

Internal distribution code:

- (A) [] Publication in OJ
(B) [X] To Chairmen and Members
(C) [] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 3 December 2008**

Case Number: T 1107/06 - 3.3.04

Application Number: 99203920.6

Publication Number: 1005867

IPC: A61K 38/16

Language of the proceedings: EN

Title of invention:

Botulinum toxins for modulating cholinergic controlled secretions

Patentee:

ALLERGAN, INC.

Opponent:

Société de Conseils de Recherches et d'Applications Scientifiques (S.C.R.A.S.)

Headword:

Botulinum toxins/ALLERGAN.

Relevant legal provisions:

EPC Art. 56, 76, 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main Request: added subject-matter (no); inventive step (no)"
"First Auxiliary Request: added subject-matter (no): subject-matter of disclaimer originally disclosed; inventive step (yes)"

Decisions cited:

G 0010/91, G 0001/93, G 0007/95, G 0001/03, G 0002/03,
T 0004/80, T 0002/81, T 0080/85, T 0322/87, T 0278/88,

T 0448/93, T 0098/94, T 0673/94, T 0615/95, T 0323/97,
T 0451/99, T 0507/99, T 1050/99, T 0860/00, T 1102/00,
T 1139/00, T 0236/01, T 0948/02, T 0435/04, T 0868/04,
T 0601/05, T 0795/05, T 1559/05

Catchword:

A disclaimer does not infringe Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed (see points 29-49).



Case Number: T 1107/06 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 3 December 2008

Appellant: Société de Conseils de Recherches et
(Opponent) d'Applications Scientifiques (S.C.R.A.S.)
42, rue du Docteur Blanche
F-75016 Paris (FR)

Representative: Morf, Jan Stefan
Abitz & Partner
Patentanwälte
Postfach 86 01 09
D-81628 München (DE)

Respondent: ALLERGAN, INC.
(Patent Proprietor) 2525 Dupont Drive
Irvine CA 92612 (US)

Representative: Klusmann, Peter Dr.
HOFFMANN EITLE
Patent- und Rechtsanwälte
Arabellastrasse 4
D-81925 München (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
12 May 2006 concerning maintenance of European
patent No. 1005867 in amended form.

Composition of the Board:

Chair: U. Kinkeldey
Members: R. Gramaglia
R. Moufang

Summary of Facts and Submissions

I. European patent No. 1 005 867 (application No. 99203920.6) entitled "Botulinum toxins for modulating cholinergic controlled secretions" was filed as a divisional application of EP 95906674.7, published as WO 95/17904 (hereafter "the parent application").

II. Notice of opposition was filed by the opponent requesting the revocation of the European patent on the grounds of Articles 100(a) and (b) EPC for lack of inventive step and insufficiency of disclosure. By an interlocutory decision dated 12 May 2006 the opposition division came to the conclusion that the patent could be maintained on the basis of the claims of the first auxiliary request (6 claims) then on file, of which claims 1 and 2 read as follows:

"1. The use of a botulinum toxin for the manufacture of a medicament for the reduction of a cholinergic controlled or cholinergic influenced secretion."

"2. The use of a botulinum toxin according to claim 1 for the manufacture of a medicament for the treatment of lacrimation."

Claims 3 to 6 were dependent on claim 1.

III. The appellant (opponent) lodged an appeal against the decision of the opposition division.

IV. The following documents are referred to in the present decision:

- E2: Brodtkorb E. et al., J. Mental Deficiency Res., Vol. 32, pages 233-237 (1988);
- E4: Mikhailov V.V. et al., Vopr. Med. Khim., Vol. 27, No. 3, pages 317-320 (1981) and English translation thereof;
- E5: Carruthers J.D.A. et al., J. Dermatol. Surg. Oncol., Vol. 18, pages 17-21 (1992);
- E8: Rossetto O. et al., in "Handbook of Botulinum Toxin Treatment" edited by P. Moore et al., 2nd edition, Blackwell Science, pages 9-14 (2003);
- E9: Kerner J., Das Fettgift oder die Fettsäure und ihre Wirkungen auf den thierischen Organismus, ein Beytrag zur Untersuchung des in verdorbenen Würsten giftig wirkenden Stoffes, Cotta'sche Buchhandlung, Stuttgart, Tübingen (1822);
- D1: Adenis J.P. et al., J. Fr. Ophtalmol., Vol. 13, No. 5, pages 259-264 (1990);
- D2: Ambache, N., J. Physiol., Vol. 113, pages 1-17 (1951);
- D3: Schantz, E.J. et al., Microbiological Reviews, Vol. 56(1), pages 80-99 (1992);
- D4: Jankovic, J. et al., New England Journal of Medicine, Vol. 324(17), pages 1186-1194 (1992);

- D5: Saga, T. et al., Jpn. J. Ophthalmol., Vol. 34, No. 1, pages 30-35 (1990);
- D6: Laccourreye, O. et al., Laryngoscope, Vol. 100, page 651-653 (1990);
- D7: Harper, K.E. and Spielvogel, R.L., International Journal of Dermatology, Vol. 25, pages 524-526 (1986);
- D8: Wainwright, R.B. et al., J. Infect. Dis., Vol. 157, pages 1158-1162 (1988);
- D9: Webster's New World College Dictionary, Fourth Edition;
- D10: MEDLINE Abstract of D11;
- D11: Price J. et al., Journal of Clinical Neuro-ophthalmology, Vol. 13, No. 1, pages 67-71 (March 1993).

V. Documents D1 to D9 were filed by a third party who submitted observations under Article 115(1) EPC. In response to these third party observations, the respondent (patentee) who had requested dismissal of the appeal (Main Request) filed a First to Fourth Auxiliary Requests. Claim 1 of the First Auxiliary Request read as follows:

"1. The use of a botulinum toxin for the manufacture of a medicament for the reduction of a cholinergic

controlled or cholinergic influenced secretion, wherein the secretion is not lachrimation."

Claims 2 to 5 were dependent claims. Claim 2 of the set of claims upheld by the opposition division had been deleted.

