129. As far as the markets for active substances used in plant protection are concerned, the markets are assumed to be at least Community-wide. The customers are, for the most part, large or fairly large undertakings that have a good overview of the market and even purchase the products on a world-wide basis. In addition, transport costs are insignificant, and there are not market access restrictions as a result of national authorization requirements on these markets.

3. *Competitive assessment*

130. The comments on the markets for active substances are dealt with first. Because competitive relationships in the fungicide, herbicide and insecticide areas are very similar, they are combined under heading (b). Discussion of trace elements follows under heading (c).

(a) **Active substances for plant protection products**

131. In each individual case, the markets for active substances consist of a single substance. In so far as the active substance enjoys patent or know-how protection, the manufacturing firm has a monopoly. The merger will not alter this situation.

132. On the markets for commodities (non-protected active substances), there are a number of suppliers; it is in principle possible for each undertaking that has the relevant technology to supply such active substances. Only Ciba operates on these markets. On the markets for active substances used in plant protection products, therefore, the merger will not create or strengthen a dominant position.

133. The manufacturers of plant protection products purchase active substances from competitors and use them for the formulation of their own products. If the active substance purchased is a patented product, the purchaser enters into a relationship of dependency. Where the patent holder manufactures an active substance which is widely used on downstream product markets, he enjoys a potentially strong position on such downstream markets, even if his own market share on such markets is relatively small.

134. According to the Commission's investigations, the parties also buy and sell active substances from and to competitors. It cannot therefore be ruled out that competitors will no longer be supplied in future and that Novartis could, as a result, strengthen its position on the downstream markets. However, such conduct is thought to be highly unlikely by the market participants surveyed. Since the competitors buy and sell active substances from and to one another, the relationships are ones of mutual dependency.

[6] OJ No L 230, 19. 8. 1991, p. 1.

(b) **Fungicides, herbicides and insecticides**

135. According to the Commission's investigations, the merger will affect the markets listed below in the fungicide, herbicide and insecticide areas. The Commission's investigations have shown that the market shares can, in some cases, differ substantially (+/-10 %). As discussed below, the market shares also vary from year to year by up to 10 %, and in some cases indeed by more. This means that, depending on the base year taken, other markets would to some extent be affected by the merger. However, this applies in only a few cases and, even then, the combined shares in markets that would be affected if a year other than the base year 1995 were taken as the reference year would be just over 15 %. The base year 1995 therefore gives a sufficiently accurate picture of the markets that would actually be affected by the merger.

136. The market share calculations are based — at any rate as far as the larger Member States are concerned — on so-called 'panel' studies carried out by other undertakings. In the case of the smaller Member States, the calculations were carried out by the parties and were checked by the Commission on the basis of comparative data provided by competitors. Ciba and Sandoz, though other manufacturers as well, sell fungicides and herbicides in some cases to other suppliers of plant protection products who in turn supply the products to the trade. In their notification, the parties attributed such sales of Sandoz or Ciba products to the relevant suppliers. Similarly, sales of plant protection products by other suppliers to Ciba and Sandoz were attributed to Ciba and Sandoz where they went on to supply them to customers. This type of market share calculation is in line with that used in the 'panel' studies.

137. In the Commission's view, the market share calculation carried out by the parties and used in the 'panel' studies does not correctly reflect the actual market position of the parties and of competitors. This applies in particular in the Member States in which Sandoz (Ciba) does not have its own sales organization, while Ciba (Sandoz) does. In such cases, it is to be assumed that the sole of products following the merger will be carried out by Novartis. Even where Sandoz and/or Ciba have established their own sales organizations but, none the less, market their own products through other suppliers, the parties' market share is based on all the products manufactured by them since the parties could, in principle, at any time threaten the undertaking doing the actual marketing with a move to take over the sale of products entirely themselves (periods of notice of twelve months are usually agreed in sales contracts). Since third parties market Ciba and Sandoz products in order to supplement their own product ranges and since therefore the Ciba or Sandoz product is to some extent sold as part of the 'package' of the other undertaking's products, it is open to question whether the product sales of Ciba and Sandoz would not decline if the sales agreements with third parties were terminated. Consequently, the assessment of the parties' market shares could in some instances be somewhat too high. However, this does not matter here since, even if no appropriate reduction is made in the parties' combined market shares, the merger will not create or strengthen a dominant position.

138. Following the merger, the parties will have a very broad product range, with some of the products being in direct competition with one another. It is therefore to be assumed that, following the merger, the product range will be rationalized. This will affect in particular products which Ciba and Sandoz have hitherto marketed for third parties in order to supplement their own product range. For this reason, and because the other undertaking could in principle terminate the sales agreement within twelve months, there are grounds for reducing the parties' market shares by those volumes which the parties have achieved through the sale of third-party products.

139. A market share calculation including products sold to competitors and excluding products purchased from competitors does not, at any rate in the fungicide sector, show any different or additional affected markets than in the case of a calculation in accordance with the 'panel' studies, and in only one instance is there a significant difference in market share of just over 5 % (potato fungicides in France, where the parties' combined market share is reduced by 5 %). In the herbicide sector, the market shares show a significant difference in the case of fruit and nuts in France, where there is similarly a reduction of 5 %. New affected markets are identified in the case of maize herbicides. Without inclusion of the products marketed through competitors, four markets with combined shares of a maximum [30—40 %] [7] (1995) are affected by the merger. If the products marketed through competitors are included, there are eight affected markets with combined market shares of up to[50—60 %].

140. Accordingly, the following markets are affected by the merger in the fungicide, herbicide and insecticide sectors:

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[7] Omitted for reasons of business secrecy and replaced by a range for publication purposes.

Fungicides for fruit and nuts

— in France ([20—30 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Portugal ([10—20 %]; Ciba [10—20 %], Sandoz [under 10 %])

Fungicides for vegetables

— in Belgium ([10—20 %]; Ciba [10—20 %], Sandoz [under 10 %])

— in France ([10—20 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Italy ([20—30 %]; Ciba [20—30 %], Sandoz [under 5 %])

Fungicides for cereals

— in Belgium ([30—40 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Germany ([10—20 %]; Ciba [10—20 %], Sandoz [under 5 %])

— in France ([20—30 %]; Ciba [20—30 %], Sandoz [under 10 %])

— in Great Britain ([20—30 %]; Ciba [10—20 %], Sandoz [under 10 %])

— in the Netherlands ([20—30 %]; Ciba [10—20 %], Sandoz [under 10 %])

— in Austria ([20—30 %]; Ciba [20—30 %], Sandoz [under 5 %])

— in Spain ([20—30 %]; Ciba [10—20 %], Sandoz [10—20 %])

Fungicides for potatoes

— in Belgium ([20—30 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Germany ([10—20 %]; Ciba [10—20 %], Sandoz [under 5 %])

— in France ([40—50 %]; Ciba [under 10 %], Sandoz [40—50 %])

— in Great Britain ([20—30 %]; Ciba [10—20 %], Sandoz [under 10 %])

— in Italy ([20—30 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Portugal ([30—40 %]; Ciba [20—30 %], Sandoz [10—20 %])

— in Spain ([30—40 %]; Ciba [30—40 %], Sandoz [under 10 %])

Fungicides for sugar beet

— in Belgium ([40—50 %]; Ciba [20—30 %], Sandoz [20—30 %])

— in France ([50—60 %]; Ciba [20—30 %], Sandoz [30—40 %])

— in Italy ([20—30 %]; Ciba [10—20 %], Sandoz under 10 %])

— in Austria ([20—30 %]; Ciba [under 5 %], Sandoz [20—30 %])

— in Spain ([20—30 %]; Ciba [20—30 %], Sandoz [under 5 %])

Fungicides for beans and peas used as cattle fodder

— in France ([30—40 %]; Ciba [under 10 %], Sandoz [20—30 %])

Herbicides for fruit and nuts

— in France ([30—40 %]; Ciba [20—30 %], Sandoz [under 10 %])

Herbicides for vegetables

— in Belgium ([20—30 %]; Ciba [20—30 %], Sandoz [under 5 %])

— in Great Britain ([20—30 %]; Ciba [10—20 %], Sandoz [under 10 %])

Herbicides for maize

— in Belgium ([40—50 %]; Ciba [under 10 %], Sandoz [30—40 %])

— in France ([30—40 %]; Ciba [20—30 %], Sandoz [10—20 %])

— in Italy ([30—40 %]; Ciba [20—30 %], Sandoz [under 10 %])

— in Austria ([40—50 %]; Ciba [20—30 %], Sandoz [20—30 %])

— in Germany ([50—60 %]; Ciba [30—40 %], Sandoz [20—30 %])

— in the Netherlands ([30—40 %]; Ciba [10—20 %], Sandoz [10—20 %])

— in Portugal ([10—20 %]; Ciba [10—20 %], Sandoz [under 5 %])

— in Great Britain ([40—50 %]; Ciba [30—40 %], Sandoz [10—20 %])

Insecticides for fruit and nuts

— in France ([20—30 %]; Ciba [10—20 %], Sandoz [10—20 %])

Insecticides for vegetables

— in Italy ([20—30 %]; Ciba [10—20 %], Sandoz [under 50 %])

Insecticides for beans and peas used as cattle fodder

— in France ([30—40 %]; Ciba [under 10 %], Sandoz [30—40 %])

141. The following comments are concerned with the markets on which the parties have achieved joint market shares of 25 % or more. However, they also apply *mutatis mutandis* to the conditions of competition on the other markets affected.

(1) *Market volumes, market shares and competitors*

Fungicides

142. The EEA-wide volume in value terms of the *markets for cereal fungicides* was about ECU 700 million in 1995, some 8 % up on 1994 after negative growth rates from 1992 to 1994. The largest markets are France (1995: ECU 322 million), Germany (ECU 186 million) and Great Britain (ECU 121 million). A comparable volume in terms of value is found, moreover, only on the markets for cereal herbicides.

143. In the market for cereal fungicides in France, Ciba gained an additional market share of [under 5 %] from 1994 to 1995, but lost [under 5 %] compared with 1992. In 1995 Sandoz lost just over [under 5 %] but roughly held its market share compared with 1992. The competitors are BASF with a market share of [20—30 %] (up by [under 5 %] on 1994, but by [10—20 %] on 1992, Bayer with [10—20 %] (down [less than 5 %] on 1992), Agrevo (a subsidiary of Hoechst and Schering) with [10—20 %] (down [less than 5 %] on 1993), Du Pont with [under 10 %] (down [less than 10 %] on 1992), and Zeneca with [under 10 %] (down [less than 5 %] on 1992). There are also Rhône-Poulenc, American Cyanamid and others, with small market shares in France and larger ones in other Member States. A similar set of characteristics, i.e. market shares which fluctuate significantly over time and many strong competitors, are also to be observed in the markets for cereal fungicides in Germany, Belgium, the Netherlands, Spain, Great Britain and Austria.

