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**Datasheet for the decision  
of 11 December 2007**

**Case Number:** T 0062/04 - 3.3.02

**Application Number:** 95402659.7

**Publication Number:** 0717993

**IPC:** A61K 31/495

**Language of the proceedings:** EN

**Title of invention:**

Use of anthelmintic compositions for treating Anoplocephala  
perfoliata infections in equidae

**Patentee:**

VIRBAC S.A.

**Opponents:**

Bayer AG  
MERIAL Limited  
Wyeth Pharmaceuticals

**Headword:**

Anthelmintic compositions/VIRBAC

**Relevant legal provisions (EPC 1973):**

EPC Art. 123(2), 56

**Keyword:**

"Amendments - added subject-matter (yes); First, third and  
fourth auxiliary requests"

"Inventive step (no); main request and second auxiliary  
request - claimed effect not demonstrated; obvious  
combinations of actives"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0062/04 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 11 December 2007

**Appellant:**  
(Patent Proprietor)

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**Decision under appeal:**

Decision of the Opposition Division of the  
European Patent Office posted 20 November 2003  
revoking European patent No. 0717993 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** H. Kellner  
J.-P. Seitz

## Summary of Facts and Submissions

I. This decision has been pronounced on 11 December 2007; therefore all citations are from the EPC 1973 in the following text.

II. European patent No. 0 717 993, based on application No. 95 402 659.7, was granted with seven claims.

Claim 1 of this patent reads as follows:

"Use of an anthelmintic composition comprising an amount of praziquantel suitable for administering to equine animals a dose of 0.5 to 2.0 mg of praziquantel per kg of animal body weight, together with an effective amount of an anthelmintic agent selected from avermectins or milbemycons or derivatives thereof for the preparation of a medicament for orally controlling and treating infestations by *Anoplocephala perfoliata* in equine animals."

III. Opposition was filed against the granted patent under Article 100(a) and (b) EPC.

The following documents were cited inter alia during the proceedings before the opposition division and the board of appeal:

(2) Lyons, E.T. et al, "Activity of Praziquantel against *Anoplocephala perfoliata* (Cestoda) in horses", J. Helminthol. Soc. Wash., 59(1), 1992, 1-4

(6) GB-A-2 252 730

(7) EP-A1-0 059 074

(42) declaration of Mr Slocombe of 7 August 2003,  
attached to the letter of opponent 03 dated  
14 August 2003 during the opposition proceedings

IV. By its decision, posted on 20 November 2003, the  
opposition division revoked the patent under  
Article 102(1) and (3) EPC.

The opposition division held that neither the set of  
claims of the main request nor the set of claims of  
auxiliary request 3 met the requirements of  
Article 56 EPC.

It first noted that the requirements of Article 83 EPC  
were fulfilled by the claims of the main request and  
auxiliary request 3, the latter also being originally  
disclosed (Article 123(2) EPC).

In particular, the several working examples contained  
in the specification of the contested patent showed  
that the skilled person would be able to carry out the  
subject-matter of the claims without undue burden.

The sets of claims of the main request and auxiliary  
request 3, however, lacked inventive step in view of  
document (2), the closest prior art, together with  
document (6) or (7). Document (2) dealt with the use of  
praziquantel in the oral treatment of *A. perfoliata*  
infestations in horses. The problem to be defined in  
view of this document was to find an improved treatment  
of these cestodes in horses. Both documents (6) and (7)

taught "synergistic effects of praziquantel combined with avermectins or milbemycins, knowing that using the combination, treatment of not only *A. perfoliata* but also other helminths as well would be achieved".

The additional feature in claim 1 of auxiliary request 3, the dosage of ivermectin or abamectin, would not provide any additional technical feature which would render the subject-matter inventive, especially since the dosages were the standard ones.

The sets of claims of auxiliary requests 1 and 2 were not originally disclosed, since an amount of 1 mg praziquantel was only disclosed in the specific examples of tables 10 and 11 in association with the specific compounds abamectin and ivermectin.

- V. The patentee (hereafter appellant) lodged an appeal against said decision and filed grounds of appeal together with a main request to maintain the patent as granted.