- VI. During the first oral proceedings of 14 March 2008, document D1 was considered by the board as representing the closest prior art for claim 1 underlying the Main Request, i.e., claim 1 of the set of claims upheld by the opposition division (see paragraph II supra). In order to show that the disclosure of document D1 was not correct, the respondent (patentee) introduced new documents D10 and D11 (the latter being the full paper for the abstract D10), which, in the respondent's view reported experimental results in contrast to the results in document D1. The board thus closed these oral proceedings, went into written proceedings again and set a four month period for the parties to file further submissions in view of these documents.
- VII. Further oral proceedings were held on 3 December 2008.
- VIII. The appellant's arguments insofar as they are relevant for the present decision may be summarised as follows:

Main request

Articles 76 and 123(2) and (3) EPC

- The reference to a reduction on page 17, line 5 of the original parent application was only made in the context of a specific example. The term "reduction" in present claim 1 thus represented a generalization

in contravention of Articles 76 and 123(2) EPC. Moreover, claim 1 of the parent application was limited to botulinum toxin (hereafter: BTX) A, unlike the present claim. Finally, the term "for the reduction" in claim 1 infringed Article 123(3) EPC because granted claim 1 read "for the treatment".

Novelty (Article 54 EPC)

- Claims 1 and 2 of the set of claims underlying the main request lacked novelty over document D1.

Inventive step (Article 56 EPC)

- The claimed use of BTX was obvious in view of document D1. According to this document, there was a decrease in lacrimal secretion on the BTX A-treated side of patients suffering from hemifacial spasms. The authors of document D1 concluded that BTX A could be used for the treatment of epiphora (excessive lacrimation). Therefore, the teaching in document D1 provided an obvious incentive for the medical treatment according to claim 2 of lacrimation (which was an example of "cholinergic influenced secretion" referred to in claim 1).
- The teaching of document D11 could not be regarded by the skilled person as being in contradiction to the disclosure of document D1. There was no disclosure in document D11 of the specific way BTX was applied, in contrast to document D1. Thus the different results might have been caused by a different location of injections. More importantly,

tear secretion for hemifacial spasm patients after BTX treatment had not been discussed in document D11.

First auxiliary request

Article 123(2) EPC

- The disclaimer in claim 1 "wherein the secretion is not lacrimation" was not allowable since it had not been originally disclosed and it did not comply with the requirements set out in decisions G 1/03 and G 2/03.

Inventive step (Article 56 EPC)

- Document D1 disclosed the use of BTX to reduce one specific cholinergic controlled or cholinergic influenced secretion, namely lacrimation. BTX was known to be an anticholinergic drug (see, e.g., page 67, right hand column, first paragraph of document D11). The use of BTX for the reduction of mucus secretion and gastrointestinal secretion was thus made obvious by document D1 alone in the light of the common general knowledge of the anticholinergic properties of BTX.
- On the one hand, document E2 disclosed the use of anticholinergic drugs to reduce drooling and salivation. Drooling and salivation were examples of mucus secretion. On the other hand, document D1 disclosed the use of BTX, an anticholinergic molecule (see, e.g., page 67, right hand column, first paragraph of document D11) to reduce one specific cholinergic controlled or cholinergic influenced secretion, namely lacrimation. The use of

BTX for the reduction of mucus secretion and gastrointestinal secretion was thus rendered obvious by the combination of documents E2 and D1.

- Document E4 showed that BTX reduced the secretion of saliva based on the same anticholinergic effect. Document E2 disclosed the use of anticholinergic drugs to reduce drooling and salivation. Therefore, the skilled person would have combined the teachings of both documents, and replaced scopolamine by BTX in order to reduce drooling and salivation. The skilled person would also have reduced the toxic levels of BTX disclosed in document E4 to the therapeutically active and acceptable amounts disclosed in document E5.
- Regarding the claimed reduction of mucus secretion, document E9 also disclosed on page XIX, third and fourth lines from the bottom, that BTX inhibited gastrointestinal secretions.
- The patent lacked evidence that BTX was indeed effective for the treatment of excessive mucus secretion and gastrointestinal secretion. Example 1 dealt with excessive sweating (a more favourable situation than excessive mucus secretion and gastrointestinal secretion).

IX. The respondent's arguments insofar as they are relevant for the present decision may be summarised as follows:

Main request

Articles 76 and 123(2) and (3) EPC

- The wording "for the reduction" in claim 1 found a basis in claim 1 of the original parent application in combination with page 17, line 5 thereof.

Novelty

- Novelty was a fresh ground of opposition which could not be introduced into the proceedings. In any case, facial spasms and lacrimation were not intertwined. In document D1, lacrimation was merely a secondary side effect whereas claim 1 was directed to the treatment of lacrimation in general. Epiphora was not equivalent to excessive lacrimation and had a range of reasons. Excessive tear production was usually a result from an irritation of the eye.

Inventive step

- The skilled person would not have turned to document D1, relating to treating facial spasms, not to reducing a cholinergic controlled or cholinergic influenced secretion.
- The authors of document D1 reported the reduction of lacrimation as an incidental effect when treating hemifacial spasms and blepharospasm with BTX. However, it was clear to the skilled person that the Schirmer test data set out in Table 1 of document D1 were inconclusive (for more detail see points 14 to 26 of the reasons).
- The skilled person would have known that the speculations in document D1 (reduction of lacrimation upon treatment with BTX) were erroneous

upon reading document D11, showing that the treatment of hemifacial spasms and blepharospasm with BTX had no impact on lacrimation.

First auxiliary request

Article 123(2) EPC

- The disclaimer in claim 1 was allowable since the subject-matter to be excluded from protection had been originally disclosed.

Inventive step

- Document D1 could not render obvious any other uses of BTX than those mentioned in document D1, namely the uses in the context of controlling or preventing facial spasms and lacrimation in the context of facial spasms.

- X. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 1 005 867 be revoked.

The respondent (patentee) requested that the appeal be dismissed (main request) or, in the alternative, that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the 1st Auxiliary Request filed with letter dated 2 January 2008.

Reasons for the Decision

Articles 76 and 123(2) and (3) EPC

1. The appellant maintains that present claim 1 contains added subject-matter because of the presence of the term "for the reduction". It is argued that the reference to a reduction on page 17, line 5 of the original parent application was only made in the context of a specific example and that the term "reduction" in present claim 1 thus represents a generalization infringing Articles 76 and 123(2) EPC.

However, the expression "in order to reduce the secretion" in claim 1 of the parent application as filed represents a basis for the term "for the reduction" in present claim 1.

It is also argued by the appellant that claim 1 of the parent application was limited to BTX A, whereas the present claim no longer comprises said limitation.

However, in the board's view, the skilled person would nevertheless derive from page 4, line 23 and from page 5, lines 23-33 of the parent application that BTX B, C, D, E, F and G can also be used instead of BTX A.