144. The EEA-wide volume in value terms of the *markets for potato fungicides* was about ECU 132 million in 1995, about 10 % up on 1992. The largest markets are the Netherlands (1995: ECU 36 million), Germany (ECU 27 million), France (ECU 17 million), Great Britain (ECU 12 million) and Belgium (ECU 10 million).

145. In the market for potato fungicides in France, the parties, with a combined market share of [40—50 %], are easily the largest competitor. In the period 1992-94, Sandoz gained an additional market share of [10—20 %], but lost [under 5 %] in 1995. Ciba lost [under 10 %], in 1993, gained [under 10 %] in 1994 and lost [under 5 %] again in 1995. The parties are followed by Bayer with [under 20 %], Du Pont with [under 20 %], Agrevo with [under 10 %] ([less than +5 %] up on 1992), JSB ([under 10 %], market entry 1995, Elf-Aquitaine ([under 10 %], market entry 1993), and Sostra with [under 10 %]. Also present on the market but with a very small market share is Rohm + Haas. The same picture, though the parties are not the overall market leaders, presents itself in Portugal and Spain and on all the other potato fungicide markets concerned. The fluctuations in market share and the multitude of strong competitors put the high market shares of the parties on the potato fungicide markets into perspective. In addition, the parties' margin of manoeuvre is also restricted by factors that are discussed in more detail below, such as the possibility of competitors increasing their output, the frequent product launches, the possibility of market entry, the price competition from generic products and the countervailing power of customers.

146. The EEA-wide volume in value terms of the *markets for sugarbeet fungicides* was about ECU 40 million in 1995, some 30 % up on 1992. The largest markets are Italy (1995: ECU 13 million), France (ECU 12 million) and Greece (ECU 6 million).

147. In the market for sugarbeet fungicides in France, the parties are the clear leaders with a combined share of [50—60 %]. Ciba added about [under 10 %], in 1995 but remained at much the same level as in 1992. Sandoz too held its market share compared with 1992. The parties are followed by Zeneca with [10—20 %] (down [under 10 %] on 1992), Du Pont with [10—20 %] down [less than 5 %] on 1992), Elf-Aquitaine with [under 5 %] (down [less than 10 %] on 1992), and Agrevo and Sostra with small market shares. Relatively large flucutations in market share and a multiude of competitors are likewise to be observed in Austria, Belgium, Italy and Spain. In Austria, Belgium and Spain, Sandoz entered the market only in 1993 and very quickly captured large market shares. Similarly, Du Pont entered the Spanish and Belgian markets. In some cases, companies left the markets (Agrevo and American Cyanamid in Belgium).

148. In the case of potato fungicides and sugarbeet fungicides, the parties' strong market position in France is prominent (market shares of [40—50 %] and [50—60 %] respectively).

[40—50 %] and [50—60 %] respectively). There are historical reasons for Sandoz's strength on the French market. After the second World War, it was in France that Sandoz's agri-division first resumed its activity. For a time, a variety of other manufacturers' products were sold there. The sales organization built up in this way later served for the marketing of Sandoz's own products. As already mentioned in the discussion of the potato fungicide markets, the parties' margin of manoeuvre is restricted, however, despite their high market shares.

149. The volume in value terms of the *market for fungicides for beans and peas used as cattle feed in France* was about ECU 28 million in 1995, down by over 20 % on 1993.

150. Sandoz in particular was able to increase its share of this market and since 1993 has won an additional [10-20 %]. Ciba gained almost [under 10 %] in 1994 but lost more than [under 5%] again in 1995. The largest competitor is Zeneca with a market share of [30-40 %], followed by the parties, Sostra [20-30 %], BASF [onder 10 %], Sumitomo [under 10 %], Rhône-Poulenc and others with smaller market shares.

Herbicides

151. The volume in value terms of the *market for fruit and nut herbicides in France* was about ECU 88 million in 1995, some 25 % up on 1992.

152. On this market, Ciba gained about [10-20 %] in the period 1992-94 but lost about [under 5%] in 1995, while Sandoz's share increased slightly from [under 5 %] to [under 10 %]. The next largest competitor, Monsanto, lost [under 10 %] market share from 1992 to 1994 but gained [under 5 %] in 1995; its share in 1995 was [20-30 %]. Other competitors are Zeneca [under 10 %], Elf-Aquitaine [under 10 %], Dow-Elanco, Sostra, Agrevo and others.

153. The volume in value terms of the *market for vegetable herbicides in Great Britain* was about ECU 11 million in 1995, roughly unchanged from 1992.

154. On this market, Ciba gained [under 5 %] market share in the period from 1992 to 1994 and lost about [under 5 %] in 1995, while Sandoz entered the market only in 1994 and straightaway achieved a share of [under 10 %]. The nearest competitors are BASF [10-20 %], American Cyanamid [10-20 %], Zeneca [10-20 %], Monsanto [under 10 %], Agrevo [under 10 %] and others.

155. The EEA-wide volume in value terms of the *markets for maize herbicides* was about ECU 298 million in 1995, comprising growth of some 7 % in 1995 although no growth was recorded from 1992 to 1994. The largest markets are France (1995: ECU 112 million), Germany (ECU 86 million) and Italy (ECU 50 million).

156. On the market for maize herbicides in Germany, the parties are clear leaders with a combined market share of [50-60 %]. In 1992-93 Ciba lost [under 10 %] but has since been able to win back [under 5 %]. In 1995 Sandoz gained about [under 10 %]. The largest competitors are Du Pont with roughly [20-30 %] ([less than 20 %] up on 1992), Rhône-Poulenc with [10-20 %] (a [under 10 %] loss of market share in 1993, but a gain of [under 5 %] since), American Cyanamid with about [under 10 %] (up [less than 5 %] on 1994), Spiess/Urania with [under 5 %] and BASF with [under 5 %] (down [less than 20 %] on 1992) Still greater market-share fluctuations occurred on the Belgian market for maize herbicides, where since 1992 Ciba has lost [10-20 %] but Sandoz has gained [20-30 %]. The market-share gainers include Zeneca (up [20-30 %]) and the losers BASF (down [less than 20 %] and Protex (down [less than 30 %]), while Rhône-Poulenc broadly maintained its market share. Just as animated are the markets in Austria, France, Italy, the Netherlands, Portugal and Great Britain. Here and in other markets for maize herbicides, Monsanto is usually represented as well (market share in each case of over [10-20 %]).

157. Sandoz's increase in market share in the maize herbicide markets is largely due to the acquisition at the end of 1994 of the pyridate (an active substance in maize herbicides) business from Agrolinz, Austria. Since 1995 Sandoz has been selling — either direct (in Germany and Belgium) or through competitors — the maize herbicide products containing the said active substance and originally belonging to Agrolinz. Even here, the — in some cases — large market shares of the parties in the maize herbicide markets are not synonymous with a correspondingly large margin of manoeuvre. This is because the margin for manoeuvre is restricted by the number of strong competitors and by factors discussed in more detail below, such as the possibility of

competitors increasing their output, frequent product launches, the possibility of market entry, price competition from generic products and the countervailing power of customers.

Insecticides

158. With the exception of the *market for insecticides for beans and peas used as cattle feed in France*, the combined market shares of the parties in the insecticides sphere are less than 25 %. The volume of the market for insecticides for beans and peas used as cattle feed is significant only in France, where it amounts to around ECU 13 million. Here too, market shares fluctuate sharply over time. The parties' competitors are Zeneca (market share of [20-30 %]), American Cyanamid ([10-20 %]), Bayer ([10-20 %]), Agrevo ([under 10 %]) and Rhône-Poulenc ([under 5 %]).

Production capacities

159. Fungicides, herbicides and insecticides are basically manufactured in the same factories (multipurpose plants). The capacity utilization of the production plants averages between [. . .] [3] and [. . .] [3]. For these reasons ([. . .] [3]), the competitors can rapidly increase their output at any time.

(2) *Product launches, market entries and potential competition*

160. As the observations on market structures show, market shares fluctuate sharply over time, this being due in particular to the frequency of product launches. The information obtained by the Commission from competitors and from national registration authorities showed that in all the markets concerned a high rate of product launches can continue to be expected.

161. The parties mention a whole series of new entrants into the markets for fungicides, herbicides and insecticides. Large Japanese undertakings, such as Sumitomo, Nissan and ISK, appear as new suppliers (see also IV/M.354 American Cyanamid/Shall, point 35). Sumitomo and Nissan entered the market by acquiring the Rhône-Poulenc subsidiary Rhodiagri in 1992. Direct entries by completely new competitors are unknown. It is not necessary to set up one's own sales network since this task is carried out by agricultural cooperatives and wholesalers. Sales promotion and advertising costs are usually absorbed by the distributor, whose expenditure is met from the margin (15-25 %).

162. Similarly, generic manufacturers, such as Griffin Corp. (USA), Sanachem (USA), United Phosphorus (India) and others, have recently entered European markets. Their market shares, however, are still small. Market entry costs for generic manufacturers are estimated at about ECU 2 million and, should new toxicologically doubtful by-products occur in production, at about ECU 15 million. Since improved products with new formulae and/or new active substances reach the market in relatively quick succession, the competitive pressure from generics is considered to be rather small by the market participants. So far, generic manufacturers have not been able to establish themselves. In general, though, the generic manufacturers do have a disciplining effect on the suppliers of original preparations, especially if there are (as yet) no products on the market which exhibit a higher 'state of the art' than the generics.

163. As the observations on the sharply fluctuating market shares made clear, manufacturers of fungicides, herbicides and insecticides who were hitherto active in particular Member States have entered the markets of other Member States. Examples are Dow-Elanco, American Cyanamid, Zeneca and others. Potential competitors in this sense are Monsanto, Rohm + Haas and FMC. Further market entries from Japanese undertakings, such as Mitsubishi and Mitsui, and increased competition from generic manufacturers from Eastern Europe and South-East Asia are expected.

164. According to the market participants, market entry into a different field (e.g. fungicides) is hardly any easier for competitors who were hitherto active in one or two fields (e.g. herbicides) than for complete newcomers. At best, there are synergies in sales and marketing, but these scarcely exist in the most important sphere, R & D. Good knowledge of maize herbicides may, however, facilitate entry into, say, the market for cereals herbicides from and R & D perspective. In this sense, Bayer, Agrevo and others are referred to as having entered the market.

165. In some markets in the field of herbicides, fungicides and insecticides, the concentration will admittedly not lead to additional market share, but one of the two undertakings involved already has a market share of over 25 % in each case. In individual cases, the market shares are over 80 %.

