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Datasheet for the decision of 13 March 2007

Case Number: T 0435/04 - 3.3.04

Application Number: 95906674.7

Publication Number: 0737074

IPC: A61K 38/16

Language of the proceedings: EN

Title of invention:
Botulinum toxins for treating hyperhydrosis

Patentee:
ALLERGAN, INC.

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

Headword:
Botulinum toxins for treating hyperhydrosis/ALLERGAN

Relevant legal provisions:
EPC Art. 56, 114(2)

Keyword:
"Admission of fresh documents - (yes)"
"Main request - inventive step - (yes)"

Decisions cited:
T 0939/92, G 0009/91, G 0010/91

Catchword:
See points 1, 2 and 31

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0435/04 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 13 March 2007

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 29 January 2004 rejecting the opposition filed against European patent No. 0737074 pursuant to Article 102(2) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
S. Perryman

Summary of Facts and Submissions

I. The appeal was lodged by the opponent (appellant) against the decision of the opposition division to reject the opposition against European patent No. 0 737 074, entitled "Botulinum toxins for treating hyperhydrosis", under Article 102(2) EPC.

II. The patent had been opposed under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC).

III. Claim 1 as granted read:

"1. The use of a botulinum toxin selected from botulinum toxins type A, B, C, D, E, F and G for the manufacture of a medicament for the treatment of excessive sweating in humans."

Claims 2 to 8 were dependent on claim 1.

IV. Documents E14 and E15 were filed with the statement setting out the grounds of appeal dated 7 June 2004.

Documents E16 to E19 were filed together with a letter setting out "additional reasons for appeal" dated 29 December 2004.

V. Auxiliary requests 1 to 6 were filed with letter of 13 February 2007.

VI. In a communication the board informed the parties that it considered documents E16 to E19 sufficiently relevant to be admitted into the proceedings.

VII. Oral proceedings were held on 13 March 2007. At the end of the oral proceedings the board announced its decision.

VIII. The following documents are referred to in this decision:

D2: Jenzer, G. et al., Schweizer Medizinische Wochenschrift, vol. 104, No. 19, 1974, pages 685 to 693

D7: US 5183462

D11: Heckmann, M.D. et al., The New England Journal of Medicine, vol. 344, 2001, pages 488-493

E1: Ambache, N., Journal of Physiology, vol. 113, 1951, pages 1-17

E6: Drobik, C. et al., HNO, vol. 43, 1995, pages 644-648

E7: M. J. Neal, Blackwell Scientific Publications 1989, "Medical pharmacology at a glance", pages 18-23

E14: Laccourreye, O. et al., Laryngoscope, vol. 100, 1990, pages 651-653

E15: Harper, K.E. et al., International Journal of Dermatology, vol. 25, 1986,

E16: US patent application serial number 09/490 754

E17: USPTO action dated 8 March 2000

E18: Respondent's response to the USPTO action dated 15 August 2000

E19: US 6,683,049

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

Admission of documents E14 to E19 into the proceedings

Documents E14 and E15 were a reaction to an argument in the opposition division's decision and were filed with the statement of grounds of appeal, i.e. at the earliest occasion possible.

The "whole breadth" - argumentation based on documents E16 to E19 was made along the lines of decision T 939/92. Although the argumentation was new, it clearly was within the frame of inventive step which was a ground of opposition already relied on.

Main request

Inventive step

Three lines of argumentation were pursued to demonstrate lack of inventive step of the claims. One started from document D7, the other from document E14 as the closest prior art document. The last was that the subject-matter of the claims was not inventive over the whole breadth of the claim.

Document D7 disclosed multiple medical and cosmetic conditions in which botulinum toxin (hereinafter referred to as BTX) had been used, that it had no side effects in humans and that it was an anti-cholinergic agent. In view of document D7 the problem to be solved was to provide a treatment by which sweating could be treated by reducing sweating. The solution to that problem provided by the patent was obvious in view of a combination of document D7 with either of documents E1, E7 or D2. Documents E1 and D2 disclosed the sweat-reducing effect of BTX, documents E7 and D7 disclosed the anti-cholinergic activity of BTX. Moreover, documents E1 and E7 reported that acetylcholine acted as a transmitter substance at the junction of the nerve and the sweat glands and thus induced sweating.