Finally, the appellant maintains that the term "for the reduction" in claim 1 infringes Article 123(3) EPC because granted claim 1 read "for the treatment".

However, since the term "for the reduction" is more restricted than the wording "for the treatment" (i.e.,

it represents a special case of treatment), no broadening of the scope of granted claim 1 occurs.

Novelty (Article 54 EPC)

2. The appellant argued lack of novelty on the basis of document D1. However, the board notes that the appellant based its opposition only on lack of inventive step and lack of enabling disclosure and that the opposition division did not introduce into the proceedings an objection under Article 54 EPC of its own motion. During the oral proceedings, the respondent did not agree to the introduction into the proceedings of this fresh ground of opposition. Therefore, in the light of decision G 10/91 (OJ EPO 1993, 421) and G 7/95 (OJ EPO 1996, 626), the board is not allowed to consider the new ground.

Inventive step (Article 56 EPC)

Claims 1 and 2

Closest prior art

3. Present claim 1 is under the form of a second/further medical use of BTX. The medical use of BTX stated in claim 1 is the reduction of a cholinergic controlled or a cholinergic influenced secretion. An example of said cholinergic controlled or cholinergic influenced secretion is lacrimation (see claim 2). The main medical use for BTX A disclosed in document D1 is the treatment of facial spasms and blepharospasm and the authors of document D1 indeed performed a series of investigations on the use of BTX type A in the treatment of these pathological conditions (see page 260, 1-h column, under "RESULTATS").

4. The potential impact of such treatment on lacrimation was also considered. The discussion of lacrimal secretion in document D1 is based on Schirmer tests. These tests are based on the use of standardized paper strips (inserted into the eye conjunctival sac for several minutes) to measure the production of tears as the distance expressed in mm reached by the liquid front. The Schirmer tests described in document D1 were performed on a patient group before and after monolateral (c.f. "d'un seul côté" on page 261, paragraph 2 (a)) injection of BTX A to alleviate hemifacial spasms. The amount of tearing was measured on both the healthy and the sick sides of the face, the test data being reported in "Tableau I" on page 261 of document D1.

5. In the light of these test results, the authors of document D1 propose (see the Abstract) the use of BTX A for the treatment of epiphora ("larmoiments invalidants"). Epiphora is an excessive tear production which may have many origins. For instance, it may be the result of an irritation of the mucosa of the eye by external agents such as dust or pollen, or it may be linked to blink reflex (see page 67, last paragraph of r-h column of document D11). In conclusion, the term "epiphora" in document D1 is broader than the specific term "cholinergic controlled or cholinergic influenced lacrimation" (see claim 2 referring back to claim 1).

6. The respondent argues that the skilled person would not turn to document D1 as closest prior art because it related to treating facial spasms and not to reducing a cholinergic controlled or cholinergic influenced secretion such as lacrimation.

However, the board does not agree with the respondent because claim 2 relates to BTX and the treatment of lacrimation and document D1 also deals with BTX and pathologies affecting the eyes and hence lacrimation (c.f. "J. Fr. Ophthalmology" and Fig. 2 of document D1).

7. Thus document D1 represents the closest prior art for the subject-matter of claim 2 as maintained by the opposition division.
8. The therapeutic agent (BTX) being the same, the difference between the invention stated in claim 2 and the teaching in document D1 lies in the fact that claim 2 referring back to claim 1 relates to the reduction of cholinergic controlled/influenced lacrimation, whereas document D1 deals with reducing lacrimation in general (see point 5 supra). The problem to be solved can be defined as identifying a clinical situation wherein lacrimation can successfully be treated with BTX. The proposed solution is the treatment of cholinergic controlled/influenced lacrimation.
9. The respondent argues that document D1 could not render obvious any use of BTX other than that of preventing facial spasms and lacrimation in the context of facial spasms. In other words, the skilled person would not be encouraged to extend this treatment in situations other than those of hemifacial spasms.
10. However, even by deciding in favour of the respondent that the teaching of document D1 is limited to the treatment of hemifacial patients, the board notes that the present formulation of claim 2 referring back to

claim 1 does not exclude patients suffering from hemifacial spasms. The only question left is thus whether or not document D1 provided an incentive to the skilled person to go in the direction of treating with BTX the special case of cholinergic controlled/influenced lacrimation referred to in claim 2 referring back to claim 1.

11. "Tableau I" of document D1 discloses a more than 25 % decrease in tearing (see point 18 below) of the sick side Vs. the healthy side in patients suffering from hemifacial spasms, after a first BTX A injection at the sick side only.
12. The board thus considers that document D1 provided such clear experimental evidence showing a reduction of tear secretion upon BTX injection around the eye that the skilled person was induced to treat excessive lacrimation of **any** origin with BTX, including what has been termed "cholinergic controlled/influenced lacrimation" in claim 2 referring back to claim 1. This board's conclusion is in keeping with the statement by the authors of this document "...essayer ce traitement dans les larmoiements invalidants..." (see end of the Abstract).
13. The respondent argues that the skilled person would have considered the Schirmer test data set out in "Tableau I" of document D1 as inconclusive for the reasons explained in detail below.
14. The first of the respondent's criticisms is that the authors of document D1 themselves acknowledged that the Schirmer test data set out in "Tableau I" of D1 were

not meaningful (see page 261, paragraph 2 (a): "Les chiffres des tests de Schirmer étant très disparates, il n'est pas possible de les étudier").

15. The board does not agree with the respondent's view above. The statement by the authors of document D1 about the variability and hence the poor utility of the Schirmer test data related to Schirmer test data **in general**, not to the particular situation under investigation. In fact, these authors went on to state (see *ibidem*) that (in spite of the variability/poor utility of the Schirmer test data in general) it was interesting to measure the amount of tearing on both the healthy and sick sides of the face in the case of patients suffering from hemifacial spasms, namely presenting a healthy side and a sick side.
16. In the board's opinion, this particular situation (hemifacial spasm patients) and test design (monolateral injection) rendered possible the measure of the **difference** in tearing between the injected side and the healthy (non-injected) side (see the term "différence" on page 261, r-h column, line 7 from the bottom and page 262, l-h column, line 5), without (or with reduced) interference originating from the inter-patient/inter-group variability, as the yardstick against which lacrimation had to be measured was the eye on the healthy (non-injected) side and nothing else.
17. The second respondent's line of argument is that the Schirmer test data described in document D1 were based on the total amount of lacrimation for the entire group and that such cumulative representation of the data would have easily been misread by the skilled person.