As explained above, undertakings which were hitherto active on a market in a particular Member State occasionally enter the markets of other Member States. Thus, as a result of the concentration, a potential competitor disappears in all those markets where only one of the undertakings involved is active. The potential competitors, however, are not just Sandoz but all other competitors active on a particular market. In the Swedish market for cereals fungicides, where Ciba has a share of [over 80 %], they are Agrevo, Zeneca, Rhône-Poulenc, Dow-Elanco and others. In addition, the above observations on market-share fluctuations (since 1993 Ciba has won [10-20 %] market share in Sweden), the large number of strong competitors (in Sweden, these are BASF and Bayer, and since 1994 Du Pont as well), market entries and exits and the frequent introduction of new products apply to these markets too.

(3) *Demand conditions*

166. For dealers and agricultural cooperatives it is essential to carry a complete range of products. The final customers, usually farmers, frequently carry out several applications in order, for instance, to treat a certain disease spectrum in different development stages of a plant. The farmer therefore requires different formulae, which he usually mixes. For the manufacturer himself, however, it is not absolutely necessary to supply a complete product range (the same applied in IV/M.392 Hoechst/Schering, point 32). In the opinion of the market participants, however, a broad product range is a competitive advantage. Sometimes, then, suppliers cooperate with a view to offering complementary products jointly on the market. For the parties, too, it will be particularly advantageous in this respect to combine their crop protection and seed-treatment products (see Part D), which are very largely distributed via the same channels.

167. Because agricultural coooperatives in some cases meet the crop protection demand of whole regions, they enjoy a certain concentration of buyer power. As Ciba and Sandoz manufacture complementary products in many areas, they will be able to supply a complete range of products after the concentration. The parties could therefore be in a position — at least to threaten — to set up their own sales organization and would hence possibly escape the disciplining effect of the agricultural cooperatives' partial concentration of buyer power. According to the Commission's investigations, such a development is admittedly possible but not very probable. Alongside dealing, there is an advisory function and so it is essential for the deal to be neutral. An individual manufacturer will hardly be able to develop a relationship of trust with the farmer to the same extent. Moreover, setting up one's own sales organization (field service, logistics such as warehousing and distribution, etc.) is very costly and hence involves considerable financial risk.

168. Brand name loyalty is of secondary importance with crop protection products. The selection criterion for a particular product is the effectiveness with which it controls weeds, insects or a given harmful organism. As soon as a more effective product comes onto the market, change quickly occurs, as the market-share fluctuations confirm.

169. It was pointed out by potential buyers that Novartis would be prevented from creating a dominant position not only by the presence of strong competitors in all the markets concerned. Should Novartis raise prices considerably in certain markets, potential buyers could threaten in future to purchase products in other herbicide, fungicide and insecticide markets from Novartis's competitors. The parties' margin of manoeuvre on pricing will therefore be influenced not merely by the competitive relations in a particular crop protection market but indirectly too by the competitive relations in all other crop protection markets.

(4) *Research and development*

170. Most suppliers of crop protection products are active in all sectors, i. e. fungicides, herbicides and insecticides, and have a correspondingly large R & D potential (R & D intensity: 10 % and over). In suitably quick succession, new products come onto the market which supersede their predecessors. A strong market position today is therefore no guarantee at all of a strong position in the future (see IV/M.354 American Cyanamid/Shell, point 33).

171. Novartis's turnover in crop protection products worldwide will be roughly twice, and in Europe roughly one and a half times, that of its nearest competitors (Agrevo, Du Pont, Monsanto, Zeneca, Bayer, Rhône-Poulenc, Dow-Elanco and American Cyanamid — each of which has a worldwide turnover of between ECU 1,4 billion and ECU 1,8 billion in the crop protection sector). Novartis's R & D capacities will be correspondingly large and the number of research successes probably high. On account of the synergies in R & D which Ciba and Sandoz will achieve as a result of the concentration, Novartis will succeed in keeping its research expenditure

lower in relative terms than that of its competitors. If the R & D intensity to date is maintained, the economies of scale just described will lead to an additional strengthening of Novartis's R & D potential. The suppliers of crop protection products are unanimous, however, in thinking that large capacities are no guarantee of the success of R & D projects. It can therefore only be assumed from the current trend that Novartis will maintain, and possibly even extend, the position as market leader which it has in the crop protection sector. Moreover, the Commission's investigations revealed that at least the parties' aforementioned competitors all have the 'critical size' necessary for effective R & D activity.

172. According to competitors, the parties will succeed, by pooling active substances in certain markets (e.g. cereal fungicides), in obtaining synergies and thus quickly bringing new and efficient products onto the market. Through the cooperation that will take place in the R & D sector, especially with regard to the development of active substances, such effects, in the Commission's opinion, are already being achieved today to some extent. The additional strengthening of the parties' position in this sector as a result of the concentration is therefore rather small.

173. Crop protection products could be partly superseded in the not too distant future by suitably genetically modified seeds. The genetic engineering modifications will result in plants protecting themselves against harmful organisms and insects (see also the observations in Part D 'Seeds'). The strong market position of Ciba in crop protection and of Sandoz in seed treatment may lead here to synergies and hence to an overall stronger market position of the parties. Knowledge of the fungicide and insecticide effects of microorganisms and the genes which trigger such effects, and of the biotechnological methods of introducing genes, can be applied both to seeds and to crop protection. According to information from market participants, however, no competitive advantages have so far resulted from simultaneous activity in seeds and crop protection.

174. With the use of fungicides and insecticides, a conflict of interest arises between the crop protection and the seed treatment divisions, since the products pursue the same goal by different means. In the herbicides sector, the products are in a complementary, not a competitive relationship. The elimination of weeds — unlike the action of fungicides and insecticides — cannot be replaced by biotechnological treatment. Herbicides serve to eliminate the weeds between the cultivated plants without damaging the plants themselves. To remove as many weeds as possible, broad-spectrum herbicides are used. The undertakings active in this sector (e.g. in addition to the parties, Monsanto and Agrevo) are therefore trying through biotechnology to make cultivated plants tolerant of herbicides. Both Ciba and Sandoz are devoting only a limited amount of R & D to this area.

175. Ciba and Sandoz hold many patents in the crop protection sector — some will expire soon and others only after the year 2000. The competitive situation described above in detail shows, however, that patent rights in these markets are not able to create dominant positions. Moreover, the potential buyers of genetic products could fall back on an older product whose patent protection has expired if the supplier(s) of the new product generation should demand excessively high prices.

(5) *Conclusion*

176. Although the parties have very high market shares in some cases, have been the market leaders in certain of these markets for some time and could also remain so on account of their strong position in the R & D sphere,

— the significant market share fluctuations over time,

— the large number of competitors in all the markets concerned,

— the likewise significant R & D capacities of competitors,

— the large number of product launches completed and also expected in future,

— the entries to and exits from all the markets concerned,

— the (price) disciplining effect of generic products, and

— the countervailing power of wholesalers and agricultural cooperatives

all show that the concentration does not create or strengthen a dominant position as a result of which effective competition would be significantly impeded in the common market or a substantial part of it.

(c) **Trace elements**

177. According to the parties, the following markets in the trace elements sector are affected by the concentration:

— Trace elements for fruits and nuts in Spain ([30-40 %]; Ciba [30-40 %], Sandoz [under 10 %])

— Trace elements for vegetables in Spain ([20-30 %]; Ciba [10-20 %], Sandoz [10-20 %]).

178. In both the markets concerned, the parties will be the market leaders. In the market for trace elements for fruits and nuts, they will be followed by Agrevo (market share [under 10 %]), Sostra ([under 5 %]), Rhône Poulenc ([under 5 %]) and Bayer ([under 5 %]). In the market for trace elements for vegetables, the nearest competitors are Rhône Poulenc ([under 10 %]) and Agrevo ([under 5 %]). The remainders of the markets ([40-50 %] and [70-80 %] respectively) are shared in each case by a large number of competitors.

Thus, 50 local firms supply 76 products for remedying the iron deficiency in vegetables and in fruits and nuts.

179. In both the markets concerned in the trace elements sector, the market shares again fluctuate over time (up or down 4 %), but not quite so sharply as in the fungicides, herbicides and insecticides sectors.

180. Ciba is also active in the markets for trace elements for fruits and nuts in France, Greece and Italy. It is the clear market leader in each of those countries, with a market share of between [20-30 %] and [60-70 %]. In Italy, Ciba is faced with competition from American Cyanamid ([10-20 %]), Du Pont [10-20 %]), Zeneca ([under 10 %]), Rhône Poulenc ([under 10 %]) and Valagro ([under 5 %]). Zeneca and Du Pont active only in Italy and since 1992 have not tried to enter another national market. In Greece, Hellapharm ([under 10 %]) and Rhône-Poulenc ([under 10 %]) are suppliers alongside Ciba. In France the remainder of the market [70-80 %] is shared by other competitors (local undertakings) among whom the firm of De Roure, Bardentane has a market share of over [10-20 %] .

181. The firms involved have no patented products in the trace elements sector. Sandoz sells no own products in this field. It is therefore uncertain whether there is any overlapping at all on these markets. The question can be left open, however, since the concentration will not create or strengthen a dominant position on these markets.

182. Given the not very large market shares of the parties, the presence of many potentially strong competitors, the multitude of smaller competitors, the fluctuation of market shares over time and the situation as regards patents, the Commission finds that no dominant position is created or strengthened on the markets for trace elements as a result of the concentration.

C. ANIMAL HEALTH PRODUCTS

1. *Animal health products except small animal ectoparasiticides*

(a) **Relevant product market**

183. Animal health products come in four types:

— vaccines,

— food additives,

— veterinary medicines,

— hygiene products.

These should be subdivided to determine the relevant product markets. In the present case, however, subdivision is not necessary for vaccines and additives, either because the parties have no activities on those markets or because the markets are not affected for the purposes of form CO.

184. The *veterinary medicines* sector is subdivided into anti-microbial drugs (antibiotics applied in the form of injections, ointments, drops, etc.), parasiticides (for preventing parasitization) and other products. The group of 'other products' is not affected by the merger.

(1) *Anti-microbial drugs*

185. As regard anti-microbials, only the market for the treatment of swine dysentery is affected. The parties are of the opinion that there is no such market, since veterinary medicines are not first administered when the disease breaks out but preventively, the primary goal being the prevention of disease. Nearly all preparations against swine dysentery are, the parties argue, indicated in more than one situation and are effective in pigs and poultry against diseases of the respiratory as well as the digestive tract. The Commission does not dispute these facts but is inclined to the view that from the customer's,

i. e. the pig-farmer's, standpoint what makes him buy the product is that it works against swine dysentery, if he wants to prevent the pigs getting sick or if he has to heal them. He will therefore not require a product to prevent disorders of the respiratory tract. In so far as all products are effective against both swine dysentery and respiratory disorders in pigs, they belong both to the market for the treatment of swine dysentery and to the market for the treatment of respiratory disorders in pigs; but there is no uniform market for both indications. However, for the purposes of this case, it is not necessary to decide on the precise market definition as, even on the narrowest market definition (market for the treatment of swine dysentery), a dominant position would not be created or strengthened.