According to document E14 patients with Frey's Syndrome, involving severe gustatory sweating after total parotidectomy, were successfully treated by topical administration of each of the three anti-cholinergic drugs scopolamine, glycopyrrolate and diphemanil methylsulfate. In relation to this document the problem to be solved was the provision of a different active ingredient in a medicament against excessive sweating. The solution of this problem provided by the patent was obvious in view of the combination of the disclosure in documents E1, E7, D2 or D7, the relevant content of these documents being the same as set out in relation to the problem-solution approach starting from document D7 above.

Inventiveness over the whole breadth of the claim:

It could be taken from documents E16 to E19 that BTX did not work on topical administration. This route of administration was however not excluded from the claims. Therefore, in view of the ruling in decision T 939/92, since one embodiment of the claim was the non-functional, topical administration, the whole claim could not be considered to involve an inventive step.

X. The respondents' arguments as far as they are relevant for the present decision may be summarised as follows:

Admission of documents E14 to E19 into the proceedings

Two of appellant's lines of argumentation to demonstrate lack of inventive step of the claimed subject-matter had not been heard before the opposition division, one based on documents E14 and D15, the other, the "whole breadth" argument, on documents E16 to E19. Since the subject of the appeal proceedings was the revision of the decision of the first instance, it was against the spirit of the appeal proceedings to submit new facts and base new arguments on them. Therefore, none of documents E14 and E19 should be admitted into the proceedings as well as the arguments based on them.

Moreover, the "whole breadth" argument was not even an argument under Article 56 EPC and should for that reason too not be admitted.

Main request

Inventive step

All the applications dealt with in document D7 were based on the activity of BTX on muscles. Sweating was not mentioned at all in the document. Hence, by applying the usual standards, document D7 did not qualify as the closest prior art document.

Document E14 was not the closest prior art document either, because it related to the treatment of so-called gustatory sweating, i.e. hyperhydrosis occurring after total parotidectomy. According to the patent however, the term "excessive sweating" was not used to describe hyperhydrotic conditions caused by a medical intervention. Hence, document E14 did not relate to the same purpose as the invention.

Document E1 presented the results of a physiological investigation on the understanding of the influence of BTX on signal transmission. Although it disclosed the reduction of acetylcholine release by BTX, it did not suggest any therapeutic use of the compound.

According to the figure on page 18 of document E7 the anti-cholinergic effect of BTX in relation to physiological processes at the neuro-muscular junction was due to a reduced acetylcholine release. In contrast, it was disclosed on page 21 that the action of acetylcholine on muscarinic receptors is responsible for sweating and that sweating can be blocked by antagonists of muscarinic receptors, such as atropine or scopolamine (page 22). Thus, due to the two

differing mechanisms the skilled person would not have derived from document E7 that sweat production could be influenced by BTX.

Document D2 was a study on the symptoms after BTX intoxication. It did not disclose the therapeutic usefulness of BTX.

Inventiveness over the whole breadth of the claim:

The "whole breadth" argument as it was developed in decision T 939/92 in the context of the evaluation of inventive step was based on the finding that an effect of compounds which was relied on in support of inventive step and which was not part of the definition in the claim, was not achieved by all of the claimed compounds. In the present case it was not disputed that all types of BTX mentioned in the claim were effective in reducing sweating. Moreover, although topical administration was not expressly excluded from the claim, it was clear from the description that the only intended route of administration was injection.

XI. Requests

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent 0 737 074 be revoked.

The respondent (patent proprietor) requested as main request that the appeal be dismissed.