It is also argued by the appellant that the number of patients involved in the experiment was not statistically sufficient (only 8 patients after the 3rd injection).

18. The board cannot adhere to the above respondent's opinion since the essence of the test was to measure the **difference** in tearing between the injected side and the healthy (non-injected) side (see point 16 supra). Therefore, said difference remains unchanged whether referred to a group of patients or to a single patient (compare, on the one hand, e.g. the third line of "Tableau I" on page 261 of document D1: "Nombre de cas" = 30; "Côté sain" = 333; "Côté malade" = 220 => difference (e.g. cumulative % decrease in tearing of the sick side Vs. healthy side for 30 patients) = $100 - [220/333] \times 100 = 34\%$, with, on the other hand, the third line of the conversion table submitted by the respondent with the letter dated 14 July 2008 (see page 2): Healthy side per patient = 11.1; Sick side per patient = 7.33 => difference (e.g. % decrease in tearing of the sick side Vs. healthy side for one patient) = $100 - [7.33/11.1] \times 100 = 34\%$). As for the respondent's criticism that the number of patients involved in the experiment was not statistically sufficient (only 8 patients after the 3rd injection), this objection is also not convincing since "Tableau I" of document D1 discloses a minimum of 25 % decrease in tearing of the sick side Vs. the healthy side already after the 1st injection practiced on 30 patients.
19. It is also the respondent's view that the conversion table (wherein the "cumulative data" of the tableau of document D1 had been converted into "lacrimation per

patient") submitted by the respondent with the letter dated 14 July 2008 (see page 2), showed that the data of "Tableau I" on page 261 of document D1 were inconclusive on the following grounds:

- A) Healthy patients and patients suffering from hemifacial spasm did not have the same lacrimal secretion. The lacrimal secretion in patients suffering from hemifacial spasms was lower.
- B) In patients suffering from hemifacial spasm, the lacrimation on the sick side was larger than that on the healthy side. The lacrimation on the sick side was similar to that of a healthy patient.
- C) Injection of BTX on the sick side increased lacrimation on the healthy side. On the healthy side, lacrimation increased after each injection of BTX.
- D) On the sick side, lacrimation decreased upon a first injection, but was restored to about normal after the second injection. A third injection then reduces lacrimation again. Thus, on the sick side, BTX could have both a reducing and an increasing or no effect on lacrimation.
- E) The overall lacrimation increased upon the treatment of hemifacial spasms with BTX.

20. In grounds A) and B) above, the respondent compares the lacrimal secretion in patients suffering from hemifacial spasms with that of "healthy patients". However, given that all the patients listed in

"Tableau I", including the control ("Témoin") have a sick side ("Côté malade"), no such healthy patients are at stake in the tests reported in "Tableau I" of document D1. Grounds A) and B) thus already fail on this deficiency and do not deserve any further consideration.

21. As for grounds C), D) and E) above, the essence of the Schirmer tests as described in document D1 is to measure the difference in tearing between the injected sick side Vs. the healthy (non-injected) side. For the reasons highlighted under point 16 supra, the "vertical" variations across "Tableau I" (grounds C and D) pointed out by the respondent are no longer critical, unlike the "horizontal" comparison (sick side Vs. healthy side). Moreover, it is clear that anything other than this comparison, such as the "overall lacrimation" emphasized by the respondent in ground E above is not relevant, be it "horizontal" or "vertical".

22. Finally, the respondent emphasized a discrepancy between the data in "Tableau I" (333 mm for the healthy side and 220 mm for the sick side after the first injection) and the data in the text of document D1 (358 mm for the healthy side and 235 mm for the sick side; see paragraph bridging pages 261 and 262), further casting doubts about the scientific quality of this reference.

However, the data in the text, teaching a $100 - [235/358] \times 100 = 35\%$ decrease in tearing of the sick side Vs. the healthy side (after the first injection), confirm rather than contradict "Tableau I" ($100 - [220/333] \times 100 = 34\%$).

Document D11

23. Document D11 has been introduced by the respondent in order to show that the treatment with BTX of hemifacial spasms or blepharospasm had no impact on lacrimation, in contrast to the results reported in document D1.

24. The authors of D11 departed from the finding that patients suffering from blepharospasm had a lower lacrimal secretion compared to their control group (see page 69, l-h column, penultimate paragraph). The idea behind their investigation was thus to try to improve this condition of dry eyes by the treatment with BTX toxin, a goal which eventually could not be achieved (see page 70, r-h column, first paragraph).

25. It is also stated in document D11 that "... all blepharospasm patients and hemifacial spasm patients had their tear production tested with the Schirmer test strips prior to each botulinum treatment and at 1 week..." (see page 68, r-h column, lines 10-14).

26. However, the board observes that document D11 contains major data relating to the measure of tear secretion before and after BTX treatment only for blepharospasm patients (see page 69, r-h column, second paragraph). Nothing is said about patients suffering from hemifacial spasms, so that document D11 does not contain any data relating to the measure of tear secretion before and after BTX treatment for patients suffering from hemifacial spasms, let alone a clear comparison between the tearing of the injected side and the healthy (non-injected) side of the faces of these

patients (see point 16 supra). Therefore, the skilled person coming across document D11 cannot draw any conclusion as to what effect a treatment with BTX exerts on tear secretion in patients affected by hemifacial spasms.

Moreover, in contrast to document D1 (see Fig. 2 on page 260), document D11 does not disclose the specific way BTX toxin is applied and in which parts of the face it is injected. Thus, the skilled person could assume that the different effects described in D11, if any, might be caused by a different location of the injection(s).

In conclusion, the skilled person would not perceive the disclosure of document D11 to be in contradiction to that of document D1.

27. In summary, none of the objections raised by the respondent for questioning the scientific validity of document D1 convince the board.
28. Since the board arrived at the conclusion (see point 12 supra) that the teaching in document D1 provided the skilled person with a strong incentive to treat excessive lacrimation of **any** origin with BTX, including what has been termed "cholinergic controlled/influenced lacrimation" in claim 2 referring back to claim 1, claim 2 lacks an inventive step. Since the embodiment of claim 2 falls within the frame of claim 1, the latter also lacks an inventive step. The main request comprising not allowable claims 1 and 2 is thus refused.