(2) *Parasiticides*

186. Parasiticides can in turn be subdivided into:

— ectoparasiticides used for the control of external parasites such as fleas and ticks, and

— endoparasiticides used for the control of internal parasites such as worms.

Both ectoparasiticides and endoparasiticides are administered to small and farm animals.

187. Consequently, the above division gives rise to four separate product markets, namely:

— Farm animal ectoparasiticides,

— Farm animal endoparasiticides,

— Small animal ectoparasiticides, and

— Small animal endoparasiticides.

188. The respective products in the above four classifications differ in terms of their effect, formulation and composition, so that they can frequently only be used for either farm or small animals. Moreover, they have different customers, e.g. typically farmers for farm animals or consumers owning household pets for small animals. Similarly, depending upon their dispensing form and their active substance, they are used either for controlling only internal or only external parasites. As such the four classifications have different characteristics and intended purposes. The parties consider that they each represent a distinct relevant product market.

189. The markets for endoparasiticides will not be affected by the merger. With the exception of small animal ectoparasiticides, the results of the Commission's investigations have confirmed the market definitions proposed by the parties. Given the competition concerns identified as a result of the in-depth examination carried out by the Commission, the assessment of small animal ectoparasiticides has been presented as a separate section from all other animal health products (see part C2).

190. *Hygiene* products consist of products intended for use in stabling and of disinfectants. In this sector only the market for products used in stabling (farm fly control) will be affected by the concentration. This market includes products for controlling flies in such premises.

191. The market for controlling stable flies differs from that for ectoparasiticides for productive livestock in that different types of insect are controlled. Ectoparasiticides for productive livestock are effective against pests which live on a host animal and sting or bite it, thereby transmitting disease. Stable flies, however, settle on the animal for a short time only and do not sting or bite it, but they cause stress and pose a hygiene problem.

192. Some of the competitors consulted do not distinguish between ectoparasiticides for productive livestock and stable fly control, or their answers intimate that products which have an effect on stinging or biting insects are also effective against stable flies. There is therefore overlapping between ectoparasiticides for productive livestock and products for use in stables, and hence there is substitutability, which must be taken into consideration in the competitive assessment.

193. The manufacture of animal health products requires active substances. The parties are of the opinion that active substances are substitutable for one another. Thus Tiamulin is substitutable for all other active substances for animal antibiotics since Tiamutin — the mark belonging to Sandoz for end products manufactures from Tiamulin — is used to treat a broad range of infectious diseases. The parties mention a whole series of active substances which are substitutable for Tiamulin.

194. In the observations on the crop protection sector (see Part B), the Commission established that active substances are basically not substitutable for one another since the substitution of one active substance for another gives rise to a new product, which must first be formulated and tested for effectiveness and whose registration has

to be applied for. Since this takes a considerable amount of time, the substitutability of active substances cannot be assumed. This statement is also valid for the animal health sector.

(b) **The relevant geographic market**

195. Animal health products are subject to national approval measures. The price differences between the member States are considerable, and there is no indication that product prices have become more closely aligned in recent years. Similarly, distribution channels differ sometimes from one country to another. Thus, in Great Britain, distribution is ensured by veterinary and agricultural wholesalers, while in France it is also ensured by pharmaceutical wholesalers.

196. According to certain information received, however, these markets could become European, or are already European to some extent. In general, a manufacturer's products do not vary from one Member State to the next. They are manufactured in central production installations and distributed from there to all countries in Europe and even the world. Thus Ciba manufactures the products in question in Great Britain, the United States and Switzerland. In addition, Council Regulation (EEC) nr. 2309/93 [8] lays down a uniform authorization procedure at Community level.

197. Active substances are required by manufacturers of animal health products (and by manufacturers of crop protection products). These are mostly large undertaking with good market intelligence and purchase the substances at least throughout Europe if not the world. Accordingly, the markets for active substances are European at the very least.

198. On the basis of the information available, the Commission believes that the definition of the relevant markets for animal health products must be national and the definition of the markets for active substances European. As regards ectoparasiticides for productive livestock, products for use in stabling and the market for the treatment of swine dysentery, however, the definition of the relevant geographic market can be left open since, even on the narrowest definition (national markets) and on all broader definitions, no dominant position is created or strengthened by the concentration. As far as small animal ectoparasiticides are concerned, reference should be made to part 2.

(c) **Competitive assessment**

(1) *Active substances*

199. Competitors pointed out that the active substance Tiamulin, which is used in particular in products for treating swine dysentery, is manufactures only by Sandoz and Ciba. The concentration would therefore give rise to a monopoly in Tiamulin.

200. Manufacturers of active ingredients are normally vertically integrated enterprises, which do not sell these products to third parties, but which use them to manufacture their own end-products, be it in the animal health sector, crop protection or, possibly, health care. In the section dealing with pharmaceuticals, the Commission established that Ciba and Sandoz manufacture active ingredients almost exclusively for internal use (see part A) and, in the section on crop protection, that only Ciba sells ingredients to third parties and this only if they are commodities (active ingredients that are no longer protected by patents or know-how). The parties confirmed that they do not sell Tiamulin to third parties. Therefore, the concentration will not change the actual competitive situation on the market for the active ingredient Tiamulin.

(2) *Ectoparasiticides for productive livestock*

201. According to the information supplied by the parties in their notification, the market for ectoparasiticides for productive livestock in Great Britain will be affected by the concentration. The combined market share would be [40-50 %] (Ciba [30-40 %], Sandoz [10-20 %]). In later submissions the parties corrected their data concerning Sandoz's market shares, because in Great Britain Sandoz does not sell formulated products but only the active substance Propetamphos (to Grampian, which actually formulates it). Sandoz is not present, therefore, on the market for finished products in Great Britain. In addition, it does not itself manufacture the active substance supplied but buys it from Nippon Kayaku, Japan. [. . .] [3].

202. [. . .]. It can, however, be regarded as certain that, after the concentration, a potential competitor — Sandoz — will drop out. The following, however, will continue to be present on the market: Bayer (market share 1995 [10-20 %]) with sharp gains since 1992 (up [5-15 %]), Grampian with about

[8] OJ No L 214, 24. 8. 1993, p. 1.

30 % (sharp increase since 1992), Mallinckrodt [10-20 %], Hoechst, MSD (Merck, Sharp and Dome), Pfizer and others with relatively small market shares. The Commission's investigations also showed that the parties' figures for own market share were probably rather high estimates.

203. Given that Sandoz was active only on the upstream market for active substances (and then merely as a distributor), [. . .] [3], that Ciba's market share is probably for the order of [20-30 %] and that there are a large number of strong competitors, the Commission has reached the conclusion that no dominant position will be created of strengthened on this market by the concentration.

(3) *Products for use in stables*

204. According to the information provided by the parties in their notification, the market for products used in stables in France would be affected by the merger. The combined market shares' would amount to [30-40 %] (Ciba [20-30 %], Sandoz [under 10]).

205. Here too, Sandoz distributes its own products mostly through other firms; this was once again not taken into account in the parties' calculation of market shares. According to an initial check carried out by the Commission, there were in 1994 seven affected markets (Great Britain, Denmark, Spain, France, Belgium, Germany and Italy) where combined market shares amounted to between [30-40 %] (Germany) and [90-100 %] (Great Britain).

206. In a submission presented after the initiation of proceedings, the parties argued that it was virtually impossible to determine exact market volumes for products used in stables. In particular, they argued, Ciba and Sandoz had been able to take into account and assess only those products for which they themselves had a market overview in the individual countries. For this reason, certain types of products for use in stables had not been sufficiently taken into account. Thus, the original estimates of market volumes in Great Britain did not include environment sprays and aerosols. The actual market volume in Great Britain was therefore not ECU 0,78 million, but ECU 4,5 million (1994), and the parties' market share therefore amounted to no more than [10-20 %] (1994) and to [10-20 %] (1995) in terms of a market volume estimated for 1995 at between ECU 3,6 million and ECU 4 million. For similar reasons, the market volume in Italy was also underestimated. There, the parties' combined market share in 1995 amounted to some [30-40 %]. In Belgium, Sandoz has since 1995 been marketing its own products itself, and this has — at any rate temporarily — meant massive losses in market shares. In Belgium, therefore, there is no longer any affected market. According to the new information, the German market too is no longer affected by the merger.

207. The competitors surveyed by the Commission put market volumes at least on the same level as, and in most cases even higher than, those estimated by the parties. One reason for this is that there are a number of overlaps between livestock ectoparasiticides and stable-fly control. it can therefore be assumed that the parties' market shares have if anything been overestimated.

208. To sum up, the relevant markets (1995) for products used in stables are as follows:

— France ([40-50 %]; Ciba [30-40 %], Sandoz [under 5 %])

— Great Britain ([10-20 %]; Ciba [10-20 %], Sandoz [under 5 %])

— Denmark ([40-50 %]; Ciba [30-40 %], Sandoz [under 10 %])

— Spain ([40-50 %]; Ciba [40-50 %], Sandoz [under 5 %])

— Italy ([40-50 %]; Ciba [30-40 %], Sandoz [under 10 %]).

(a) Market structure

209. In the relevant markets for stable-fly control, Ciba in particular has a strong market position with market shares amounting to [30-40 %] and more. The market shares which Sandoz will transfer to Novartis are relatively small at [under 10 %]. Furthermore, Sandoz has gained market share only in Denmark ([under 10 %] since 1993) and has maintained its share in the other relevant markets, except for France, where there were massive losses of market share (a loss of [less than 20 %] since 1993). Similarly, Ciba has lost [10-20 %] market share in France, but has also lost [under 10 %] market share in Denmark. Ciba gained [under 10 %] in the other relevant markets.

210. In France the competitors are Bayer (market share 1995 [. . .] [3], with fairly substantial growth since 1993 ([. . .] [3]), Mallinckrodt ([. . .] [3])), with market share losses since 1993 ([. . .] [3])), Sogeval ([under 10 %] and a large number (60-80) of other competitors with small market shares.

211. In Denmark the parties' competitors are Mallinckrodt (market entry 1993, market share

1995 [. . .] (3)), Estromat ([10-20 %]), with gains since 1993, KvK ([under 5 %], with market share losses since 1993, and a large number of other competitors with very small market shares.

212. In Italy the parties' competitors are Bayer (1995 market share [. . .] (3)), which has been suffering market share losses since 1993, Hoechst ([. . .] (3)), Copyr (about [. . .] (3)) and many other competitors with smaller market shares. A similar pattern, i. e.a few larger competitors and a large number of smaller competitors and market shares which fluctuate over time, emerges in Spain, where the competitors with the largest market shares after the parties are Esteve ([30-40 %]) and, once again, Bayer ([. . .] (3)).

213. These facts show that the parties will, after the merger, be market leaders in a few Member States but will, in any event, be faced with at least one, and often two, strong competitors and a large number of smaller competitors. The distinct fluctuations in market shares over time are also an indication of intense competition.