With its letter of 11 October 2007, it submitted four further sets of claims as auxiliary requests 1 to 4. Another set of claims was filed with letter dated 5 December 2007 as auxiliary request 5.

Claim 1 of the set of claims of auxiliary request 1 reads:

"Use of an anthelmintic composition comprising an amount of praziquantel suitable for administering to equine animals a dose of **1.0 or 2.0** mg of praziquantel per kg of animal body weight, together with an effective amount of an anthelmintic agent selected from

**ivermectin and abamectin suitable for administering to equine animals a dose of 0.2 mg of ivermectin or abamectin per kg of animal body weight**, for the preparation of a medicament for orally controlling and treating infestations by *Anoplocephala perfoliata* in equine animals" (differences with respect to claim 1 as granted highlighted in bold).

Claim 1 of auxiliary request 2 differs from claim 1 as granted in the addition of the word "synergistically" after "together with", the resultant wording calling for use of a "**synergistically** active amount of an anthelmintic agent selected from avermectins or milbemycins or derivatives thereof".

The wording of the set of two independent claims of auxiliary request 3 is:

"1. Use of an anthelmintic composition **in the form of a paste** comprising an amount of praziquantel suitable for administering to equine animals a dose of **1.0 or 2.0** mg of praziquantel per kg of animal body weight, together with an effective amount of **abamectin suitable for administering to equine animals a dose of 0.2 mg of abamectin per kg of animal body weight**, for the preparation of a medicament for orally controlling and treating infestations by *Anoplocephala perfoliata* in equine animals.

2. Use of an anthelmintic composition **in the form of an oral drench** comprising an amount of praziquantel suitable for administering to equine animals a dose of **1.0 or 2.0** mg of praziquantel per kg of animal body weight, together with an effective amount of **ivermectin**

**suitable for administering to equine animals a dose of 0.2 mg of ivermectin per kg of animal body weight**, for the preparation of a medicament for orally controlling and treating infestations by *Anoplocephala perfoliata* in equine animals" (differences as inserted with respect to claim 1 as granted highlighted in bold).

Claim 1 of auxiliary request 4 differs from claim 1 as granted in the replacement of the definition of the quantity of praziquantel as "0.5 to 2.0 mg" by the quantities "**1.0 or 2.0 mg**", as in claim 1 of auxiliary request 1, and in the addition of the word "**synergistically**" after "together with" as in claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 5 read:

"Use of an effective amount of an anthelmintic agent selected from avermectins or milbemycins or derivatives thereof to increase the activity of praziquantel against *Anoplocephala perfoliata* in an anthelmintic composition comprising an amount of praziquantel suitable for administering to equine animals a dose of 0.5 to 2.0 mg of praziquantel per kg of animal body weight for the preparation of a medicament for orally controlling and treating infestations by *Anoplocephala perfoliata* in equine animals" (the word "*Anoplocefala*" as filed, corrected by the board).

However, this auxiliary request was not admitted into the proceedings.

VI. On 11 December 2007, oral proceedings took place before the board in the presence of the representatives of the

appellant and the representatives of respondents (opponents 02 and 03); duly summoned, respondent (opponent 01) had informed the board in advance that it did not wish to attend the hearings.

- VII. The appellant mainly argued that, with respect to inventive step, the conclusions of the opposition division were not correct since they were influenced by the assumption that treatment of helminths other than *A. perfoliata* was to be achieved by the combination of praziquantel and avermectins or milbemycins. The invention of the patent in suit, however, was based on an increase in the activity of praziquantel against *A. perfoliata* in horses without any respect to other helminths, in particular to nematodes.

The tables belonging to examples 10 and 11 of the patent in suit showed a synergistic effect leading to higher efficacy of combined praziquantel and abamectin or praziquantel and ivermectin than the single actives exhibited alone, in particular for dosages of 1 or 2 mg/kg body weight of praziquantel together with 0.2 mg/kg body weight of the other active respectively.

Since documents (6) and (7) did not deal with *A. perfoliata*, and not even with any helminth infestations of horses in particular, they could not lead the skilled person to the teaching of the patent in suit.