First auxiliary request

Article 123(2) - disclaimer

29. Claim 1 of the first auxiliary request contains the disclaimer "wherein the secretion is not lacrimation". The appellant maintains that this disclaimer does not comply with the requirements of Article 123(2) EPC.
30. Example 5 of the patent application as filed is concerned with the use of botulinum toxin in the treatment of excessive cholinergic controlled or influenced secretions. It has the title "The Use of Botulinum toxin Types A-G in the Treatment of Excessive Sweating, Lacrimation or Mucus Secretion or Other Cholinergic Controlled Secretions". After mentioning the treatment of a patient with excessive sweating and indicating dosage and administration regimens, the following is stated (page 7, lines 32-36, of the published "A2" application):

"Excessive sweating, tearing (lacrimation), mucus secretion or gastrointestinal secretions are positively influenced by the cholinergic nervous system. Sweating and tearing are under greater cholinergic control than mucus or gastric secretion and would respond better to toxin treatment. However, mucus and gastric secretions could be modulated through the cholinergic system. All symptoms would be reduced or eliminated with toxin therapy in about 1-7 days."

It follows from this passage that there is a specific disclosure of the use of botulinum toxin in the treatment of lacrimation in the application as filed.

However, this use is described in positive terms as part of the invention, not in negative terms as something to be excluded from it. Therefore the appellant argued that the disclaimer as such is not originally disclosed and could only be justified if it fell under any of the exceptions accepted in decisions G 1/03 and G 2/03 of the Enlarged Board of Appeal (OJ EPO 2004, 413 and 448).

31. Prior to the above-cited decisions, it was widely accepted that a disclaimer could in principle be allowed when **the subject-matter to be excluded was disclosed** in the European patent application as filed as an embodiment of the invention. This principle emerged from the very first decision allowing the introduction of a disclaimer into a claim. The relevant passages of this decision (T 4/80, OJ EPO 1982, 149) are as follows:

"2. [...] The features of the current Claim 1, apart from the disclaimer [...] are supported in Claim 1 as first published. The subject-matter expressly excluded from protection and defined by the technical features in accordance with Rule 29(1) EPC, namely the use of formoses produced directly from synthesis gases containing formaldehyde, was originally disclosed by the applicant as a possible, particularly economical embodiment of the invention [...].

3. At the request of the applicant, such subject-matter can subsequently be excluded from the protection sought by a wide claim by means of a disclaimer, if the subject-matter remaining in the

claim cannot be defined more clearly and concisely directly, i.e. by positive technical features (Art. 84 EPC). Those conditions are satisfied in this case. [...]

4. The fact that the disclaimer in part concerns the subject-matter of an earlier, not previously published national application or corresponding patent is no bar to such a formulation. [...]."

According to the understanding of the present board, the decision thus justified the allowability of the disclaimer not by its purpose, but by the fact that the subject-matter to be excluded was originally disclosed by the applicant as a possible embodiment of the invention.

32. The principles developed in decision T 4/80 were applied or cited with approval in several other decisions (see e.g. T 80/85 of 12 March 1987, point 3; T 98/94 of 13 July 1995, point 2.3; 673/94 of 7 May 1998, point 3). An illustrative example is the following passage in decision T 448/93 of 24 November 1994 (point 2.2):

"The established jurisprudence of the Boards of Appeal, see e.g. T 4/80 OJ EPO 1982, 149, is that originally disclosed subject-matter may be excluded from a wider claim by a disclaimer if the subject-matter remaining in the claim cannot technically be defined directly (positively) more clearly and concisely."

33. It is well-known that the European practice and case law concerning disclaimers in general was put into question by the decision T 323/97 (OJ EPO 2002, 476) which considered that all disclaimers have to strictly comply with the prohibition of adding subject-matter contained in Article 123(2) EPC. However, even in this decision the principle that an embodiment "positively" disclosed in the application as filed can be disclaimed appears not to have been questioned as it follows from the following passage in point 2.4.1 of the reasons:

"Moreover, the reference to decision T 4/80 appears to concern solely the 'formal' admissibility of a disclaimer used to exclude from a patent claim subject-matter **originally disclosed** as a particular embodiment of the invention. T 4/80 confirmed that an **embodiment of an invention specifically disclosed in an application as filed** can be deleted from a claim by means of a disclaimer, if '... the subject-matter remaining in the claim cannot be defined more clearly and concisely directly [...].'. This, together with the fact that Article 123(2) is not mentioned, shows that the admissibility of disclaimers is dealt with in decision T 4/80 only with respect to the issue of clarity." [emphasis added]

34. The strict approach adopted in decision T 323/97 with respect to disclaimers in general caused two other boards to refer questions of law to the Enlarged Board. The first of these referral decisions, T 507/99 (OJ EPO 2003, 225), contains a thorough analysis of the development of the EPO case law on disclaimers and

submitted three questions to the Enlarged Board.

Question 1 was worded as follows:

"Is an amendment to a claim by the introduction of a disclaimer unallowable under Article 123(2) EPC for the sole reason that neither the disclaimer **nor the subject-matter excluded by it** from the scope of claim have a basis in the application as filed?" [emphasis added]

It already follows from the wording of this question that the decision T 507/99 started from the premise that a disclaimer may only arguably infringe Article 123(2) if the application as filed contains no basis for it, neither in negative terms (i.e. if it was disclosed as not being part of the invention) or in positive terms (i.e. if it was disclosed as an embodiment of the invention). The referral decision was therefore only made after ascertaining whether a basis, be it "negative" or "positive", could be found in the case at hand:

"Neither the disclaimers as such **nor the excluded subject-matter** have been regarded by the Board as being disclosed in the application as filed [...]."(point 3 of the reasons, emphasis added).

35. In the second referral decision, T 451/99 (OJ EPO 2003, 334), the present board, in a different composition, referred the following question to the Enlarged Board:

"Is the introduction into a claim of a disclaimer not supported by the application as filed admissible, and therefore the claim allowable

under Article 123(2) EPC, when the purpose of the disclaimer is to meet a lack-of-novelty objection pursuant to Article 54(3) EPC?"