(b) New products, potential competition

214. Although the markets for products used in stables have shown only very slight growth and indeed, in some cases, have actually shrunk, it is in general anticipated that new products will continue in future to come onto the market. One reason for this is that flies develop resistance to certain active substances within a relatively short time (3-5 years), making it necessary to develop new products.

215. The parties put the costs of developing new products for use in stables at about ECU 7 million. If the manufacturer already has a distribution network, launching a new product will not entail any major additional costs. If the manufacturer does not have a distribution network, he may also sell his products through the intermediary of third parties, as Sandoz, for example, does (distribution at least up to the end of 1994 largely through firms which are also competitors).

216. Competitors already operating in a Member State are not faced with any major entry barriers to another national market. This is in particular because a manufacturer's products hardly differ from one member country to another. The necessary registration of products, for which the plant protection authorities are responsible, takes between six months and a maximum of three years, depending on the Member State in question. Potential competitors in this respect are therefore at the very least Bayer, Mallinckrodt and also Hoechst. If account is taken of the fact that there are overlaps between livestock ectoparasiticides and the market for stable-fly control, Grampian, Pitman-Moore, American Cyanamid, MSD (Merck, Sharp and Dome), Pfizer and others are also (potential) competitors.

217. Market entry is not very costly, particularly for generics manufacturers. If a manufacturer can prove that his product is identical in quality to an already authorized product, he can entrust the manufacture of the generic to subcontractors and does not therefore have to establish his own production facilities. However, generics have not managed to establish themselves so far. As a rule, market entry by generics manufacturers occurs only for products that are based on active ingredients with which there are no resistance or other problems. The parties mentioned the generics manufacturers Farnharn, Fermone/Troy Biosiences and Denka, which have since 1990 entered the French market for stable-fly control.

(c) Demand conditions

218. Products for stable-fly control are sold by the parties or their national companies, or by the third parties to whom distribution has been entrusted (e.g. Sanofi until the end of 1994), to agricultural cooperatives or to wholesalers who in turn sell the products either through their own dealers or through third parties. The parties established clientele in the plant protection area is largely identical to that in the markets for stable-fly control. Consequently, what has already been stated in the discussion regarding plant protection applies here too: if the parties were to try to increase product prices significantly, customers could not only turn to competitors' products but could also threaten to obtain their future supplies of herbicides, insecticides and fungicides from the parties' competitors. The parties' room for manoeuvre in setting prices is thus effectively restricted.

(d) Research and development

219. An assessment of the effects of the parties' R & D potential on future competitive relationships cannot be confined to stable-fly control but must be placed in a broader framework. This is in

particular because of the overlaps with livestock ectoparasiticides and also because substances falling within the plant protection area (particularly insecticides) may also be effective against parasites and stable flies.

220. In the animal health products sector, Ciba and Sandoz invest [. . .] [3] of their total turnover in research and development, this being about the average for the sector. All the major competitors have in recent years developed new active substances and are engaged in research and development activities; this is the case in particular with Bayer, Hoechst, Rhône Mérieux, Pfizer, MSD and also American Cyanamid. In the case of some of these companies, indeed, ectoparasiticides are one of their core segments.

221. Activities in the health care and plant protection areas may give rise to synergies with activities in the animal health sector. Research in the animal health sector uses substances from plant protection research and, to a lesser extent, from research into health care in order to test their suitability for combating animal diseases or insects. However, such substances are to a large extent obtained from external sources (universities or other companies). In addition, such synergies are in most cases also achieved by the abovementioned competitors.

222. The parties derive advantages at the very most from the size of their R & D divisions. Here once again (cf. part B), a given 'critical mass' has to be reached for R & D activities to hold out the prospect of success. All the abovementioned competitors of the parties achieve this critical mass.

(e) Summary regarding markets for stable-fly control

223. Although the parties will in some cases have market shares of over [40-50 %] and become the market leader in the markets for products for use in stables,

— the relatively small market share additions,

— the market share fluctuations over time,

— the further product launches which may be expected,

— the presence in all instances of at least one strong competitor and a large number of smaller competitors,

— the possibility that strong competitors may enter national markets on which they have not hitherto operated,

— the countervailing power of customers,

— the presence of competitors which are also strong in the R & D area

all show that the merger will not create or strengthen a dominant position on the markets specified.

(4) *Market for the treatment of swine dysentery*

224. According to the parties, it is not possible to determine turnover and market shares on these markets because the preparations that can be used for the treatment of this disease all have other indications as well. It cannot therefore be established, the parties argue, whether a customer is using the purchased product for the treatment or prevention of a respiratory disease or dysentery. Sandoz's turnover in Europe with Tiamutin in 1995 was [. . .] [3]; this includes sales for all indications (e.g. anti-infectiva for poultry). However, the parties assume that Sandoz has a market share of the order of [. . .] [3] in individual countries as regards the treatment of swine dysentery. They do not therefore rule out the possibility that in Greece and Italy, i. e. in those Member States in which Ciba also supplies a product based on Tiamulin (Dynamutilin), the combined market shares will be over [. . .] [3]. The Commission's investigations did not produce any more precise figures but suggest that the parties' position on this market will be of the order of magnitude indicated.

225. Products for the treatment of swine dysentery are also supplied by Upjohn/Pharmacia, Dow Elanco and in particular a large number of generics manufacturers. Some of these products are generics based on Tiamulin, while others are based on other active substances such as Lincomycin, Lincomycin and Spectinomycin, Tylosin and Metronidazol. These active substances are no longer covered by patent protection; they are therefore also produced by generics manufacturers.

226. Patent protection for Tiamulin too has expired in Europe, the only exception being France, where Sandoz's patent was extended until 1997. It is therefore possible (or will be shortly) for third parties to produce Tiamulin and formulate the corresponding products. Tiamulin is today manufactured to an equivalent quality level by Archemia/Geopharma, Milan, as well as by

Sandoz and Ciba. Archemia also exports Tiamulin. Because the markets for the treatment of swine dysentery are very small markets, there is no doubt that Archemia could supply the whole market demand. According to competitors, it would take from one to three years for them or another third party to be able to produce Tiamulin of satisfactory quality. Further market entry could therefore be expected, if the prospects for profits on this market are positive.

227. Since the parties' product can be used not only against swine dysentery but also for the treatment of respiratory diseases and disorders of the digestive tract in pigs and poultry, the parties are not in a position to raise the prices of their products solely on the market for the treatment of swine dysentery. A price increase of their product on those markets on which the parties' position is less strong (according to parties' estimates the combined market shares are below 15 % in the whole segment for end-products that are based on Tiamulin) would in all probability result in market share losses that would have an impact on the earnings situation. The parties' room for manoeuvre in setting prices is therefore restricted for this reason and because price increases would very probably lead to market entries.

228. For all these reasons (a few strong competitors, whose products are based on active ingredients other than Tiamulin, a large number of generics manufacturers, the limited room for manoeuvre in setting prices, the probability of further market entries if the parties were nevertheless to increase their prices), the Commission concludes that the merger will not create or strengthen a dominant position on the markets for the treatment of swine dysentery, if such a narrow product market definition were in fact applicable.

2. *Small animal ectoparasiticides (SAE)*

(a) **Relevant product market**

229. In the light of the comments received from competitors and the Commission's own understanding of the operation of SAE, the Commission considers that it would be too simplistic to consider small animal ectoparasidicides as constituting a homogeneous relevant product market. In particular, this would have the effect of underestimating the strength of the merging parties' market position.

(1) *Segments of the SEA product market*

230. The SAE product market comprises a number of segments. It can be split in two main ways:

(i) according to the place where the product is administered, namely:

— on the animal, or

— in the environment (or off-animal);

(ii) according to the nature of the product, i.e.:

— adulticides which kill adult parasites and often also larvae, and

— IGRs (insect growth regulators), which are essentially sterilants and break the reproduction cycle.

231. There is some linkage between the two breakdowns described above. Many adulticides are applied typically to the animal, e.g. flea collars, dusting powders, shampoos and spot-on applications. Many IGRs are applied to the animal's environment, however, since to break the flea reproduction cycle effectively, it is absolutely necessary to deal with the potential flea problem from the animal's environment. However, this does not mean that all adulticides are applied on-animal and that all IGRs are applied to the environment. The market is evolving, products are becoming more sophisticated and innovative with the result that the above simplistic and characteristic division is breaking down. One such innovation is Ciba' new product, called Program, an IGR which is administered to the animal in pill form.

232. The evidence collected by the Commission from competitors tends to confirm that adulticides and IGRs cannot be considered as full substitutes. Certainly an IGR has no effect against adult parasites. As regards the use of an adulticide as an IGR, it is true, as has been argued by the parties, that dead fleas do not lay eggs. However, this sidesteps the issue. The approaches are conceptually completely different. An adulticide can be seen as a short-term solution whereas an IGR as a necessary instrument for a long-term solution. Repeated application of an adulticide does not treat the problem at source, i.e. flea reproduction. Adulticides and IGRs should therefore be seen as complementary products.

233. Of the competitors surveyed (Bayer, Hoechst, Mallinckrodt, Pfizer, Rhône-Mérieux, Sanofi, and

Virbac), more than half (4/7) considered that adulticides and IGRs were *not* substitutes. Of the remaining three, two took the view that adulticides and IGRs were clinically substitutable. But it was also stated that in practice both treatments complemented one another in providing a rapid and effective solution. Some competitors intend to develop an on-animal IGR as this was necessary in order to have a complete SAE portfolio.

(2) *Combination products*

234. Competitors also pointed to the development of combination products (i.e. containing both an adulticide and an IGR). They therefore combine the short-term advantages of the adulticide, which kills the initial flea population, with the long-term advantages of the IGR, which combats flea reproduction. Combination products are gaining ground, although in overall terms they still represent a small proportion of the market.

235. According to information provided by the parties, all combination products currently marketed in Europe are of the spray or aerosol type. All are applied to the environment, none on the animal.

236. In the Commission's opinion, the existence of an adulticide and an IGR in a combined SAE product is not an indicator of substitution between the two products. On the contrary, it serves to conform the need to address both aspects of the flea problem and therefore to underline the complementary nature of IGRs and adulticides.

(3) *Price comparison*

237. The notifying parties have also provided price data for adulticides in the British, Irish and Dutch markets ([9]). Price comparison has been carried out on the basis of the monthly cost of treating the animal. The results ([10]) are as follows:

United Kingdom

	Product	Manufacturer	Price Index
Adulticides	Tiguvon	Bayer	100
	Frontline	Rhône-Mérieux	98
IGR	Program	Ciba	128

Ireland

	Product	Manufacturer	Price Index
Adulticides	Tiguvon	Bayer	100
	Frontline	Rhône-Mérieux	72
IGR	Program	Ciba	136

The Netherlands

	Product	Manufacturer	Price Index
Adulticides	Tiguvon	Bayer	100
IGR	Program	Ciba	133

([9]) These are the affected national markets identified by the parties at the level of the overall SAE market.