- VIII. The respondents' arguments submitted in writing and during the oral proceedings may be summarised as follows:



In their view the opposition division was right in its decision on inventive step. Supplementarily, objections of insufficient disclosure and lack of novelty were maintained.

With respect to the question of inventive step, the respondents submitted that examples 10 and 11 in the patent in suit failed to show a synergistic effect of the combination of praziquantel and abamectin or ivermectin. Among other objections, they pointed out that it was unclear whether the pastes or drenches produced according to examples 1 to 9 respectively were used, as indicated for instance at the top of the tables representing the results, or if other medicaments were used which contained the actives in different relations in terms of concentration (according to the data within the tables themselves).

Additionally, they submitted that, in view of the teaching of document (2) together with document (6), the question of a synergistic effect was irrelevant anyway, because in document (6), combinations of praziquantel and avermectins or milbemycins were disclosed to lead to improved efficacy against cestodes in domesticated animals.

- IX. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or alternatively on the basis of one of the sets of claims filed as auxiliary requests 1 to 4 with its letter of 11 October 2007 or on the basis of the set of claims filed as auxiliary request 5 with letter of 5 December 2007.

The respondents (opponents 02 and 03) requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.
  
2. *Auxiliary request 5; admissibility*

The set of claims which the appellant sought to introduce as auxiliary request 5 with its letter dated 5 December 2007, a few working days before the date of the oral proceedings, is late-filed *per se*. It can not constitute an answer to newly-raised arguments and was not *prima facie* allowable because of various problems with regard to clarity and original disclosure. The features in its claim 1 are rearranged together with additional features from the description, resulting in a highly complex further assessment. For these reasons the board exercises its power of discretion, and auxiliary request 5 is not admitted into the proceedings.

3. *Auxiliary requests 1, 3 and 4; Article 123(2) EPC*

Since each claim 1 of auxiliary requests 1, 3 and 4 identically contains the feature "administering to equine animals a dose of **1.0 or 2.0** mg of praziquantel", these requests are discussed together with respect to the requirements of Article 123(2) EPC.

3.1 In the application as filed, the use of a dose of 1.0 mg of praziquantel per kg of animal body weight together with abamectin or ivermectin is disclosed only within the tables annexed to examples 10 and 11 and as a comment on the table of example 10 in the last paragraph before its heading.

In the table relating to example 10, for instance, the value 1.0 mg/kg praziquantel is set out together with 0.2 mg/kg abamectin as having been administered when carrying out one of five experiments relating to various dosages of these two actives. In the sequence of these five experiments, with the value for abamectin fixed at 0.2 mg/kg body weight of the animal, the value for praziquantel changes decreasingly from 5, 2, 1.0, and 0.5 mg/kg to 0.1 mg/kg (the order of the experiments as originally shown in the table, namely in rising quantity of praziquantel administration, has been reversed for the sake of simpler comparison during the following assessment). Thus, one of these experiments relates to the use of a dose of 1.0 mg of praziquantel per kg of animal body weight together with 0.2 mg/kg abamectin.

3.2 In the text associated with this table, however, it is consistently confirmed that the praziquantel/abamectin-containing pastes of examples 1 to 5 were used in the experiments listed within the table (see the first paragraph of the text under the heading "example 10", the title of its table and page 9 of the application as filed, lines 15 to 17). The most rigorous text in this context is that on page 9, lines 15 to 17, namely: "A high level of efficacy was demonstrated by the combination formula of examples 2, 3, 4 and 5". The

description of these examples contains nothing other than the variations of the amounts of praziquantel and abamectin present in the pastes, resulting in the conclusion that "the combination formula" cannot mean anything other than the combined amounts of these actives. But in examples 1 to 5, the values for praziquantel calculated with respect to a fixed value for abamectin of 0.2 mg/kg are 25, 5, 2.5, 1.25 and 0.5 mg/kg, none of them being 1.0 mg/kg.

The same conclusions result from example 11, text and table *mutatis mutandis*, the second active together with praziquantel being ivermectin.

3.3 Thus, it is at least unclear whether the basis of examples 10 and 11 is the dosages of the actives set out in the tables or those in the description of the produced medicaments (examples 1 to 9). This issue was also addressed by respondent (opponent 03) by reference to the declaration of Mr Slocombe of 7 August 2003, attached to the letter dated 14 August 2003 during the opposition proceedings (document (42); see there paragraph 28 beginning on page 14).