The term "not supported" appears to have been used in that decision in order to encompass both a negative and a positive disclosure of the subject-matter to be excluded. This can be deduced from the following passages:

"Claim 1 as now worded refers to two specific groups of peptides: those which possess the generically defined features, but of which 13 are excepted, and those 13 which, while also possessing these features, are nonetheless excluded from protection by means of a disclaimer. **Neither of these two groups** is explicitly identified in the application as filed. [...]"
(point 4 of the reasons, emphasis added)

"Thus, following decision T 322/87 [...], the disclaimer in claim 1 now under consideration would not be allowable, because, as already mentioned in point 4 above, there is no specific mention in the application as originally filed of two groups of peptides: **the 13 peptides of document (1), now disclaimed**, and the remaining peptides embraced by the generic definition of the class of peptides." (point 24 of the reasons, emphasis added)

36. It follows from the above analysis that both referral decisions relied on the assumption that disclaiming subject-matter which was positively described as an

embodiment of the invention in the application as filed may comply with the requirements of Article 123(2) EPC: the questions referred were formulated in a way that no answer was requested concerning the allowability of a disclaimer in a situation where it had either a negative or a positive basis in the original disclosure.

37. In the decisions G 1/03 and G 2/03 the Enlarged Board addressed the issue of disclaimers in the framework of the questions referred to it. This limitation clearly transpires from a passage contained in point 2 of the reasons of both decisions:

"More specifically, the Enlarged Board of Appeal has to deal with the allowability of disclaimers which have not been disclosed in the application as filed. In this context, the term 'unsupported' disclaimer is used in T 451/99, the President's comments and third parties' observations. The expression 'unsupported' is avoided in the following reasons, since the term 'support' in Article 84 EPC has a different meaning. Instead, the expression undisclosed is used."

38. It is thus apparent that the legal analysis of the Enlarged Board was not concerned with situations where the application as filed provides sufficient basis for the disclaimer nor did it need to elaborate on the precise conditions under which such basis would have to be accepted.

The present board is unable to identify any passage in the Enlarged Board's opinion which would indicate or imply that the premise on which the referring boards

had framed their questions (i.e. that a disclaimer may be allowable under Article 123(2) EPC if its subject-matter was disclosed in negative or positive terms) was put into question. In particular it is noted that, as the above-cited passage shows, the term "undisclosed" was substituted for the term "unsupported" used in decision T 451/99 only for the reason of avoiding any confusion with the requirements of Article 84 EPC. The language chosen does therefore not imply that the term "undisclosed disclaimer" was meant to encompass situations where the subject-matter to be excluded was not disclosed negatively but only in positive terms, i.e. as an embodiment of the invention. Those situations were not within the ambit of the referral questions and it can safely be assumed that the Enlarged Board if it had intended to leave this ambit would have made this explicit in its reasons.

39. This understanding of the Enlarged Board's opinion finds further support in the wording and the structure of the answers given to the questions referred:

"1. An amendment to a claim by the introduction of a disclaimer may not be refused under Article 123(2) EPC for the sole reason that neither the disclaimer **nor the subject-matter excluded by it** from the scope of the claim have a basis in the application as filed.

2. The following criteria are to be applied for assessing the allowability of a **disclaimer which is not disclosed** in the application as filed: [...]" (emphasis added)

It is apparent that the answer no. 1 closely follows the wording of question no. 1 referred by decision T 507/99 (see point 34 above) and is therefore not concerned with a situation where the subject-matter to be excluded has a positive basis in the application. Furthermore, the necessary logical link between answer no. 1 and answer no. 2 implies that the term "disclaimer which is not disclosed" refers to the situation described in answer no. 1, i.e. to a situation where neither the disclaimer nor the subject-matter excluded by it has a basis in the application as filed.

40. The above understanding of the Enlarged Board's opinion is also reflected in the decision T 1139/00 of 10 February 2005 in which the competent board had to consider a claim to a balloon for a medical device which contained a disclaimer in respect of balloons made by a certain process. The application as originally filed did not place any importance on the method of manufacture of the balloon, and the only method specifically described was the one disclaimed. The board distinguished this situation from those considered by the Enlarged Board:

"It follows both from the questions put to the Enlarged Board as well as from the Order of G 1/03 that this decision concerns only situations where the subject-matter excluded from the scope of a claim did not have a basis in the application as filed. [...]

In the present case, by contrast, the subject-matter excluded by the disclaimer is supported by

the application as filed. The situation is, as expressed by respondent OII in its letter dated 29 September 2004, the opposite to that considered in G 1/03. Therefore, the present disclaimer is not one covered by the decision G 1/03. [...]" (points 2.3 and 2.5 of the reasons)

In the light of the decision G 1/93 (OJ EPO 1994, 541), the board went on to examine whether the disclaimer led to an unwarranted advantage of the patent proprietor, was damaging to the legal security of third parties, or provided a technical contribution to the subject-matter of the claimed invention. Reaching a negative conclusion on all these points, it held the disclaimer allowable under Article 123(2) EPC.

41. The view that a disclaimer may be acceptable if the excluded subject-matter has been originally disclosed in positive terms as an embodiment is also embraced by the Guidelines for Examination in the EPO (Part C, Chapter III, point 4.20):

"A claim's subject-matter is normally defined in terms of positive features indicating that certain technical elements are present. Exceptionally, however, the subject-matter may be restricted using a negative limitation expressly stating that particular features are absent. This may be done **e.g. to remove non-patentable embodiments disclosed in the application as filed (see T 4/80, OJ 4/1982, 149)** or if the absence of a feature can be deduced from the application as filed (see T 278/88, not published in OJ).

[...]

With respect to the allowability of a disclaimer not disclosed in the application as filed, see VI, 5.3.11." (emphasis added)]

42. The board is aware, however, that a more restrictive approach has recently emerged in the case law of the boards of appeal (see decisions T 1050/99 of 25 January 2005, points 2 to 7; T 1102/00 of 1 June 2004, point 4; T 236/01 of 15 September 2005, point 6; T 868/04 of 10 May 2006, point 3.4; T 795/05 of 13 December 2007, point 7.1; T 1559/05 of 15 November 2007, point 2.1). According to this approach disclaimers which exclude subject-matter disclosed as an embodiment of the invention are regarded as non-disclosed disclaimers and held unallowable unless they fall under one of the exceptions laid down in decisions G 1/03 and G 2/03. In order to decide whether the present board should adopt the same approach and thereby also depart from the prior established case, it is necessary to analyse the relevant arguments more closely.

43. In the decision T 1050/99 (see points 6 and 7 of the reasons) considerable weight is placed on a passage in the Enlarged Board's opinion in G 1/03 concerning disclaimers which exclude non-working embodiments. This passage (at point 2.5) starts as follows:

"2.5 Non-working embodiments

2.5.1 In some submissions, starting from the premise that a disclaimer is always a mere waiver of part of the invention, the consistent position

is taken that a disclaimer may be used for any purpose, ie also for excluding non-working embodiments. [...].