Reasons for the decision

Admission of documents E14 to E19 into the proceedings

1. Not even the case law developed by decisions G 9/91 (OJ EPO 1993, 408) and G 10/91 (OJ EPO 1993, 420) requires a Board of Appeal to confine its examination of whether the decision under appeal was correct solely to reviewing whether it was correct on the facts and the claims before the first instance (see for example point 19 of the "Reasons"). It is also legitimate on appeal to challenge the decision under appeal in reaction to the reasons given in that decision on the basis of new facts, or by putting forward new claims to which the reasoning of the decision under appeal is not applicable (Case Law of the Boards of Appeal of the European Patent Office, 5th edition, VII.D.7.5.2 (c), (d)). Putting forward such new facts or claims is not prima facie against the "spirit" of the appeal proceedings (though it may raise the question of whether remittal of the case to the first instance might be appropriate). The introduction of relevant new documents at the beginning of appeal proceedings is not objectionable. The board considers documents E14 to E19 to be relevant, because documents E14 and E15 deal with the treatment of excessive sweating and documents E15 to E19 are concerned with botulinum toxin. Moreover, the documents were submitted with the statement of the grounds of appeal and with a further letter only half a year later, i.e. early in the appeal proceedings. Therefore, pursuant to Article 114(2) EPC the board decides to allow documents E14 to E19 into the proceedings.

2. It has been established in the case law of the Boards of Appeal of the EPO that Article 114(2) EPC is not a basis to disregard arguments not submitted in due time (Case Law of the Boards of Appeal of the European Patent Office, 5th edition, VI.F.5). Whether arguments relating to a ground of opposition already relied on, are convincing or not, is not a criterion for them to be disregarded.

Main request

Inventive step

3. Lack of inventive step under Article 100(a) EPC was the only ground of opposition relied on in the present case. Therefore, this is the sole issue in this decision.

4. The approach taken in EPO case law to ensure as objective an assessment of inventive step as possible is the problem-solution approach. The first step in this approach is to define the closest prior art. The closest prior art is, for example, a document that the inventor would select as the most promising starting point because the teaching it describes is the closest to the invention. A document thus qualifies itself as the most promising starting point if its teaching pursues the same purpose as the invention. Selecting a document as the closest prior art that does not pursue the same purpose as the invention or, in other words, from which the problem according to the invention cannot be derived, incorporates an ex-post-facto element, since the inventor has in mind the problem that he has to solve but not another problem or another purpose.

5. The appellant developed the problem-solution approach starting either from document D7 or from document D14 as the closest prior art. Therefore, the board will in the following examine according to the above criteria which of the two is to be considered as the closest prior art document.

6. Document D7 describes multiple ways of using botulinum toxin in the medical and cosmetic fields. No mention is made in the document of sweating, let alone excessive sweating, either with or without reference to BTX. In the light of the above, it therefore follows that document D7 is not the closest prior art.

7. Document E14 relates to the treatment of Frey's Syndrome, also known as gustatory sweating, an after-effect of operations performed on the glandula parotis. About half a minute after the start of food consumption, severe perspiration occurs in the cheek area on the operated side (see for example document E6, page 644, the first sentences in the left column). The document describes the double-blind evaluation of the treatment of Frey's Syndrome with topical 2% diphemanil methylsulfate of 15 patients (see the title). The authors conclude that this topical agent can be used safely to control Frey's syndrome (see "Conclusions"). In addition, it is mentioned that gustatory sweating had been successfully treated also by topical administration of scopolamine and glycopyrrolate cream (see page 652, right column, first full paragraph).

8. The respondent submits that the teaching described in document E14 does not pursue the same purpose as the

invention and is therefore not the closest prior art, since in the patent in suit the term "excessive sweating" was not used to mean excessive sweating as an after-effect of operations. This definition of the term "excessive sweating" can, he claims, however, be derived from page 488 of document D11: "Primary hyperhidrosis is defined as excessive, uncontrolled sweating without any discernible cause".

9. The board is not convinced by this argument. For one thing, the cited passage defines "primary hyperhydrosis", not "excessive sweating". The fact that "primary hyperhidrosis" is described as "excessive, uncontrolled sweating without any discernible cause" does not, however, mean that, conversely, "excessive sweating" is to be understood exclusively as "primary hyperhydrosis", i.e. "sweating without discernible cause". On the contrary, the qualifier "primary" suggests rather, in the board’s opinion, that other hyperhydrotic conditions exist too. Moreover, contrary to the respondent's argument, no limiting definition of the term "excessive sweating" can be derived from the patent in suit. The board therefore considers that the term "excessive sweating" in the patent in suit refers to any excessive perspiration, whatever the cause.

10. Document E14 therefore represents the closest prior art document.

11. Neither in the patent specification itself nor in any submission by the respondents is an advantage of the treatment with BTX compared to the treatment with diphemanil methylsulfate or any of the other agents referred to in document E14 put forward. The problem

underlying the patent can therefore be formulated as the preparation of alternative compounds for the treatment of excessive sweating.

12. The solution to this problem according to the invention is the use of BTX of types A, B, C, D, E, F and G.

The appellant has not contested the submission that the various BTX types actually solve this problem. Nor does the board see any reason to raise any objection.

13. In the assessment of inventive step, the question therefore arises whether the skilled person would have derived the solution of the above-formulated problem in an obvious way from document E14 on its own or from document E14 in combination with other documents of the prior art.

14. The relevant disclosure content of a document is composed of all pieces of information that a skilled person derives from that document when reading it at the priority date of the patent in suit with common general knowledge.

15. The appellant argues that the solution according to the patent, i.e. the subject-matter of claim 1, would be apparent to the skilled person in an obvious way by combining the teachings of documents E1, E7, D2 or D7 with that of document E14. The skilled person would derive from document D2 that the diminution in perspiration was caused by BTX and from document E1 that BTX reduced perspiration in cats. Documents E1, E7 and D7 disclosed that acetylcholine was the transmitter substance released at the nerve - sweat gland -

junction, whereas documents E1 and E7 taught the anti-cholinergic effect of BTX. Finally, document D7 showed that BTX had already been applied to human beings successfully and safely for the treatment of a variety of pathological conditions.

16. In the board's judgement an analysis of the documents from the point of view of the skilled person at the time of priority and without knowledge of the invention would produce the following results:

Document E1

17. This document is a scientific publication entitled "A further survey of the action of clostridium botulinum toxin upon different types of autonomic nerve fibres". The experiments described in this publication follow on from earlier studies in which it was established that BTX specifically influences cholinergic and not adrenergic nerve fibres. The focus of publication E1 is the study of the influence of BTX on other cholinergic nerve fibres than those already studied. The document describes inter alia experiments with intra-ocular injections, retrobulbar injections and the nerves leading to the sweat glands, the so-called sudomotor nerves. These were selected because of the accessibility of their post-ganglionic elements. The experiments with these nerve fibres were carried out as follows: Young kittens were given an injection of toxin in one forelimb and one hindlimb pad. The contra-lateral pads were injected with inactivated toxin. After a certain time interval following toxin injection, the kittens were anaesthetised with, inter alia, ether. At a certain stage in anaesthesia, sweat appeared on

the control, but not on the botulinum injected pad. Then stimulation of previously exposed nerves was begun with a stimulus adequate to excite sweating. Sweat appeared on the control pads but not on the intoxicated pad. In the latter case, sweat appeared also on the toes of the pad which had not been injected with toxin.

The results are summarised in the summary section as follows:

"2. Postganglionic fibres of the cholinergic variety are susceptible, whether they occur in the parasympathetic, or in the sympathetic, system. The short ciliary nerves were chosen as an example of the former, and the sudomotor fibres as an example of the latter."

18. The board is convinced that the notional skilled person not knowing the invention would derive nothing more from document E1 than the teaching that post-ganglionic nerve fibres of the cholinergic sub-type are susceptible to the effect of BTX and would not, therefore, as the appellants would make the board believe, draw conclusions on any sweat-preventing activity of BTX in medicine.

Document E7

19. Document E7 consists of several pages from the textbook "Medical pharmacology at a glance". A figure appears on page 18 under the title of the sixth chapter "Drugs acting at the neuromuscular junction" showing inter alia that acetylcholine (ACh) functions as a transmitter substance at the transition from a

cholinergic nerve ending to the muscle. In the same figure, under the title "Agents that reduce ACh release", reference is made to botulinum toxin as well as hemicholinium, Mg^{2+}, Co^{2+}. This is the only reference to BTX in document E7.

The skilled person therefore is taught that BTX **reduces the release** of acetylcholine in connection with the transmission of nerve impulses from the nerve to the muscle.

20. It is reported on page 21 of document E7, right-hand column, first full paragraph, that acetylcholine is the transmitter substance for "some postganglionic sympathetic nerves, e.g. thermoregulatory sweat glands [...].". It is stated in the same column that there are acetylcholine receptors of the nicotinic and muscarinic sub-type (second full paragraph) and that sweating is one of the effects of acetylcholine on muscarinic receptors (fifth full paragraph).

The skilled person can derive from the right-hand column on page 22 that muscarinic receptor antagonists inhibit the effect of the acetylcholine released from postganglionic parasympathetic nerve endings by - this can be seen from the figure on page 22 - blocking the receptor. It is also recorded there that "parasympathetic effector organs vary in their sensitivity to the blocking effect of antagonists" but that "secretions of salivary, bronchial and sweat glands are most sensitive to blockade". The skilled person can also derive from the figure on page 22 that "atropine, scopolamine, ipratropium, tropicamide,

benzhexol and others" are muscarinic receptor antagonists.

The skilled person thus is further taught by document E7 that acetylcholine is involved in perspiration and that the effect of acetylcholine and hence perspiration can be prevented by **blocking the muscarinic receptor** and thus the attachment of acetylcholine with muscarinic receptor antagonists.

21. In summary, the skilled person learns from document E7 on the one hand that some agents block neuromuscular transmission by preventing the release of acetylcholine and on the other that sweating may be prevented by blocking muscarinic receptors with the respective antagonists. The board considers that, in view of the problem to be solved (see point 11 above), the skilled person would disregard the teaching in document E7 relating to BTX and to processes at the neuromuscular junction because he/she would not expect from it any assistance in solving this problem. Rather, if at all, the skilled person would take into account the part of document E7 mentioning sweating. In this part, however, BTX is not mentioned.

22. Moreover, the board is convinced that even if the skilled person recognized from the disclosure of document E7 that BTX had an "anti-cholinergic" effect at the neuromuscular junction in the sense that it reduces or abolishes acetylcholine activity, he/she would not be prompted to use this effect for the treatment of sweating, because according to document E7 the physiological reason causing the lack of activity of acetylcholine at the nerve-muscle transition is

fundamentally different from that causing prevention of sweating. In the board's view such a combination could only be made with hindsight knowledge.

Document D2

23. Document D2 describes the symptoms that occur in connection with BTX Type B **poisoning**. As can be seen from Figure 6 one such symptom is the reduction of perspiration. However, in the board's judgement, the transfer of an observation of a detrimental effect of a compound in the context of toxication to a field where this same effect evolves a beneficial consequence, goes against the sort of conclusions that a skilled person would naturally draw from such an observation in that context, which is rather to avoid the application of the substance in order to avoid the symptoms of poisoning. Thus, the converse conclusion, i.e. that the substance can be used as a medicament is not obvious and would need inventive skill. Hence, the skilled person would not derive from document D2 that BTX can be used as a medicament against severe sweating.

Document D7

24. Document D7 is an American patent specification that was published in February 1993, i.e. only 10 months before the priority date of the disputed patent. The skilled person derives from this document that the biological target of BTX is the striated muscle where it blocks "release of the acetylcholine neurotransmitter from the presynaptic membrane resulting in varying degrees of effective denervation of the muscle in regions contacted by the toxin", that

BTX can be used safely in the treatment of human beings, as well as numerous possible medical and cosmetic treatments, e.g. inhibition of tooth wear, cosmetic wrinkle reduction, stroke and cerebro-spinal injury, cerebral palsy, multiple sclerosis and Parkinson's disease. There in no reference to sweating in document D7.

25. While the board accepts the appellant's argument that the document teaches that BTX can be safely applied to human beings without exerting its poisonous effects, the board cannot see however in the absence of a reference to sweating any hint in it to the invention.

Document E14

26. Finally, the closest prior art document E14 itself does not mention BTX.

27. From the above analysis of the disclosure to the skilled person from documents E1, E7, E14, D2 or D7, the board concludes that neither the teaching of document E14 alone, nor a combination of the teaching of document E14 with any of the teachings of documents E1, E7, D2 or D7 - either singly or when combined so as to build a picture representing the common general knowledge at the priority date - would have led the skilled person in an obvious way to use BTX instead of diphemanil methylsulfate or any of the other agents mentioned in document E14 in the treatment of excessive sweating, since none of the documents establishes a direct link between BTX and the medical application of it in the treatment of excessive sweating. This link

could only be obtained by a retrospective way of looking at the invention, which is to be avoided.

28. Finally, the board considers it a sign of the presence of an inventive step that, despite the many diseases referred in document D7, which as noted above is published only ten months before the priority date of the patent, excessive sweating is specifically not referred to.

29. As far as the last argument, inventiveness over the whole breadth of the claim, is concerned, the board observes the following:

With reference to documents E16 to E19 the appellant argues that BTX cannot produce its effect after topical application. The subject-matter of claim 1 is not, however, limited to a particular form of administration and therefore includes topical application. The desired effect, i.e. the treatment of sweating, is therefore not achieved by all the alternatives of the claim. In such a case, the principles set out in decision T 939/92 (OJ EPO 1996, 309) require inventive step to be denied.

30. The board cannot endorse this argumentation.

The subject-matter on which the board had to rule in decision T 939/92 was a product. The product was defined in the claim by a general formula, a so-called Markush formula. According to the description, all the compounds encompassed by the formula had a herbicidal effect. This effect was not an explicit feature of the claim. However, as part of the problem-solution

approach it was taken into account for formulating the problem. In the above-mentioned decision, the problem was defined as: "Preparation of further (alternative) compounds with a herbicidal effect" (paragraph 26). In view of the evidence, the board decided that it was not plausible that all the compounds falling within the claim solved the problem, i.e. that they all had a herbicidal effect.

The board ruled that only those compounds could count as the invention that were recognised as the solution to the technical problem. Since the subject-matter of the claim did encompass non-inventive compounds, it was not held to involve an inventive step (see point 27).

The subject-matter was thus not inventive because, for part of the subject-matter, the desired purpose according to the invention was not achieved.

31. The board regards the principle underlying decision T 939/92 as being that, for the presence of an inventive step to be acknowledged, the purpose **according to the invention** of all the subject-matter falling within a claim must be plausibly achieved. Although decision T 939/92 was based on a product claim, this principle can, in the board's view, also be applied to the present case, where a second medical use is at stake. If the principle is applied, the following finding can be made: Within the framework of the present second medical use claim, the purpose according to the invention consists of the treatment of excessive sweating (see also the problem formulated in point 11 above). The form of administration is thus not part of the purpose underlying the invention. In the light of

the present second medical use claim, the only question that could arise in connection with the argument put forward by the appellant is therefore whether, by analogy with the principles set out in T 939/92, all the BTX types referred to in the claim are suitable for the treatment of excessive sweating. This question does not arise, however, because, unlike the substance claim underlying the cited decision, the purpose in the present second medical use claim **is** an explicit feature of the claim that has a limiting effect, i.e. the claim refers only to those compounds with which sweating can actually be treated successfully. The possibility theoretically falling within the claim of an ineffective topical use of BTX therefore does not provide a basis for an attack according to the principles formulated in decision T 939/92.

32. The subject-matter of claim 1 and dependent claims 2 to 7 of already the main request therefore fulfils the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

P. Cremona U. Kinkeldey