3.4 Consequently, a value of 1.0 mg of praziquantel per kg of animal body weight to be used together with 0.2 mg abamectin or ivermectin per kg of animal body weight cannot be derived **clearly and unambiguously** from the application as filed, and claims 1 of the auxiliary requests 1, 3 and 4 containing this value extend the content of the application. They do not fulfil the requirements of Article 123(2) EPC.

4. *Main request and auxiliary request 2*

4.1 Article 100(c) EPC was not addressed in the opposition proceedings, and the main request relates to the set of claims as granted.

The claims of auxiliary request 2 differ from the claims as granted only by addition of the word "synergistically" in claim 1, which is derivable from the application as filed and does not broaden the scope of the claim.

Thus, in both cases, Articles 123 and 84 EPC are of no relevance.

As to Article 100(b) EPC, the board is convinced that, based on praziquantel and avermectins or milbemycins, the teaching of the patent in suit can be carried out without undue burden. With respect to dosages to be administered, the skilled person will start with usual amounts of these well-known substances, and with routine work he will find out the corresponding ranges for successful administration.

With respect to the question of novelty, as the facts on file stand, the board intends, under the particular circumstances of the case, to deal first with the assessment of the requirements of inventive step.

4.2 With respect to these inventive step requirements, the obligatory features of the patent in suit are to be considered:

4.2.1 Concerning the main request, its claim 1 relates to the

use of a composition

(a) comprising praziquantel,

(b) together with an agent selected from avermectins or milbemycins

for the preparation of a medicament

(c) for the treatment of infestations by *Anoplocephala perfoliata*

(c1) in equine animals,

(c2) the treatment being administered orally.

The adjective "anthelmintic" and the wording "an effective amount of" (main request) merely provide clarifying information while characterising the avermectins or milbemycins. They only rule out embodiments that would not be suitable to fulfil the features (c), namely to be appropriate for successful oral treatment of *A. perfoliata* infestations in horses. Therefore, they do not appear in the characterisation of the relevant features of the teaching in the patent in suit as presented above.

With respect to the requirement that the amount of praziquantel comprised in the composition be "suitable for administering to equine animals a dose of 0.5 to 2.0 mg of praziquantel per kg of animal body weight", the board finds that it is fulfilled in a wide range of concentrations of praziquantel in the composition and has no reliable relation to the actual dose to be administered to an infested horse. Therefore, this requirement is not a feature that can be considered as an exact dosage in the assessment of inventive step (in this context see also the letter of respondent (opponent 02) dated 1 October 2004, page 12,

paragraph 6), and it does not appear as a feature of the teaching of the patent in suit as presented above either.

4.2.2 Document (2) constitutes the closest prior art.

It relates to the use of

(a) praziquantel,

(c) for the treatment of infestations by *Anoplocephala perfoliata*

(c1) in equine animals,

(c2) the treatment being administered orally

(see page 3, left column, paragraphs 1 and 2 under the heading "Results and discussions", and page 2, left column, last paragraph, to page 3, left column, first paragraph below table 1).

4.2.3 In the light of this prior art and with respect to the problem underlying the patent in suit, which the appellant considered to relate to an improvement, the following facts have to be taken into account:

(a) As set out under point 3.3 of this decision, it is at least unclear whether the basis of examples 10 and 11 is the dosages of the actives set out in the tables or those based on the description of the produced medicaments (examples 1 to 9).

(b) The dosage of each of two actives to be administered to an animal and being present together mixed up in one liter of paste or drench has to be in a certain correlation to the concentration in which it is contained in the medicament. The higher the concentration, or the

lower the quantity of excipients, and the higher the quantity of medicament to be administered, the higher the dosage of administration of both of the actives will be. But at least the relation between the two actives cannot be changed by variation of the quantity of paste or drench to be administered or by any additional variation of excipients. The consequence of this fixed relation is that in the present case of a constant dosage of abamectin or ivermectin of 0.2 mg/kg body weight of the animal, the dosage of praziquantel with respect to a certain mixture of the two actives in a particular paste or drench (examples 1 to 9) is fixed too, namely for instance at amounts of 25, 5, 2.5, 1.25 and 0.5 mg/kg body weight of the animal (examples 1 to 5).