2.5.2 Disclaimers are, however, not to be allowed in this situation. If a claim comprises non-working embodiments, this may have different consequences, depending on the circumstances. [...]"

Nothing in this passage suggests that, as assumed in decision T 1050/99 (points 6 and 7), it concerns the exclusion of non-working embodiments that were specifically disclosed in the application as filed. As already set out above, the Enlarged Board restricted its analysis to so-called undisclosed disclaimers which, in the light of the questions referred, were not meant to include disclaimers excluding subject-matter originally disclosed as embodiments in positive terms.

44. A further argument made in order to support the restrictive approach is that in cases where a positively disclosed embodiment is later disclaimed it could not be inferred from the original disclosure that the applicant intended to exclude the subject-matter of the disclaimer from the scope of protection (see T 1102/00, point 4). Although this observation is correct in itself, it does not lead to the conclusion that the disclaimer necessarily fails for this reason to comply with Article 123(2) EPC. The fact that the technical teaching of an application as filed discloses subject-matter as part of the invention which is not comprised in the amended claim does as such not justify an objection under Article 123(2) EPC. To hold

otherwise would be in sharp contrast to the established case law which e.g. accepts that an applicant or proprietor may under certain conditions amend Markush formulae by "shrinking" the definitions of substituent groups. Reference is made to decision T 615/95 of 16 December 1997 which had allowed, under Article 123(2) EPC, deletions of one originally disclosed meaning from each of three independent lists of sizeable length, wherein each list specified meaning for different residues in a generic chemical formula defining the subject-matter of the main claim at issue in that case. Such deletions are considered allowable if they (1) do not result in singling out any hitherto not specifically mentioned individual compound or sub-class of compounds, but maintain the remaining subject-matter as a generic group of compounds differing from the original group only by its smaller size, and (2) do not lead to particular combination of specific meanings of the respective residues which was not disclosed originally, or in other words, do not generate another invention (see also decision T 948/02 of 5 April 2005, point 2.4.1). Thus, the mere fact that an amended claim encompasses less than what was originally disclosed as the subject-matter of the invention is per se not bad under Article 123(2) EPC.

45. The board therefore considers that the decisive question to ask in the present circumstances under Article 123(2) EPC is not whether the skilled person could infer from the original disclosure that the applicant intended to exclude the subject-matter of the disclaimer from the scope of protection. Rather it has to be ascertained whether there is a clear and unambiguous disclosure of the subject-matter remaining

in the claim. Applying the established yardstick to be used in the framework of Article 123(2) EPC, such disclosure may be explicit or implicit. Implicit disclosure includes what any person skilled in the art would consider necessarily implied by the patent application as a whole (see T 860/00 of 28 September 2004, point 1.1)

46. The board takes the view that when there is a generic disclosure of the invention together with a specific disclosure of an illustrative or preferred embodiment falling under the generic disclosure, the skilled person will normally imply that **all the other embodiments** comprised in the generic disclosure without being mentioned specifically **also** form part of the invention. The non-exemplified or non-preferred embodiments are thus implicitly disclosed as the logical complement of the exemplified or preferred embodiments.
47. In the present case, the original disclosure taught the skilled person that it could use botulinum toxin in the treatment of excessive cholinergic controlled or influenced secretions. The use of the toxin was described as particularly well-suited for the treatment of excessive sweating and lacrimation. The skilled person would therefore have understood that botulinum toxin can be used in the treatment of lacrimation as well as in the treatment of all other excessive cholinergic controlled or influenced secretions. The subject-matter of claim 1 of respondent's auxiliary request can thus be clearly and unambiguously derived from the application as originally filed.

48. The view expressed in the present decision finds further support in a number of decisions dealing with amendments of applications where both a general and a preferred range were originally disclosed. In such a situation, a combination of the preferred disclosed narrower range and one of the part-ranges lying within the disclosed overall range on either side of the narrower range is considered to be unequivocally derivable from the original disclosure of the patent in suit and thus supported by it (see T 2/81, OJ EPO 1982, 394 and the further decisions cited in Case Law of the Boards of Appeal of the EPO, point III.A.2.1, page 262, second full paragraph).

49. The board therefore comes to the conclusion that it should not embrace the restrictive approach adopted in the decisions cited under point 42 above but should continue to follow the prior established case law. Claim 1 of the respondent's first auxiliary request is thus considered to comply with the requirements of Article 123(2) EPC.

Inventive step

Closest prior art

Document E4

50. According to document E4, about 0.2 mg of BTX A were administered to rats to induce botulism, i.e., BTX poisoning (see page 1 of the English translation, under "Method"). One of the many symptoms associated with BTX poisoning was "stoppage" (i.e. complete termination) of the secretion of saliva (see page 2, third paragraph under "Results"). In the board's view, it is unrealistic that the skilled person would depart from

document E4 as the most promising springboard to the present invention, since administering huge amounts (0.2 mg) of BTX for the purpose of inducing BTX poisoning and "stoppage" of salivation (document E4) represents a different situation from administering nanogram (10^{-9} g) amounts (see page 4, line 24 of the patent) of BTX for reducing, inter alia, excessive salivation (present invention).

Document E2

51. Document E2 discloses the use of transdermal scopolamine to reduce drooling (salivary gland hypersecretion) and salivation (see page 233, abstract). Drooling and salivation are examples of mucus secretion.
52. The difference between the teaching in document E2 and the present invention, as recited in claim 1 of the first auxiliary request lies in the nature of the pharmacologically active agent (transdermal scopolamine Vs. BTX). Therefore, document E2 represents the closest prior art for the subject-matter of claim 1 at issue.
53. The problem to be solved is the provision of an alternative agent (to transdermal scopolamine) for reducing a cholinergic controlled or cholinergic influenced secretion, wherein the secretion is not lacrimation. The proposed solution lies in using BTX.
54. As for the issue whether the above problem has been solved by patent in suit, the appellant raised the objection that the patent lacked evidence that BTX was indeed effective for the treatment of excessive cholinergic influenced secretion other than sweating,

- e.g. for the treatment of excessive mucus secretion and gastrointestinal secretion. In the appellant's view, Example 1 dealt with a patient treated with BTX for excessive sweating, the latter being under greater cholinergic control (see page 4, line 51 of the patent) and hence Example 1 related to a more favourable situation than reducing excessive mucus and gastrointestinal secretion.
55. The above objection is dealt with by the board under Article 56 EPC and not under Article 83 EPC (insufficiency of disclosure) because the then opponent raised an objection under Article 83 only insofar as the claims then on file covered an **increase** of cholinergic controlled or cholinergic influenced secretion. No objection by the then opponent was raised against the claims covering a **reduction** of cholinergic controlled or cholinergic influenced secretion (see paragraph 4 of the decision under appeal). There is also no evidence before the board showing that such reduction of secretion upon BTX treatment cannot be achieved.
56. When taking the above objection as one under Article 56 EPC (that the claims cover situations which do not solve the problem), reference is made to decision T 601/05 of 24 April 2008, point 6.4 of the reasons, wherein the competent board concluded that this question does not arise in circumstances where the effect to be achieved (here: the reduction of secretion) is an explicit feature of the claim.
57. Thus the board is satisfied that the problem highlighted in point 53 supra has indeed been solved.

58. The relevant question to be answered in deciding the inventive step issue is the assessment of whether or not the prior art provided an incentive to the skilled person to go in the direction of the above proposed solution.
59. According to the appellant, document D1 disclosed the use of BTX to reduce one specific cholinergic controlled or cholinergic influenced secretion, namely lacrimation. BTX was known to be an anticholinergic drug (see, e.g., page 67, right hand column, first paragraph of document D11). The use of BTX for the reduction of mucus secretion and gastrointestinal secretion was thus made obvious by document D1, in the light of the common general knowledge about the anticholinergic properties of BTX.
60. In the board's opinion, the authors of document D1 did not investigate the biochemical mechanism underlying the reduction of tear secretion upon injection with BTX A. Even if they had been aware that BTX A was anticholinergic, the fact that a drug is anticholinergic is not a sufficient condition for reducing a cholinergic controlled or cholinergic influenced secretion (see T 435/04, point 22 of the reasons). This is because the anticholinergic activity is a very broad concept encompassing a large number of compounds. Therefore the use of claim 1 is not made obvious by document D1, taken in the light of the common general knowledge about the anticholinergic properties of BTX.

61. In a further line of argument, the appellant reasoned that on the one hand, document E2 disclosed the use of anticholinergic drugs to reduce drooling and salivation. Drooling and salivation were examples of mucus secretion. On the other hand, document D1 disclosed the use of BTX, an anticholinergic molecule (see, e.g., page 67, right hand column, first paragraph of document D11) to reduce one specific cholinergic controlled or cholinergic influenced secretion, namely lacrimation. The use of BTX for the reduction of mucus secretion and gastrointestinal secretion was thus rendered obvious by the combination of documents E2 and D1.
62. The board first observes that it is not correct to conclude that E2 discloses the use of anticholinergic drugs in general to reduce drooling and salivation: only scopolamine seems to be active, whereas the use of other anticholinergic drugs is "limited" (see page 233, abstract). Secondly, scopolamine is a post-synaptic muscarinic receptor antagonist (see decision T 435/04, last three lines of point 20), in contrast to BTX, which is a presynaptic receptor antagonist (see document D11, page 67, r-h column, lines 4-5 and document E8, page 11, under "Mode of action", taken as expert opinion). This different mode of action is also shown by the fact that BTX has a longer activity and need not be administered continuously as is the case for scopolamine. Therefore, the skilled person would not combine the teachings of document E2 and D1 and arrive in an obvious way at the solution referred to in point 53 supra.

Combining documents E4 and E2 or E2 and E5

63. The appellant maintains that document E4 showed that BTX reduced the secretion of saliva based on an anticholinergic effect and that the skilled person would have combined the teachings of documents E4 and E2 in order to reduce drooling and salivation.
64. However, as already highlighted under point 50 supra, document E4 does not disclose any reduction of the secretion of saliva but rather its "stoppage" (i.e. the complete termination thereof) upon administration of 0.2 mg of BTX A to induce botulism, i.e., BTX poisoning (see page 2 of the English translation, first line of the last paragraph). In the board's view, administering huge amounts (0.2 mg) of BTX for the purpose of inducing BTX poisoning and "stoppage" of salivation (document E4) is not predictive of a situation wherein nanogram (10^{-9} g = 10^{-6} mg) amounts (see page 4, line 24 of the patent) of BTX are administered for reducing excessive salivation (present invention). Moreover, the skilled person coming across document E4 was taught (see page 1, second paragraph and page 3, second full paragraph) that botulism damaged the parasympathetic section of the vegetative nervous system. In view of these differences in dosage and potential damage, it is unrealistic that the skilled person would combine the teachings of documents E4 and E2. Nor would the skilled person combine the teachings of documents E4 and E5 and reduce the toxic levels of BTX disclosed in document E4 to the therapeutically active and acceptable amounts disclosed in document E5. This is because document E5 related to inhibiting the release of acetylcholine in the motor neurons to alleviate skin wrinkles, a

situation completely diverging from the claimed use, i.e. the reduction of the secretion by glands, which are not muscle-related.

Combining documents E9 and D1

65. Finally, reference is made by the appellant to document E9, which discloses on page XIX, third and fourth lines from the bottom, that botulinum toxin inhibits gastrointestinal secretions. It is the appellant's view that combining the teaching of document E9 with that of document D1 would render obvious the use of BTX for the reduction of mucus secretion and gastrointestinal secretion.
66. However, document E9 relates to poisoning with BTX (botulism) and its deleterious effects. The board has already established (see point 64 supra) that the skilled person would not take into consideration any document relating to the toxic effects of BTX. This conclusion should thus be extended to document E9. It should be noted in passing that the term "Vertrocknung in Mund und Schlund" (see page XX, line 10 of document E9; a situation the skilled person seeks to avoid) is consistent with the wording "stoppage of salivation" referred to on page 2 of the English translation of document E4, first line of the last paragraph. Finally, the criticism against document D1 expressed in point 60 supra (the fact that a drug is anticholinergic is not a sufficient condition for reducing a cholinergic controlled or cholinergic influenced secretion) also applies to this combination of documents.

67. In conclusion, identifying BTX among all possible cholinergic drugs as being particularly useful as alternative to scopolamine for reducing a cholinergic controlled or cholinergic influenced secretion, wherein the secretion is not lacrimation (see point 53 supra), must be regarded as involving an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of claims 1 to 5 of the 1st Auxiliary Request filed with letter dated 2 January 2008 and pages 2 to 4 of the amended description filed at the oral proceedings.

The Registrar:

Chair:

P. Cremona

U. Kinkeldey