([10]) The Commission acknowledges that the data provided by the parties also contained an example where an adulticide produced by Mallinckrodt, namely Pulvex, in the Netherlands had an index of 262. However, this may be a niche product or related to Mallinckrodt's market positioning more generally.

238. On this basis, the IGR 'Program' would seem significantly more expensive than two of the main adulticides, Tiguvon and Frontline. Although this result is not fully conclusive in view of the remark concerning Pulvex (see footnote 5), it would seem to indicate insignificant price competition between the IGR, Program, on the one hand and the two adulticides, Tiguvon and Frontline, on the other.

(4) *Distribution channels*

239. The Commission draws no significant distinction between SAE products distributed through vets and the OTC sector (over-the-counter, i.e. shops, retail stores and supermarkets). A further sub-division of the SAE-market is therefore not necessary. It is true that the more recent and more expensive products tend to be sold through vets, but after a period of at most 3 to 5 years, provided no complications have emerged, they become available through the OTC sector. Furthermore, buyers have access to both distribution channels, where largely identical products may be obtained.

(5) *Conclusions on the definition of the product market*

240. In the light of the above information, the following conclusions can be drawn:

— although a clear and undisputed product market definition is not possible, the following statements can be made:

— an IGR is a poor substitute for an adulticide at least in the short term (initial application of Program needs to be combined with an adulticide),

— under clinical conditions both an IGR and an adulticide can break the flea reproduction cycle. However, an effective anti-flea treatment in practice requires both aspects (long and short term) to be addressed,

— the majority of competitors consider that IGRs and adulticides are not substitutes,

— of those remaining, the majority recognize either the complementary nature of an IGR and an adulticide or the desirability in competitive terms (complete product range) of having an IGR,

— the existence of combination products is evidence of the complementary nature of IGRs and adulticides,

— the market is becoming more sophisticated.

Consequently, it is essential for each competitor to be able to manufacture an IGR, which in turn means that it must have access to an active ingredient required for the development of such a product.

241. The analysis of competitive relations is carried out at the level of the overall SAE market, but because of the importance of IGRs for the future development of the market, particular account is taken of the parties's combined position with regard to this market segment.

(b) **Geographical reference market**

242. The parties consider that there is a clear trend towards Europe-wide markets. They refer to the measures aimed at harmonizing national laws within the Community and in particular they point to the introduction of a standardized Community registration procedure and the creation of a European Medical Evaluation Agency. They also indicate that products are manufactured in centralized production facilities from which they are sold to all European countries and they claim that price differences between Member States are increasingly being levelled out.

243. The Commission acknowledges this integration trend but nevertheless considers that conditions of competition are not yet sufficiently homogeneous to allow the conclusion to be drawn that there is Community-wide market. In particular, different national registration and approval requirements still apply, there is considerable variation in the competitors' market shares in the various Member States and differences remain in distribution arrangements. For example, Sandoz sells its own products in the various Member States through various competitors. [...] [3].

244. An accurate price comparison on a cross-border basis is complicated by product heterogeneity. However, price differences of the order of 25 to 50 % in the case of a number of the leading SAE products may be viewed as evidence of national markets.

245. Nevertheless, some of the major competitors are present in more than one Member State. Moreover, the same active ingredient is in some

cases licensed to different parties in different Member States. Therefore, a proper competition assessment must have regard to this wider dimension. In fact, in relation to the area where the Commission has identified grounds for serious concern (IGR-active ingredients), the national position is of much less importance and regard must be had to the position at the European and even world level.

(c) **Competitive assessment**

(1) *Market structure*

246. On the SAE market there are a few fairly large and many fairly small competitors. A large number of smaller players sells relatively simple, unsophisticated products, often through the OTC sector.

247. The parties have been unable to provide market share data at the national level broken down into adulticides and IGRs. The parties point to the extreme difficulty of deriving accurate market share data and in fact much of the initial data provided by the parties had to be corrected to reflect products manufactured by Sandoz but marketed by other parties, e. g. Sanofi. Consequently, in seeking to carry out its analysis of the future market position of the merging parties, the Commission has been obliged to adopt a pragmatic approach.

248. The last revised, i. e. corrected, market share data provided by the parties do not distinguish between the IGR and adulticide segments. At the national level there are three affected products markets, namely Great Britain, Ireland and the Netherlands.

MARKET SHARES

(Total market: parties' estimates)

Great Britain

	Size (1)	Ciba	Sandoz	Total	Bayer	R-Mérieux	Mallinckrt
1993	[...]	[...]	[...]	[...]	[...]		[...]
1994	[...]	[...]	[...]	[...]	[...]	[...]	
1995	[...]	[...]	[...]	[...]	[...]	[...]	[...]

(1) Market size in ECU millions.

Netherlands

	Size (1)	Ciba	Sandoz	Total	Bayer	R-Mérieux	Virbac
1993	[...]	[...]	[...]	[...]	[...]		[...]
1994	[...]	[...]	[...]	[...]	[...]		[...]
1995	[...]	[...]	[...]	[...]	[...]		[...]

(1) Market size in ECU millions.

Ireland

	Size (1)	Ciba	Sandoz	Total	Bayer	R-Mérieux	Mallinckrt
1993	[...]	[...]	[...]	[...]	[...]		[...]
1994	[...]	[...]	[...]	[...]	[...]		[...]
1995	[...]	[...]	[...]	[...]	[...]	[...]	

(1) Market size in ECU millions.

249. Novartis will as a result of the merger become the leading market player in all three markets and particularly in Great Britain. Its most important competitors are Bayer and Rhône-Mérieux. The strong growth of the overall SAE market is evident with total market volume doubling in all three national markets in the space of two to three years.

250. Since Great Britain is at present by far the largest market, the Commission will focus its attention below on that market in particular. Nevertheless, it is quite probable that, in the light of the above market share data, the parties' IGR market share is even higher in other Member States. In any event analysis of the situation in Great Britain may be regarded as indicative of the broader picture at European level.

251. The parties' position in the overall market in Great Britain is strong. According to their own figures, 1995 market shares for competitors are as follows: Bayer [10-20 %], Rhône-Mérieux [under 10 %], Mallinckrodt [under 5 %]. These figures show that at the global level the parties have a combined market share approximately four times greater than the next two competitors and 20 times greater than the third. The other competitors in Great Britain have extremely small market shares and, according to the Commission's investigations, sell relatively simple, unsophisticated products.

252. The above picture is broadly confirmed by the (confidential) data published by the British Veterinary Institute, which cover only distribution through vets. It is almost impossible to estimate the size of the OTC market. According to the Commission's investigations, there are no significant competitors in the OTC market who do not figure in the BVI list. The Commission estimates indicate that the BVI data covers 70 % or more of the total British market.

(253) BVI market shares (quarter IV 1995) are as follows:

Ciba	[30–40 %]
Sandoz (Sanofi)	[10–20 %]
Total	[50–60 %]
Bayer	[10–20 %]
Rhône-Mérieux	[10–20 %]
Virbac	[10–20 %]
Mallinckrodt	[under 5 %]
Pfizer	[under 5 %]
Hoechst	[under 5 %]

On the BVI data Ciba-Sandoz will be the clear market leader with more than half the market.

254. The Commission does not consider Sanofi or Pfizer to be independent competitors. Even if Sanofi and Pfizer sell products under their own brands, the products are manufactured by Sandoz, with Sanofi and Pfizer organizing marketing, distribution and branding.

255. Given the new marketing and distribution resources that Sandoz will enjoy through the merger with Ciba, there will be little incentive to continue these contracts upon expiry of the current contracts. In fact, Sandoz has already terminated its distribution contract with Sanofi as regards farm fly products. The Commission is also aware that in June 1996, Sandoz gave notice to terminate an existing distribution contract with another competitor.

256. It is true that Virbac sells products employing two IGR-active ingredients different from Sandoz's Methoprene. The first is Pyriproxifene which is supplied by Sumitomo. However, the other, Fenoxycarb, is produced and supplied by Ciba. In addition, Virbac is dependent for other active ingredients, e. .g. the adulticide, Diazine, manufactured by Ciba. In any event Virbac is a very much smaller company than Novartis and does not have comparable financial resources.

257. The biggest competitor is Bayer, but even Bayer purchases active ingredients from Novartis. In particular Bayer purchases Methoprene from Sandoz fur use in its product Bolfo Plus. [...] [3]. There is therefor a major contractual link between the merging parties and their biggest competitor. Given the strength of Novartis' market position and the contractual link between Novartis and Bayer in an area (IGRs) where Novartis will have particular strength, it is questionable whether Bayer will actually compete significantly with Novartis.

(2) *IGR segment*

258. It has proved extremely difficult to secure accurate market share data for IGR and adulticide products. The only data that the parties have been able to provide giving a breakdown between adulticides and IGRs has been at European level and is as follows:

1995 EU MARKET SHARES

(Adulticidesr/IGRs: parties' data)

	Market share	Comments from the parties
IGR	+/- 100 %	Ciba's Program is practically the only product here Sandoz is not active
IGR/A [1]	> [. . .]	Sandoz's market share exceeds [. . .] Ciba is not active
Adulticides	< 15 %	Market shares probably under [. . .], but largest market segment

[1] IGR/A are combined products containing a separate IGR and adulticide as active ingredients.

259. The parties have argued that IGR-only products and combined products should be considered as separate segments with the result that, since only one of the parties is in each segment, neither can be considered as affected markets. The Commission cannot accept this position. Since the parties themselves claim substitutability between adulticides and IGRs, there must according to their own submission also be a substitution possibility between IGR products and combined products.

260. The Commission has received from a competitor an estimate for the combined Ciba/Sandoz IGR market share in a number of Member States as follows:

1995 IGR MARKET SHARES FOR THE PARTIES

(competitor estimates)

Member State	Market size ECU million (mio. ECU)	Ciba plus Sandoz
Great Britain	10,7	[70–80 %]
Germany	4,8	[70–80 %]
France	3,9	[90–100 %]
Netherlands	1,2	[90–100 %]

Although the market shares in the IGR-segment could not be established with certainty, there is reason to believe that the parties' shares at European level are in the region of [80—90 %] to [90—100 %].

261. Ciba sells Program in Great Britain, a product containing the IGR active ingredient, Lufenuron. Sandoz is not itself directly present in the market in Great Britain, but does sell combined products through its competitor Sanofi. Sanofi sells Acclaim Plus, a combined product manufactured by Sandoz for Sanofi and containing the Sandoz IGR active ingredient Methoprene. Similarly, Pfizer markets Canovel, also a combined product containing the Sandoz IGR active ingredient Methoprene.

262. Ciba's Program is a particularly successful IGR in the USA. It treats the environmental problem from the animal, not as is the case for all other IGRs currently sold in Europe, from the environment. It avoids all of the following difficulties involved in using an adulticide or an IGR from the environment:

— lack of convenience,

— problem of compliance with the application instructions by pet owner because application involves some effort,

— application not always successful,

— difficulty of access to some of the affected parts,

— large area to be treated,

— health hazards caused by spraying the animal.

(263) Ciba conducted a major advertising campaign for Program in the United States. Particular significance attaches to market developments in the United States, because they usually foreshadow developments in Europe. Although Program is on sale both in Europe and in the US, it is only in the US market that Ciba has so far invested significant resources in product advertising. The scale of Ciba's success in the United States is shown in the following table:

(All figures in ECU '000)

Year	Europe	World (incl. US)
1990	0	[...]
1991	0	[...]
1992	[...]	[...]
1993	[...]	[...]
1994	[...]	[...]
1995	[...]	[...]

264. According to the Commission's findings, neither Hoechst, Mallinckrodt nor Rhône-Mérieux currently sells IGR products in either pure or combined form, either in Great Britain or elsewhere in Europe. Nor does Bayer have an on-animal IGR, which — as shown above — is of particular importance in relation to future market development.

265. Six out of the seven major current competitors state that there is a trend towards on-animal IGRs and the seventh acknowledges the success of Program, the only known on-animal IGR at the present time. Six companies also confirm that on-animal IGRs are superior to off-animal IGRs. Six again confirm that they do not possess an on-animal IGR and most would wish to develop such a product. The seventh appears to do so, but the Commission is not aware of the availability of this product in the market place. It can therefore be concluded that possession of an IGR will be of crucial importance for competitors to secure their future market position.

266. In this respect the loss of potential competition to Ciba from Sandoz is particularly important. The Commission understands that Sandoz has already developed an on-animal IGR using Methoprene as an active ingredient which is currently on sale in the US.

(3) *Active ingredients*

267. A vitally important factor in the overall competitive assessment is the degree of supply of active ingredients by Novartis to other market competitors. In contrast to the markets in the plant protection sector (see part B), it is evident in the SAE field, for both IGR- and adulticide-active ingredients, that supply arrangements are one-sided, i. e. from Novartis to competitors and not vice versa. The Commission is not aware of any adulticide or IGR ingredient purchased by Novartis from a competitor.

268. The Commission has in the IGR segment identified five active ingredients with which IGRs could be produced ([11]):

IGR-Active ingr.	Owner	Patent expiry
Methoprene RS + S	Sandoz	expired, Sandoz has applied for an extension of patent protection for Methoprene S
Phenoxycarb	Ciba	March 1999
Lufenuron	Ciba	October 2005
Flufenoxuron	American Cynamid	April 2005
Pyriproxyfene	Sumitomo	April 2004

Three of these five active ingredients are controlled by the merging parties. Sandoz supplies Methoprene indirectly (contained in the delivered end-product) to Sanofi, Pfizer and directly to Bayer. Once the merger is concluded, there will hardly be any incentive for Novartis to continue this supply (see above 'market structure'). According to the Commission's investigations, for the majority of competitors it is impossible to secure their supply of active ingredients from either American Cynamid or Sumitomo.

(4) *Potential entry through alternative supply sources for Methoprene*

269. The Commission acknowledges that Methoprene is no longer covered by patent protection. However, there would appear to be at least three major problems to finding a valid alternative generic supplier for Methoprene.

([11]) The parties have also identified a sixth, Triflumuron owned by Bayer. However, Bayer would seem to prefer its licensed alternatives Pyriproxyfene and Methoprene to its own product.

270. First, there appears to be difficulty in securing an appropriate supplier. The parties identified two potential suppliers ([12]) in Hungary. According to the Commission's findings Egis Pharmaceuticals will not supply Methoprene alone, only the finished product. Babolna-Bio would be willing to supply Methoprene, but according to competitors it is doubtful that it would be able to supply all the different kinds of Methoprene potentially required by existing customers of Sandoz. For example, Methoprene S is an improved formulation with a longer lasting effect and is today only manufactured by Sandoz. Even if the generics manufactured in Hungary and China could in clinical terms equal Sandoz's product, the market and the fact that competitors in Member States have not purchased these generics prove that the Methoprene manufactured in Hungary and in China is not an adequate alternative to Sandoz's active ingredient.

271. Second, any potential supplier would have to be able to supply the product to the required specifications. According to the available information, manufacturers of generics do not at present possess the necessary know-how and therefore cannot achieve the necessary purity standards of Methoprene.

272. For active ingredients and end-products already registered there exist so-called 'masterfiles', which contain all information necessary for the application to the national authorities for registration. The masterfile is the property of the enterprise that applied for the registration. No access to the masterfile has to be granted to third parties even after any patents have expired. A third problem, therefore, is that further delay would be caused by the need of regulatory authorities to conduct further trials to validate the safety and efficacy of the finished product containing the substituted active material. More generally, the Commission's enquiries have confirmed that even if Methoprene were available today in the desired quantities, it could take on average four to five years to develop a new on-animal IGR.

([12]) The only other supplier worldwide of which the Commission is aware is the Tianjin Institute of Pesticides in China. This supplier was not mentioned by the companies as a possible source and must in any event be considered as likely to suffer from the same handicaps as the two potential Hungarian suppliers.

(5) *Demand-side bargaining power*

273. The demand side is extremely fragmented, being individual consumers purchasing products mainly through vets and pet-shops, etc. The Commission considers that little, if any, significant demand-side bargaining power exists. Nor have the parties invoked any.

(6) *Conclusion*

274. Given Novartis' market strength in the SAE market as a whole and for IGRs in particular, coupled with competitors' dependence on the continued supply of other active ingredients and Methoprene in particular, it is sufficiently probable that Novartis will not be adequately constrained by competitors in the future. The merger will therefore create a dominant position in this market.

(d) **Undertaking proposed by the merging parties**

275. The parties have recognized the Commission's concerns with regard to Novartis' future market position and in particular in relation to the supply of Methoprene. In order to remove these concerns, they have proposed the following undertaking.

'Both undertakings hereby declare their willingness on behalf of Novartis AG to provide within a time period of 2 years after the merger constituting Novartis to any serious and appropriate interested party for application in small animal ectoparasiticides for sale in Europe an non-exclusive and unlimited licence for the production of the active ingredient RS and S Methoprene. The licensee will have access to the necessary technical data and the master file. The term of this licence will be fair and reasonable, with the turnover-related licence fee not exceeding 5 % and the duration not exceeding 10 years, and with the initial contribution payable to cover costs being offset against the licence fee. If the turnover of the licensee is realized with products containing several active ingredients, the licence fee will be calculated only for the part of the product containing Methoprene. For the time between the conclusion of the contract and the commencement of production by the licensee, but subject to a maximum period of two years, Novartis is willing to supply Methoprene to the licensee on normal market conditions.'

(e) **Assessment of proposed undertaking**

276. Through the merger, the parties will acquire an extremely strong position in the market for SAEs, in particular as regards IGR active ingredients which are critical to future market developments and which they supply to a number of market competitors. Ciba enjoys patent rights with respect to two IGR active ingredients, namely Lufenuron and Fenoxycarb; Sandoz held the original rights for Methoprene, which have now expired, but an application for a prolongation of its patent with respect to Methoprene S is pending. Sandoz is the only manufacturer worldwide of Methoprene S and possesses the corresponding valuable technical and process know-how.

277. The proposed undertaking enables competitors to purchase a licence for the production of RS and S Methoprene. As a result, the adverse competition consequences caused by the combination of the IP-rights for the three IGR active ingredients are avoided. Methoprene will remain available in the market place for use by competitors in the development of the next generation of IGRs. A complete technical package incorporating the details of the master file will be made available to competitors. This will facilitate the development of Methoprene-based IGRs by competitors. The granting of licences will therefore maintain market access for other producers who will have to compete against the other significant advantages of Novartis.

278. At the same time, existing competitors will have the ability to free themselves of any supply dependency on Novartis for Methoprene, whether of the S or RS type. Consequently, in implementing their business strategy in the SAE sector, they will be unconstrained by any supply dependency on Novartis for Methoprene.

279. In the light of the above, the Commission considers that while Novartis will still be the leading SAE producer in Europe and will enjoy a strong market position, it is no longer foreseeable with sufficient probability that the merging parties will be able to behave to a significant extent independently of their competitors.

280. In order to enable the Commission to monitor the implementation of the undertaking during the two-year period, the parties are required to submit a three-monthly report containing the following information:

— Methoprene licence requests received,

— Methoprene licence requests granted,

— where a Methoprene licence request is not granted, the reasons for refusal,

— details of Methoprene RS and S supplied, either in the form of active ingredients or contained in finished products, to third parties.

D. SEEDS

1. ***Definition of the product market***

281. The production of seeds involves the breeding/development, progagation/production and marketing of the seed. There are seeds for all types of (useful) plants, such as sugarbeets, maize, wheat, barley and grapes. The different types of seed are not mutually substitutable and thus each constitutes a relevant product market (see also IV/M.556 Zeneca/Vanderhave, point 11.

282. Competitors suggested that the market should be defined in narrow terms. The farmer, on the basis of certain criteria, first of all decides to grow a particular type of crop and then has to choose between various types of seed for the cultivation of the crops selected. Depending on the climate and the condition of the soil, seeds used in one region are not interchangeable with seeds used in another. Consequently, there are relevant product markets for these regionally differentiated seed types. Because all efficient competitors produce seeds for all regions, however, it is sufficient for the purposes of this case to delimit the market without differentiation according to regional seed type.

283. In the production of seeds there are two different stages: breeding and commercial production (see also IV/M.556 Zeneca/Vanderhave, point 12 *et seq.*). The commercial production of seeds can be further subdivided into two stages: the seed cultivated by the seed firm — the 'basic seed' — is propagated under contract by cooperatives and farmers to become the unpurified finished seed. After propagation, the seed is purified, sorted and packed in the seed company's processing plants or at third undertakings.

284. The manufacturing stages describes are not defined by the parties as separate product markets

since the seed remains the property of the seed company throughout the entire preparation process, i. e. not bought and sold. At most, there is a market for the propagation of the basic seed on which the cooperatives and farmers supply this service.

285. The seed companies occasionally exchange breeding material (germplasm) in order to develop improved basic seed. Common hybrids are developed in the process i. e. the lines of two undertakings are crossed. This activity is usually practised by only one undertaking, with the non-active undertaking receiving a licence fee. Germplasm is increased and renewed by the individual seed companies through a long process of breeding and can be compared to intangible property in the chemicals and engineering industries which is patented. Germplasm is therefore not sold by the parties or the other competitors to third parties. According to information from competitors, there are many undertakings which produce seed and rely on germplasm from foundation seed houses (these institutions specialize in collecting germplasm produced by undertakings and distributing it to other undertakings for crossing). Thus there are markets for germplasm. As mentioned, however, the parties sell no germplasm to third parties and so are not active on these markets.

2. *Geographic market*

286. As regards the *markets for seeds*, the earnings potential of a particular seed is the decisive motive for buying that seed. Since climate and soil condition vary from one region to the next, regionally differentiated seed produces the highest return. Thus products are required which are differentiated by region or climatic zone (see also IV/M.556 Zeneca/Vanderhave, point 14 *et seq.*).

287. Before seed can be sold, it must be registered in a Member State. If registration is applied for and the seed matches requirements, it will be included in the national list and hence automatically in the European Catalogue. It can subsequently be sold throughout the Community. In addition, the parties' figures show that seed is supplied in the Member States at very different prices.

288. The seed companies do not produce seed in all the Member States but only in a few countries, some of which are outside Europe. Export and import quotas are correspondingly high, therefore.

289. For the purposes of this case, the definition of the geographic reference market can be left open since neither on the narrowest (i. e. national) nor on a wider definition of the seed markets is a dominant position created or strengthened (see the points below).

290. Since seed is cultivated for particular climatic zones, the *market for the propagation of seed* must be defined by climatic zone; to a certain extent, such zones cross national borders. In Europe four climatic zones are distinguished, at different latitudes. European markets are supplied to a certain extent with seed which was developed and produced (and propagated too) in the corn belt of the United States. A geographic delimitation by climate zone must therefore include all similar zones around the world.

3. *Competitive assessment*

(a) **Markets for the propagation of seed**

291. In the markets for the propagation of seed there are thousands of agricultural cooperatives and farmers who provide a propagation service. The income which a cooperative or a farmer earns from providing the service is very small and therefore of secondary economic importance. Moreover, only in the case of maize seed is there any overlapping as a result of the concentration and even that is on a small scale. The effects of the concentration on competitive relations in the markets for the propagation of seed — all seeds, not just maize seed — are therefore small. Furthermore, because all seed producers are present on this market, the farmer has a choice. For these reasons, an abuse of buyer concentration of power is not possible. On the market for the propagation of seeds, therefore, no dominant position is created or strengthened.

(b) **Markets for seed**

(1) *Market structure*

292. The market shares which the parties will attain after the concentration exceed 15 % in the following markets only:

— grain maize seed in Greece ([30-40 %], Ciba [20-30 %], Sandoz [under 5 %]).

— grain maize seed in Spain ([30-40 %], Ciba [30-40 %], Sandoz [under 5 %]).

293. The gains in market share are relatively small, so that the market positions of the parties are strengthened only marginally by the concentration. This is underscored by the fact that Sandoz's market share has fallen since 1992 by [under 5 %] in Greece and has never exceeded [under 5 %] in Spain in the last three years. Only Ciba has a strong market position, its share remaining roughly constant [30-40 %] in Spain and doubling from [10-20 %] (1992) to [20-30 %] (1994) in Greece.

294. The most important competitor is Pioneer with a market share of [40-50 %] in Greece and [30-40 %] in Spain. In Greece Pioneer lost [under 10 %] in market share between 1992 and 1994 but gained [under 5 %] in Spain over the same period. A further major competitor in Greece is Limagrain with a market share of [under 10 %] (down]less than 5 %] on 1992). Limagrain is also active in Spain but its market share there is tiny. Also present in Spain is Zeneca with a market share of ‹ 5 %; in Greece Zeneca's share is very small. The parties and the market participants consulted mention other competitors both in Spain and Greece, but their market shares are very small.

(2) *Potential competition and market entries*

295. As the example of Greece shows, market-share gains and losses are possible in a short period of time. New varieties whose earnings potential exceeds that of the existing seed quickly establish themselves on the market. Brand name loyalty is of secondary importance (see also IV/M.566 Zeneca/Vanderhave, point 21). The Commission's investigations showed that every year a large number of new products come onto the markets.

296. Specific know-how in one or several seed markets is of only limited use if an undertaking wishes to be active on other seed markets. Possible entry into a particular product market depends on the germplasm which an undertaking has. Similarly, breeding methods, production, marketing and sales require specific knowledge which varies according to the product market in question.

297. The parties refer to two new entrants to the forage maize seed markets since 1990: Mycogen and Golden Harvest. According to the Commission's investigations, they are not significant competitors, and this is why they are not mentioned by the parties as competitors in Spain and Greece.

298. Ciba is active in the markets for forage maize seed only, where Sandoz — as shown — does not have a strong market position. Apart from these markets, though, Sandoz is active in other seed markets and in some cases has a large market share, e. g. in the market for flower seeds in Belgium [60-70 %]), the market for sugarbeet seeds in Great Britain([80-90 %]) the same market in Sweden ([90-100 %])and the same market in Ireland ([80-90 %]). Since Ciba has no suitable germplasm in these markets and since the development of such germplasm is a lengthy business, it could not be regarded as a potential competitor of Sandoz even before the proposed concentration. Thus, the competitive situation in those seed markets where only Sandoz is active will remain fundamentally unaffected by the concentration.

(3) *R & D*

299. Since improved products quickly establish themselves on the market, the R & D potential of a competitor is of decisive importance as regards the assessment of its market position. The parties spend about 10 % of the turnover generated in the seeds sphere on R & D. Strong competitors in the R & D field are: Pioneer, Limagrain, DeKalb, Seminis, Zeneca/Vanderhave, Cargill and KWS (Kleinwanzleber Saatzucht). The most important innovation was the hybridization of maize in the 1920s. The development of new seed products leads to increased returns of about 1 % a year on average.

300. As already mentioned in the discussion of the markets for crop protection products (see Part B), the knowledge acquired in the seeds sphere about the use of biotechnology and genetic engineering methods for the introduction of genes with particular properties (e. g. resistances) and the knowledge from the crop protection sphere about the fungicidal and insecticidal effects of microorganisms and certain genes can be applied both to crop protection and to seeds. Thus Ciba has already applied in Europe for approval for genetically modified hybrid maize which protects

itself against European corn borer grubs. Sandoz's strong position in seeds (except in grain maize seed) and Ciba's strong position in crop protection will possibly produce corresponding synergies in R & D. According to information form competitors, however, there have so far been no competitive advantages from simultaneous activity in seeds and crop protection.

301. The new technologies developed in recent years (in particular in molecular biology and genetic engineering) will probably lead to new market entrants. The parties and their competitors expect that several undertakings will bring new seed products onto the market. These include: Pioneer, Dekalb, Monsanto (soya seed which protects itself against harmful organisms and insects and is resistant to herbicides is already being brought onto the market to a certain extent), KWS, Mycogen, Plant Genetic Systems, Calgen, Zeneca, Seminis and Rhône-Poulenc.

302. It was pointed out by competitors that the new field of biomolecular engineering will require additional investment in personnel and equipment. Since this technology will not replace but complement existing traditional biotechnology methods, seed firms are forced to spend extra resources on R & D. The resultant costs can be borne more easily by suitably large business units. The Commission's investigations showed, however, that the necessary 'critical mass' will be attained by at least Pioneer and Zeneca. Similarly, the other competitors mentioned will not necessarily suffer disadvantages since cooperative schemes between seed suppliers are to be found particularly in R & D (see also IV/M. 556 Zeneca/Vanderhave, point 19).

(4) *Oligopolistic market dominance*

303. The parties and Pioneer will attain a joint market share in Greece and Spain of [70-80 %] and [70-80 %] respectively. The question of oligopolistic market dominance thus arises. In IV/M.556 Zeneca/Vanderhave, point 26, it was assumed that other breeding undertakings will see opportunities for profit and will therefore breed new generations of seeds if any one undertaking were to exploit its market position by raising prices. This also applies here since transport costs are relatively insignificant and the cost of market entry for undertakings already engaged in the seeds business is put at ECU 2 to 5 million. In view of the above observations on market entry conditions, this applies only to firms which are already active in markets for grain maize seed. These include at least Limagrain, Pau/Rustica, KWS and Zeneca. Zeneca and Limagrain, moreover, already have small market shares in Spain and Greece.

304. In addition, in the markets for grain maize seed, the extent of product differentiation is considerable. Since the farmer chooses what for him is the optimum seed on the basis of many criteria (soil condition, time of growth, probable return, etc.), there are accordingly in the market for grain maize seed a great many products each with different properties. The products are consequently heterogeneous; every supplier therefore has a certain freedom as regards pricing. This is also borne out by a comparison of Sandoz's and Ciba's average prices for maize seed in Spain and in Greece. Ciba supplied maize seed at prices which were up to 100 % higher than those of Sandoz.

305. The fairly large loss of market share by Pioneer in Greece and its gain in Spain are a further indication that there will be no oligopolistic behaviour by the leading market competitors.

(c) **Summary of the seeds part**

306. In view of:

— the small gains in market share,

— the fluctuating market shares over time,

— the large number of competitors,

— the presence of a few strong competitors in the R & D field, and

— the justified presumption that Ciba was not a potential competitor in those markets where Sandoz is strongly represented,

the Commission has reached the conclusion that the merger will not create or strengthen a dominant position in the markets for seeds.

E OVERALL ASSESSMENT

1. *Health-care products*

307. The proposed merger will not lead to the creation or strengthening of a dominant position on the part of the parties either on the relevant national markets for medicinal products or on the markets for active substances. Similarly, it is not to be anticipated as far as future markets are concerned that the proposed merger will lead to the creation or strengthening of a dominant position.

2. *Plant-protection products*

308. In the plant protection area, the merger will not create or strengthen a dominant position as a result of which effective competition would be significantly impeded in the common market or in a substantial part of it.

3. *Animal-health products*

309. The Commission's investigations have shown that the merger will not create or strengthen a dominant position on the markets for active substances, farm animal ectoparasiticides, stable-fly control and the treatment of swine dysentery. Provided that the parties fulfil the undertaking they have given, this assessment of the proposed merger also applies to the markets for small animal ectoparasiticides.

4. *Seeds*

310. Nor will the proposed merger lead to the creation or strengthening of a dominant position on the relevant seed markets.

CONCLUSION

311. For the reasons set out above, subject to the condition that the undertaking given by the parties is fulfilled, it is to be assumed that the proposed merger will not lead to the creation or strengthening of a dominant position as a result of which effective competition would be significantly impeded in a substantial part of the Community. Subject to that condition, therefore, the merger is to be declared compatible with the common market and with the functioning of the EEA Agreement pursuant to Article 2 (2) of the Merger Regulation and Article 57 of the EEA Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The notified merger between Ciba-Geigy AG and Sandoz AG is hereby declared compatible with the common market and with the functioning of the EEA Agreement, subject to the condition that the undertaking given by the parties and set out in point 275 is fulfilled.

Article 2

The parties shall report to the Commission in accordance with point 280 of this Decision.

Article 3

This Decision is addressed to:

1. Ciba-Geigy AG
CH-4002 Basel

2. Sandoz AG
CH-4002 Basel.

Done at Brussels, 17 July 1996

For the Commission

Karel VAN MIERT

Member of the Commission