- (c) When the pastes and drenches produced in examples 1 to 9 are used, the high clearance effects may be initiated by the higher dosages of praziquantel alone, which are for instance 25, 5, 2.5, 1.25 and 0.5 mg/kg instead of 5, 2, 1.0, 0.5 and 0.1 mg/kg as set out in the table of example 10 (see also points 3.1 and 3.2 of this decision). The same arguments apply *mutatis mutandis* to example 11.

Thus, considering all the details as disclosed in the application as filed with respect to the experiments, a synergistic effect cannot be deemed to have been demonstrated.

- 4.2.4 Accordingly, in the light of document (2) as closest prior art and in view of the conclusion that no



particular positive effect is shown for the teaching of the patent in suit with respect to this document, the problem underlying the patent in suit can only be seen in the provision of a further composition for the same purpose.

- 4.2.5 This problem is solved by the provision of the composition according to claim 1 as granted (main request), comprising an anthelmintic agent selected from avermectins or milbemycins in addition to praziquantel.
- 4.2.6 Having regard to the worked examples of the patent in suit, the board is convinced that the problem has been solved.
- 4.2.7 Document (6) is a publication in the same field as that of document (2), namely the treatment of helminth infestations of domesticated animals. Document (6) refers in particular to anthelmintic compositions including praziquantel together with ivermectin, moxidectin or doramectin (see claim 7 together with claim 1) being efficacious in the control of nematodes and cestodes (see document (6), page 2, lines 10 to 13 together with examples 3, 5 and 6). *Anoplocephala perfoliata* is a cestodic tapeworm (see for instance the title of document (2) and its page 1, last three lines of right column to page 2, end of left column), and ivermectin is a preferred avermectin-related compound of the patent in suit (see for instance document (6), example 3).

Since the skilled person, trying to solve the problem related to the patent in suit, thus knows document (6)

and its teaching, the board can only conclude that the subject-matter of claim 1 of the main request does not involve an inventive step.

- 4.3 Even if it were assumed that the synergistic effect was successfully demonstrated in the patent in suit, the board could not come to any other conclusion.

In document (6) it is disclosed that simultaneous administration of praziquantel with other anthelmintics results in enhanced efficacy in the control of cestodes in domesticated animals. Praziquantel alone had already been used for many years to control cestode infestations (see document (6), page 2, lines 8 to 13).

This "enhancement of efficacy" does not relate to the activity of praziquantel on other helminths, since the authors see the activity on other helminths as a further, additional effect. They refer to "improved efficacy in the control of cestodes, **together** with simultaneous control of nematode infestations" (see document (6), page 2, lines 12 and 13; emphasis added by the board).

One of the "other helminthics" to be used from the teaching of document (6) is ivermectin in its property of an avermectin-related compound (see page 1, lines 16 to 18). It is reported to be inactive against tapeworms (cestodes) as a single compound. In these circumstances, the enhancement of the efficacy of praziquantel with respect to cestodes through being used together with ivermectin necessarily reflects more than the addition of the effects of the single compounds; in other words, there is a synergistic effect.

4.4 In claim 1 of auxiliary request 2 the wording "a synergistically effective amount of" refers to a particular way in which the avermectins or milbemycins should interact in the medicament to be prepared, that is synergistically. It may be introduced as a functional feature because it is assumed that, as soon as synergism is involved and disclosed in the patent in suit, it would only be routine work for the skilled person to find out the quantities of the synergistic compound that would work. As a consequence, this functional feature, added to a claim merely as a verbal description of the assumed interaction of the actives, cannot by itself be considered to contribute to inventive step in the present case.

Since the addition of the wording "a synergistically effective amount of" is the only difference in claim 1 of auxiliary request 2 with respect to claim 1 of the main request, the reasoning leading to the conclusion of lack of inventive step applies *mutatis mutandis* to claim 1 of auxiliary request 2.

4.5 In the circumstances of the case, the arguments of the appellant cannot succeed:

4.5.1 The appellant argued that in the description of trial 1 (example 10 of the patent in suit) and trial 2 (example 11 of the patent in suit) the dosages to be administered were set out separately from the information about the "formulation", the word "formulation" meaning the combination of excipients administered with respect to the pastes or drenches of examples 1 to 9.

The first two sentences following each of the headings "Trial 1" and "Trial 2" concerned the dosages, namely 0.2 mg/kg abamectin or ivermectin (first sentence) and ranges from 0.1 to 5 mg/kg and 0.5 to 2 mg/kg praziquantel (second sentence), which corresponded to the data in the tables. The addition "and formulations in accordance with examples ..." referred only to the composition of excipients and not to the concentrations of actives in the pastes or drenches.

The board cannot agree for the following reasons:

Each of the descriptions of the trials in the tables clearly consists of three parts: administration of abamectin or ivermectin alone, administration of praziquantel alone in different dosages, and administration of the mixed actives in a constant dosage of 0.2 mg/kg of abamectin or ivermectin and a variable dosage of praziquantel (see tables).

These three parts are reflected by the paragraphs following the headings "Trial 1" and "Trial 2", beginning with a description of the administration of the medicament containing pure abamectin or ivermectin, followed by the range of dosages in the administration of pure praziquantel and ending in the description of the administration for the medicaments containing mixed actives by reference to the examples 1, 2, 3, 4 and 5 and to 6, 7 and 8 respectively.

Thus the information about dosages of abamectin or ivermectin and praziquantel in the medicaments containing one single active cannot be transferred to

the dosages for the medicaments containing mixed actives.

Additionally, this argumentation of the appellant cannot explain the further statements in the application as filed on the administration of the pastes or drenches produced in examples 1 to 9 (see the titles of the tables and the wording "A high level of efficacy ..." as set out above under point 3.2 of this decision).

Finally, even if this argumentation were successful, the board's arguments set out under point 4.3 of this decision, assuming acknowledged disclosure of synergism in the teaching of the patent in suit, would still prevent it from being maintained.

4.5.2 The appellant submitted that in the whole of (6) there was no particular information indicating that the activity of praziquantel really could be enhanced with respect to the treatment of *A. perfoliata* infestations in horses (which could be synonymous with claiming a synergistic effect). The trials in document (6) were all performed on lambs and thus were directed to specific helminths in sheep. The efficacy of the coadministration of praziquantel with other anthelmintic agents was shown only with respect to the clearance of one or a plurality of species being resistant to other medicaments, and there were no experiments comparing the mixture with the single actives alone.

This argumentation, however, only meets the case, when a synergistic effect could be considered a reality,

despite the discrepancies in the examples preventing the disclosure of the application as filed from being regarded as evidence of such an effect.

Nevertheless if the board were to believe that a synergistic effect exists with regard to the teaching of the patent in suit without corroborating evidence, it would have also to believe that a synergistic effect is set out in document (6).

However and in contrast to this argumentation, where a synergistic effect is not acknowledged with respect to the patent in suit, there is no need for proof of such an effect in the prior art either. The mere existence of compositions containing praziquantel and avermectins or milbemycins together and their use in the same technical field render the teaching of the patent in suit obvious.

- 4.5.3 Another of the appellant's arguments was that in view of the teaching of document (2) the skilled person had no reason to enhance praziquantel containing medicaments by adding another anthelmintic, because in document (2) the efficacy of praziquantel was praised and only a reduction of the dosage was envisaged (see (2), page 3, left column, last paragraph).

The board cannot agree with that either:

In document (2), the need for further research in order to reduce the dose rate of praziquantel is addressed. The author sees a possibility in ensuring the efficacy of the lower dosages of praziquantel alone. The person skilled in the art reading this document, however,

knows about other possibilities from the prior art and, in particular with regard to document (6), will also take into account the fact that an additional anthelmintic may have the same effect of improved efficacy. In any case, it is obvious to try coadministration.

5. Thus the subject-matter of auxiliary requests 1, 3 and 4 does not meet the requirements of Article 123(2) EPC, and the subject-matter of the main request and auxiliary request 2 does not meet the requirements of Article 56 EPC.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald