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Datasheet for the decision of 9 October 2007

Case Number:	T 0826/04 - 3.3.08		
Application Number:	92903535.0		
Publication Number:	0571410		
IPC:	C12N 7/04		
Language of the proceedings:	EN		

Title of invention: Herpes simplex virus-1 deletion variants and vaccines therof

Patentee: Crusade Laboratories Limited

Opponent: BIOVEX LIMITED

Headword: HSV-1 variants/CRUSADE

Relevant legal provisions:

Relevant legal provisions (EPC 1973): EPC Art. 54, 56, 111(1)

Keyword:

"Main request - claims as granted" "Novelty (yes)" "Remittal (no)" "Inventive step (yes)"

Decisions cited:

G 0002/88

Catchword:

-



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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0826/04 - 3.3.08

DECISION of the Technical Board of Appeal 3.3.08 of 9 October 2007

Appellant: (Patent Proprietor)	Crusade Laboratories Limited P.O. Box 1716 Glasgow G51 4WF (GB)
Representative:	Clegg, Richard Ian Mewburn Ellis LLP York House 23 Kingsway London WC2B 6HP (GB)
Respondent: (Opponent)	BIOVEX LIMITED 12 St. James's Square London SW1Y 4RB (GB)
Representative:	Perry, Robert Edward Gill Jennings & Every LLP Broadgate House 7 Eldon Street London EC2M 7LH (GB)
Decision under appeal:	Interlocutory decision of the Opposition Division of the European Patent Office posted 22 April 2004 concerning maintenance of European patent No. 0571410 in amended form.

Composition of the Board:

Chairman:	L.	Galligani		
Members:	М.	R.	Vega	Laso
	С.	Rennie-Smith		

Summary of Facts and Submissions

- I. European patent No. 0 571 410 with the title "Herpes simplex virus-1 deletion variants and vaccines thereof" was granted on European patent application No. 92 903 535.0, which was filed as International application under the PCT on 30 January 1992. The patent was granted with one set of claims for the Contracting States AT, BE, CH, LI, DE, DK, FR, GB, IT, LU, MC, NL and SE (claims 1 to 9) and a second set of claims for the Contracting States ES and GR (claims 1 to 19).
- II. Claims 1 and 8 for all designated Contracting States except Spain and Greece read as follows:

"1. A variant of HSV-1 strain 17, the genome of which variant is modified with respect to that of HSV-1 strain 17 within the Bam HI \underline{s} region of the internal repeat R_L (0.81-0.83 mu) and within the counterpart region of the terminal R_L (0-0.02 mu) such that the variant lacks neurovirulence.

8. A process for the preparation of a variant as defined in claim 1, which process comprises introducing a modification within the Bam HI \underline{s} region of the internal repeat R_L (0.81-0.83 mu) of HSV-1 strain 17 and within the counterpart region of the terminal R_L (0-0.02 mu) such that the resulting variant lacks neurovirulence."

III. The patent was opposed on the grounds of Article 100(a) and (b) EPC, in particular that the claimed subjectmatter lacked novelty (cf. Article 54 EPC) and an inventive step (cf. Article 56 EPC), and that the patent did not disclose the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

In an interlocutory decision issued in writing on IV. 22 April 2004, the opposition division found that, whereas the requirements of Article 83 EPC were satisfied, the invention defined in claim 1 of the main request for the Contracting States AT, BE, CH, LI, DE, DK, FR, GB, IT, LU, MC, NL and SE (claims as granted) lacked novelty in view of the recombinant nonneurovirulent RE6 virus described in documents (4), (13) to (16) and (19) (see infra, Section XIII). The opposition division held that the RE6 virus represented a variant of HSV-1 strain 17 which was modified in the regions specifically mentioned in claim 1, and that "since modifications are defined in the opposed patent as including substitutions (page 2, section [0011]), the modifications within the BamHI s region of the internal repeat R_{L} (0.81-0.31[sic] mu) and within the counterpart region of the terminal R_L (0-0.02 mu) would include those characterised in RE6." Having noted that no evidence had been provided by the patent proprietor in support of its allegation that the recombinant RE6 virus was not available to the public at the relevant date, the opposition division found that this virus formed part of the state of the art and that, consequently, the invention defined in claim 1 could not be considered to be new within the meaning of Article 54 EPC.

Moreover, the subject-matter of claim 7 of the set of claims according to the first auxiliary request

(claims 1 to 8 filed on 4 February 2004) was found to lack novelty in view of document (19) (see *infra*, Section XIII).

Finally, taking into account the amendments introduced into the claims of the second auxiliary request, the opposition division decided that the patent and the invention to which it related met the requirements of the EPC, and that, accordingly, the patent could be maintained on the basis of this request and an amended description filed during the oral proceedings.

V. The proprietor of the patent (appellant) lodged an appeal against the interlocutory decision of the opposition division. With its statement of grounds of appeal dated 2 September 2004, the appellant re-filed two sets of claims corresponding to the main request and the first auxiliary request on which the opposition division had adversely decided. New evidence in support of the appellant's arguments on novelty was also filed.

> In its statement the appellant submitted that, although inventive step in respect of the main request and the first auxiliary request had not been dealt with explicitly in the decision under appeal, "the argument and appropriate line of reasoning [for the main request] is the same as that put forward to the OD in the proprietors submissions of 26 February 2001 and 04 February 2004, specific reference is made to these submissions (Article 10a(2) RPBA) and the arguments contained therein, particularly those arguments relating to the issue of inventive step." (note introduced by the board). The appellant submitted further that "Although the decision of the OD on the

matter of inventive step (5.3) refers to the claims of AR2 (where the modification is limited to a deletion), the reasoning of the OD is not dependent on the modification being a deletion and can be followed for the claims of the MCR or AR1, which accordingly [...] are inventive under Article 56 EPC."

- VI. With a letter dated 16 September 2004, the appellant filed further evidence in the form of a declaration.
- VII. The respondent (opponent) submitted observations in reply dated 20 January 2005, arguing in respect of the issue of novelty and raising objections under Article 84 EPC.
- VIII. Both parties requested oral proceedings in the event that the board did not intend to grant their respective requests.
- IX. The parties were summoned to oral proceedings. In a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA), as it entered into force on 1 May 2003 (now Article 15(1) RPBA), the board expressed its provisional opinion on the issue of novelty with regard to claims 1 and 8 of the main request, drawing the attention of the parties to the meaning commonly given to the term "within" which was present in both claims. It was indicated in the communication that "If, after the discussion at oral proceedings, the board concludes that none of documents D4, D13 to D16 and D19 prejudices the novelty of the subject-matter of either the main request or the auxiliary request, the issue of inventive step may have to be discussed." The board did however not deem it

necessary to provide any comments in this respect at that stage of the proceedings.

- X. In response to the board's communication, the appellant submitted additional observations and further documentary evidence.
- XI. In a letter dated 12 September 2007, the respondent informed the board that it would not attend the scheduled oral proceedings, but that the arguments put forward in its submission of 20 January 2005 were maintained for consideration by the board.
- XII. Oral proceedings were held on 9 October 2007 in the absence of the respondent.
- XIII. The following documents are mentioned in the present decision:
 - (1): J. Chou et al., Science, 30 November 1990,Vol. 250, pages 1262 to 1266;
 - (2): M. Y. Taha et al., J. Gen. Virol., 1989, Vol. 70, pages 705 to 716;
 - (3): M. Y. Taha et al., J. Gen. Virol., 1989, Vol. 70, pages 3073 to 3078;
 - (4): R. L. Thompson et al., Virology, 1989, Vol. 172, pages 435 to 450;
 - (12):J. Chou and B. Roizman, Journal of Virology, March 1990, Vol. 64, No. 3, pages 1014 to 1020;

- (13):R. L. Thomson et al., Virology, 1983, Vol. 131, pages 180 to 192;
- (14):R. L. Thomson et al., Journal of Virology, August 1985, Vol. 55, No. 2, pages 504 to 508;
- (15):R. L. Thomson and E. K. Wagner, Virus Genes, 1988, Vol. 1:3, pages 261 to 273;
- (16):R. L. Thomson et al., Virus Genes, 1988, Vol. 1:3, pages 275 to 286;
- (19):R. L. Thompson and J. G. Stevens, Virology, 1983, Vol. 131, pages 171 to 179;
- (20):N.D. Stow and N. M. Wilkie, Virology, 1978, Vol. 90, pages 1 to 11;
- (21):H. S. Marsden et al., Journal of Virology, November 1978, Vol. 28, No. 2, pages 624 to 642.
- XIV. The arguments of the appellant, as far as they are relevant to the present decision, can be summarized as follows:

Main request - Claims as granted for the Contracting States AT, BE, CH, LI, DE, DK, FR, GB, IT, LU, MC, NL, SE

Article 54 EPC - Novelty

The decision of the opposition division was wrong in its assessment of the availability to the public of the recombinant RE6 virus as well as in finding that the RE6 virus is a variant of HSV-1 strain 17.

The publication of document (21) in which the RE6 virus was described did not create an obligation for its authors to supply this virus freely. There was also no evidence that Dr Thomson, the main author of documents (4), (13) to (16) and (19) had requested permission to make the RE6 virus "freely available". Moreover, it was established case law of the boards of appeal that availability to the public required an enabling disclosure. In determining whether there was an enabling disclosure of the RE6 virus it had to be considered that no deposit or genomic sequence was available for RE6, either at the priority date of the patent or at the present date. Moreover, the recombinant RE6 virus was not the inevitable result of following the method of document (13). In the unlikely event that the RE6 virus was obtained by this method as one recombinant amongst many, one could never isolate and positively identify it as RE6. It was also not possible to reproduce the RE6 virus from available sequence information because there was simply not enough available information. Thus, the task of reproducing RE6 constituted an undue burden on the interested person.

The opposition division found the recombinant RE6 virus to fall within the scope of claim 1. In doing so, the opposition division must have considered RE6 to be a **variant** of strain 17. However, RE6 being a HSV-1/HSV-2 intertypic recombinant, it could not be considered as a variant of strain 17 but as an artificial recombinant strain which *per se* was distinct from strain 17. Claim 8 related to a process for the preparation of a **variant** of HSV-1 strain 17. In point 4.2.3 of its decision, the opposition division itself referred to the method described in document (19) as producing **strains**, not **variants**. Moreover, the method in question did not have as its inevitable result the creation of non-neurovirulent viruses and, in fact, none of the recombinants created by Marsden (document (21)) and Stow (document (20)) applying the method were reported to lack neurovirulence.

Remittal to the opposition division

Since the patent was fifteen years old, further proceedings before the opposition division and, possibly, a subsequent appeal could last until its expiry. Not only it was fairer for the patentee to have a final decision by the board in the present proceedings, but also it was important for the public to know as soon as possible what behaviour the patent did and did not prohibit.

Article 56 EPC - Inventive step

Document (4) was the closest prior art. Having regard to the statements in this document, in particular those on page 439, right column, first full paragraph, the skilled person would be sceptical as to whether the regions at 0.81-0.83 of the genome of HSV-1 strain 17 were the sole regions involved in neurovirulence. In documents (15) and (16), a fragment mapping between 0.698 and 0.721 mu of the wild-type HSV-1 strain 17 genome had been purported to restore neurovirulence of the non-neurovirulent RE6 virus, and the authors of document (4) expressly did not rule out the possibility that the non-neurovirulent phenotype displayed by RE6 was solely a result of its intertypic genomic structure.

XV. The arguments put forward by the respondent in writing were as follows:

> Main request - Claims as granted for the Contracting States AT, BE, CH, LI, DE, DK, FR, GB, IT, LU, MC, NL, SE

Article 54 EPC - Novelty

The opposition division was correct in assuming that the RE6 virus had been made available to the public and could therefore be considered in the analysis of the validity of the claims. It was a general convention that following publication scientists were obliged to share reagents with others such that work could be confirmed and further developed. It was not necessary to consider the theoretical availability of the recombinant RE6 virus because, as was evident from several documents on file, *inter alia* from document (4), prior to the priority date of the patent the virus in question had already been given to a member of the public, ie. to Dr Thompson. There was no evidence on file that Dr Thomson would be under some form of implied confidentiality with regard to the RE6 virus.

The arguments put forward by the appellant concerning the meaning of the term "variant" gave rise to serious concerns as to what the claims meant and rendered them objectionable under Article 84 EPC. If a distinction between the subject-matter of claim 1 and the recombinant RE6 virus was made on the basis that the term "variant" did not include "artificial recombinants" like RE6, there was an inconsistency between the appellant's interpretation of the term "variant" and what the appellant sought to protect.

- XVI. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request (the patent as granted) or the first auxiliary request both filed with the statement of grounds of appeal.
- XVII. The respondent requested in writing that the appeal be dismissed.

Reasons for the Decision

Main request - Claims as granted for the Contracting States AT, BE, CH, LI, DE, DK, FR, GB, IT, LU, MC, NL, SE

Article 54 EPC - Novelty

Claim 1

1. Claim 1 as granted is directed to a non-neurovirulent variant of HSV-1 strain 17, the genome of which variant is modified with respect to that of HSV-1 strain 17 within the Bam HI \underline{s} region of the internal repeat R_L (0.81-0.83 mu) and within the counterpart region of the terminal R_L (0-0.02 mu).

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- 2. In its adverse decision on the novelty of claim 1, the opposition division held that the recombinant non-neurovirulent RE6 virus described in documents (4), (13) to (16) and (19) represented a variant of HSV-1 strain 17 which was modified in the regions specifically mentioned in the claim at issue. For the following reasons the board disagrees with the opposition division's assessment.
- 3. It has been established in the jurisprudence of the Enlarged Board of Appeal that, when deciding on the novelty of a claimed invention, a basic initial consideration is to construe the claim defining the invention in order to determine its technical features, so that the protection conferred by the claim can be determined and a comparison can be made with the state of the art (cf. G 2/88, OJ EPO 1990, 93; point 7 of the Reasons).
- 4. In the present case, claim 1 as granted specifies that the genome of the claimed variant is modified with respect to that of HSV-1 strain 17 within the Bam HI s region of the internal repeat R_L (0.81-0.83 mu) and within the counterpart region of the terminal R_L (0-0.02 mu) such that the variant lacks neurovirulence. As the board stated in its communication in preparation for the oral proceedings, the term "within" commonly means "inside, not beyond", and a different interpretation of this term is not derivable from the patent as granted. Thus, claim 1 at issue must be interpreted as being directed to variants of HSV-1 strain 17 which have been rendered non-neurovirulent by a modification of the genome of HSV-1 strain 17 which affects the region between 0.81 and 0.83 mu and its

counterpart between 0 and 0.02 mu, the modification **not** extending beyond the boundaries of these regions.

- 5. Thus, the decisive question in the context of assessing novelty of claim 1 is whether or not the recombinant non-neurovirulent RE6 virus described in documents (4), (13) to (16) and (19) is a variant of HSV-1 strain 17 modified within the regions specified in the claim.
- 6. As stated by the opposition division in point 3.4.2 of the decision under appeal, the RE6 virus, which is defined in the literature as an intertypic recombinant, was produced by marker rescue of a temperaturesensitive mutant of HSV-1 strain 17 Syn⁺ with wild-type HSV-2 strain HG_{52} fragments (see document (19), page 172, left column, paragraph under the heading "Virus"). It is apparent from Figure 2 in document (13), which the opposition division considered to represent a consensus of the available map data (see also Figure 1 in document (19)), that most of the genome of the RE6 virus is derived from the genome of HSV-1 strain 17, except for two regions which are derived from the genome of HSV-2 strain HG_{52} , the first region extending from 0 to approximately 0.2 mu, and the second from 0.72 to 0.83 mu. Thus, the modifications present in the genome of the recombinant RE6 virus with respect to that of HSV-1 strain 17 cannot be considered to be within the Bam HI s region of the internal repeat R_L (0.81-0.83 mu) and within the counterpart region of the terminal R_L (0-0.02 mu), as required in claim 1, as they extend well beyond those regions.
- 7. The fact that the modified regions in the genome of the recombinant RE6 virus overlap with the regions

specified in claim 1 at issue does not necessarily affect the novelty of the invention as claimed. Article 54(2) EPC defines the state of the art as comprising "everything made available to the public by means of a written or oral description, by use, or in any other way". According to decision G 2/88 (supra; see point 10 of the Reasons), "[t]he word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection." In the board's judgement, neither the particular regions of the genome of HSV-1 strain 17 specified in claim 1 nor the teaching that a modification within these regions leads to a variant lacking neurovirulence were made available to the public by the description of the recombinant RE6 virus in documents (4), (13) to (16) and (19).

- 8. In view of the above, the opposition division's finding that claim 1 lacks novelty over the recombinant nonneurovirulent RE6 virus cannot be upheld.
- 9. The further finding of the opposition division with respect to the issue of novelty, namely that the recombinant R3616 virus described in document (1), which was derived from HSV-1 strain F (see Figure 1 in document (1)), could not be considered as a variant of HSV-1 strain 17 and that, consequently, could not destroy the novelty of the subject-matter of claim 1, has not been questioned by the respondent. Having examined the relevant evidence on file, the board has no reason to do so of its own motion.

10. It follows from the above that, having regard to the prior art documents (1), (4), (13) to (16) and (19) cited in connection with the issue of novelty, a variant of HSV-1 strain 17 as defined in claim 1 cannot be considered to form part of the state of the art at the relevant date of the patent. Thus, the subjectmatter of claim 1 is new within the meaning of Article 54 EPC.

11. In view of this finding, further issues concerning novelty discussed by the parties in their respective written submissions in appeal proceedings (see sections XIV and XV above), in particular whether or not the RE6 virus was available to the public at the relevant date, and whether or not this virus can be considered as a variant of HSV-1 strain 17, do not need to be discussed in this decision. Neither do the objections raised by the respondent to the clarity of the claims.

Claim 8

12. Since the opposition division decided against the novelty of claim 1 of the main request, the issue of novelty with respect to the subject-matter of claim 8 as granted was not discussed in the decision under appeal. However, the subject-matter of claim 8, which relates to a process for the preparation of a variant as defined in claim 1, is identical to that of claim 7 of the first auxiliary request discussed in the decision under appeal. Thus, the reasons given by the opposition division in support of its finding of lack of novelty based on document (19) (see point 4.2 of the decision under appeal) have to be examined.

- 13. The opposition division based its decision on the finding that document (19) not only described the recombinant RE6 virus, but also identified clearly the method for its isolation as well as its nonneurovirulent character.
- 14. In view of the finding concerning the novelty of a variant as defined in claim 1 (see points 1 to 11 above), the conclusions reached by the opposition division in respect of the novelty of the claimed process for the preparation of such a variant (cf. claim 8) are not tenable. As the claimed variant is novel with regard to the recombinant RE6 virus described in document (19), the process for its preparation as defined in claim 8 must be considered to be novel as well.
- 15. In this respect, no further arguments or evidence have been put forward by the respondent on appeal. The board thus concludes that, in view of the evidence on file, the invention defined in claim 8 as granted is new within the meaning of Article 54 EPC.

Remittal to the opposition division

16. The board having reached the conclusion that the main request met the novelty requirements of Article 54 EPC, the question then arose whether or not to remit the case to the opposition division for consideration of the issue of inventive step. Since the decision under appeal had considered that issue with regard to the second auxiliary request but not the main request, such remittal would be a possibility, for example to give the parties the opportunity to argue the issue at two instances. The decision whether or not to remit is a discretionary one which the board must exercise in accordance with the facts and circumstances of a particular case.

- 17. In the present case the appellant argued strongly against remittal (see section XIV above), observing, *inter alia*, that inventive step of the main request, although not discussed in the decision under appeal, was argued in the opposition proceedings and the decision under appeal dealt with the inventive step of other requests and there was no substantial difference between the requests so far as inventive step was concerned.
- 18. The Board notes that this was in fact the appellant's case on inventive step as presented in its grounds of appeal (see paragraph 7.0 on page 17 thereof) and that the respondent made no comment whatsoever on inventive step in its reply. In its communication the board warned the parties that, if novelty of the main request were to be established, inventive step might then be discussed at the oral proceedings. The respondent however elected not to make any written submissions in response to the communication and not to attend the oral proceedings.
- 19. In all the circumstances the board is satisfied that the respondent had all the usual opportunities to make submissions on inventive step and, in not availing itself of those opportunities, did so at the risk of the matter being decided without further submissions from it. The respondent must also be assumed to know

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the law and procedure of the Boards of Appeal, including Article 11(3) RPBA, as it entered into force on 1 May 2003 (now Article 15(3) RPBA), which provides:

"(3) The Board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case."

- 20. Accordingly, the board does not consider that it would be unfair to the respondent not to remit the case but to proceed to consider inventive step of the main request. Since the appellant presented several reasonable arguments why it would be fair to it for the board to deal with inventive step without remittal, the board concludes that, so far as procedural matters are concerned, the balance of the arguments is in favour of the appellant.
- 21. The remaining question which, in the Board's view, is the single most important factor in the exercise of the discretion to remit or not in the present case, is the relative complexity of the issue of inventive step. Since the appellant simply maintained the same arguments on that issue which it presented at first instance, since the respondent presented no arguments at all on the issue in the appeal, and since matters have been to some extent simplified generally by the its decision on novelty, the board concludes that the issue is not particularly complex. It is certainly no more complex, and indeed is perhaps a little less complex, than when the appeal proceedings began.

22. Accordingly, the board concludes that this is a case in which it would be appropriate not to remit the case to the first instance but to deal with the issue of inventive step itself.

Article 56 EPC - Inventive step

- 23. In the decision under appeal, the issue of inventive step was decided by the opposition division only in respect to the amended claims of the second auxiliary request. Claims 1 and 7 of this request differed from the corresponding claims 1 and 8 as granted essentially in that the modification introduced into the genome of HSV-1 strain 17 was specified to be a deletion.
- 24. In its decision, the opposition division discussed in detail the lines of argument against inventive step put forward by the opponent (the present respondent) with respect to the claims as granted. These lines of argument were based on either document (4) or document (1) as closest prior art (see point 5 of the annex to the notice of opposition).
- 25. With respect to document (4), the opposition division concluded that the invention defined in claim 1 involved an inventive step because, starting from this document as closest prior art, a person skilled in the art seeking to provide a further derivative of HSV-1 strain 17 lacking neurovirulence would not have been directly instructed to create deletions within the regions specified in claim 1. The opposition division also stated that, even if the skilled person had been given this information, in view of the statements by the authors of document (4) - which were said to be

consistent with the information provided in documents (13) to (16) - it could not be considered that he/she would have had a reasonable expectation that the outcome would be a virus lacking neurovirulence (see points 5.3.1 to 5.3.5 of the decision under appeal).

- 26. The board notes that, even though the opposition division referred in its reasoning to **deletions** within the regions specified in claim 1, the reasons given in the decision under appeal in favour of an inventive step concern actually the non-obviousness of the particular teaching concerning **the regions of the** genome to be modified, rather than the type of modification to be introduced (ie. a deletion). This is clear from the acknowledgement by the opposition division of the proprietor's argument that the information in documents (13) to (16) pointed to neurovirulence being conferred by several genes or gene loci (see point 5.3.4 of the decision).
- 27. Thus, when inventive step in view of document (4) in combination with any of documents (1), (2) and (3) was assessed by the opposition division, the particular choice of the regions specified in both claim 1 of the second auxiliary request and claim 1 as granted was seen as the technical contribution of the claimed invention to the art.
- 28. This is even clearer when one examines the reasons given by the opposition division for its decision that, starting from document (1) as the closest prior art, the invention defined in claim 1 of the second auxiliary request involved an inventive step. According

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to the opposition division, document (1) described that HSV-1 strain F could be rendered non-neurovirulent by a 1000 bp **deletion** in the γ_1 34.5 gene lying in the regions specified in claim 1. The technical problem to be solved was then defined as the provision of an alternative non-neurovirulent HSV-1 strain (see point 5.3.6 of the decision).

- 29. The opposition division found that, bearing in mind the uncertainty concerning the existence of the γ_1 34.5 gene in HSV-1 strain 17 (as documented in documents (2) and (3)), and also the widely-held view at the relevant date that HSV-1 strain 17 syn⁺ differed significantly from other strains in the structure of the loci at 0-0.2 and 0.81-0.83 mu (as documented in document (12)), a person skilled in the art would not have reasonably expected to succeed in obtaining a variant of HSV-1 strain 17 lacking neurovirulence when carrying out the deletion experiment described in document (1) for HSV-1 strain F.
- 30. The board infers from the reasoning of the opposition division that, in the present case, an inventive step is to be seen not in the particular type of modification introduced into genome, but in the teaching that the regions of the genome of HSV-1 strain 17 specified in claim 1 are directly involved in neurovirulence, and that their modification results in a variant lacking neurovirulence. Since these regions are the same in claim 1 of the second auxiliary request considered by the opposition division and in claim 1 as granted, in the board's understanding the reasoning of the opposition division applies equally, *mutatis mutandis*, to claim 1 as granted.

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- 31. In spite of the fact that in its statement of grounds of appeal the appellant expressly addressed the issue of inventive step in respect of the main request (see section V above), and that in a communication to the parties the board indicated that this issue might have to be discussed at oral proceedings (see section IX above), no arguments were put forward by the respondent which may contradict the reasons given by the opposition division in support of an inventive step.
- 32. In the absence of any arguments to the contrary, the board is satisfied that, for the same reasons given by the opposition division in the decision under appeal in connection with the second auxiliary request, the invention defined in claim 1 as granted involves an inventive step within the meaning of Article 56 EPC.

Sufficiency of disclosure - Article 100(b) EPC

33. The findings of the opposition division with respect to sufficiency of disclosure have not been questioned, and the board sees no reason to do so of its own motion.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the first instance with the order to maintain the patent as granted.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani