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D E C I S I O N
of 20 May 2005

Case Number: T 0027/04 - 3.3.8

Application Number: 90310149.1

Publication Number: 0419182

IPC: C12N 15/51

Language of the proceedings: EN

Title of invention:
New HCV isolate J-1

Patentees:

Oya, Akira, Dr., Director General of the National Institute of Health of Japan, on behalf of the National Institute of Japan, et al

Opponent:

Innogenetics N.V.

Headword:

Japanese hepatitis C virus/CHIRON

Relevant legal provisions:

EPC Art. 123(2)(3)

Keyword:

"Main request - added subject-matter (no)"

"Main request - extension of the protection conferred (no)"

Decisions cited:

T 0823/96

Catchword:

-



Case Number: T 0027/04 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 20 May 2005

Appellants:
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 19 November 2003
revoking European patent No. 0419182 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
M. B. Günzel

Summary of Facts and Submissions

I. An appeal was lodged by the patentees (appellants) against the decision of the opposition division to revoke the European patent No. 0 419 182 (application number 90 310 149.1) on the basis of the claims as granted. These claims were found to contravene the requirements of Article 123(2) EPC.

II. Claims 1 and 7 **as granted** for all Contracting States except Spain read as follows:

"1. A polynucleotide in substantially isolated form comprising a nucleotide sequence of at least 15 nucleotides from a J-1 HCV isolate, said J-1 HCV isolate having at least 90% nucleotide sequence homology with the J-1 sequence of any one of Figures 7 to 10 or 13 to 18, wherein said nucleotide sequence of at least 15 nucleotides is distinct from the nucleotide sequence of HCV isolate HCV-1."

"7. A purified polypeptide comprising an amino acid sequence which:

- (a) is encoded by a nucleotide sequence as defined in any one of claims 1 to 4 or in the HCV sequences deposited and defined in claim 6, said coding being in frame with the corresponding amino acid sequences set out in Figures 7 to 10 or 13 to 18;
- (b) comprises an antigenic determinant; and
- (c) is distinct from the sequence of the polypeptides encoded by the HCV isolate HCV-1."

- III. Together with its statement of grounds of appeal, the appellants filed a main request and auxiliary requests I to VI.
- IV. The opponent (respondent) filed observations in reply to the statement of the grounds of appeal.
- V. The board issued a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal in which provisional and non-binding opinions of the board were expressed to the parties.
- VI. In reply to the board's communication both parties submitted observations. With these observations filed with letter dated 19 April 2005, the appellants also filed a new main request and auxiliary requests I to XIII for all Contracting States except Spain and a corresponding main request and auxiliary requests I to XIII for the Contracting State Spain.
- VII. Oral proceedings took place on 20 May 2005 at which the appellants filed a new main request for all Contracting States except Spain.
- VIII. Claims 1 and 4 of the **main request** for all Contracting States except Spain read as follows:

"1. A polynucleotide in substantially isolated form comprising a nucleotide sequence of at least 20 nucleotides from a J-1 HCV isolate, said nucleotide sequence having 100% nucleotide sequence homology with the J-1 sequence of any one of Figures 7, 8, 15 or from nucleotides 5095 to 5266 of Figure 16, wherein said nucleotide sequence of at least 20 nucleotides is

distinct from the nucleotide sequence of HCV isolate HCV-1."

"4. A purified polypeptide comprising an amino acid sequence which comprises at least 15 amino acids which

- (a) is encoded by a nucleotide sequence as defined in claim 1 or in the HCV sequences deposited and defined in claim 3, said coding being in frame with the corresponding amino acid sequences set out in Figures 7, 8, 15 or 16;
- (b) comprises an antigenic determinant encoded by the nucleotide sequence as defined in (a); and
- (c) is distinct from the sequence of the polypeptides encoded by the HCV isolate HCV-1."

Claim 2 related to a method of detecting HCV polynucleotides in a test sample using a polynucleotide as defined in claim 1 as a probe. Claim 3 related to polynucleotides comprising a sequence of at least 20 nucleotides from J1 HCV isolates present in specific plasmids deposited under different accession numbers and wherein said nucleotide sequence was distinct from the nucleotide sequence of HCV isolate HCV-1. Claim 5 was dependent on claim 4 and required the polypeptide of claim 4 to be immobilised on a solid support. Claims 6 and 7 related to an immunoassay for detecting the presence of anti-HCV antibodies in a test sample (human blood or a fraction thereof) using a polypeptide as defined in any one of claims 4 or 5, wherein the polypeptide was not immunologically cross-reactive with HCV-1.

IX. Claim 1 of the **main request** for the Contracting State Spain related to a method of preparing a polynucleotide as defined in claim 1 of the main request for all Contracting States except Spain, wherein said method comprised:

- "a) Chemical synthesis by methods known per se; or
- b) DNA replication by methods known per se; or
- c) Transcription or reverse transcription by methods known per se; or
- d) Restriction enzyme digestion and ligation into a vector by recombinant DNA techniques known per se."

Claim 2 of the main request for the Contracting State Spain related to a method of preparing a polypeptide as defined in claim 4 of the main request for all Contracting States except Spain, wherein said method comprised:

- "i) Chemical synthesis by methods known per se; or
- ii) Translation from the corresponding nucleic acid sequence by methods known per se; or
- iii) Expression of a recombinant expression system comprising the nucleotide sequence encoding the polypeptide by methods known per se; or
- iv) Isolation from virus by methods known per se."

X. The following document is referred to in the present decision:

D1: EP-A1-0 318 216 (publication date: 31 May 1989)

XI. The arguments of the appellants (patentees), insofar as they are relevant for the present decision, may be summarised as follows:

Main request

Articles 123(2), (3) EPC

- The nucleotide sequence "from nucleotides 5095 to 5266 of Figure 16" was individualised in the application as originally filed and defined as a region having a particular low degree of homology with the HCV-1 isolate. It was evident from Figure 16 that a separate J1 HCV clone started at nucleotide 5095 and ended at nucleotide 5266. The 5095-5266 section of the J1 HCV isolate was clearly identified (individualised) as one of three separate sections of the C200 region from the J1 HCV isolate. These three sections of the C200 region were explicitly referred to in the description as filed, which also indicated that a separate clone from the J1 HCV isolate equivalent to the 5-1-1 region of the HCV-1 isolate was cloned into mp19 R1 site and maintained in DH5 α -F'. Several m13 phage supernatants from this cloning exercise were pooled and deposited with the ATCC. The section from nucleotide 5095 to nucleotide 5266 of Figure 16 corresponded to the J1 HCV clone equivalent to the 5-1-1 region of the HCV-1 isolate as shown by comparison with the (nucleotide and amino acid) sequences of the 5-1-1 HCV-1 fragment disclosed in Figure 1 of document D1.

- The omission of the feature "said J-1 HCV isolate having at least 90% nucleotide sequence homology with the J-1 sequence of any one of Figures.." in claim 1 of

the main request when compared to granted claim 1 did not extend the protection conferred. In claim 1 as granted the nucleotide sequence of at least 15 nucleotides was not required to be from the regions shown in the Figures indicated in the claim nor to have any particular degree of homology with any J1 HCV sequence. It was only required to be derived from a J1 HCV isolate as defined in the claim. Thus, the limitation to very specific sequences of particular regions from the J1 HCV isolate was not an extension of the protection conferred. Moreover, the polynucleotide of claim 1 as granted was completely undefined except for the presence of the (undefined) nucleotide sequence of at least 15 nucleotides. No other limitations or specific requirements were associated with the claimed polynucleotide.

- According to common general knowledge (e.g. as evidenced by dictionaries and a textbook on file), the definition of "antigenic determinant" - as used in claim 4(b) - was the same as for "epitope", i.e. a site on an antigen or a part of an antigen recognised by an antibody. Both terms had the same technical meaning and were used interchangeably. Thus, the term "antigenic determinant" used in the claims as granted had exactly the same meaning as the term "epitope" found in the application as originally filed.

- All the amendments introduced in the claims in comparison to those granted were occasioned by reasons of opposition - so as to overcome objections raised for insufficiency of disclosure, lack of novelty and of inventive step. The claims of the main request fulfilled the requirements of Article 123(2) EPC and,

since the claimed subject-matter had been limited in comparison to the claims as granted, they also fulfilled the requirements of Article 123(3) EPC.

XII. The arguments of the respondent (opponent), insofar as they are relevant for the present decision, may be summarised as follows:

Main request

Articles 123(2), (3) EPC

- The feature "from nucleotides 5095 to 5266 of Figure 16" was not found in the application as originally filed and it was an arbitrary choice that was not directly and unambiguously derivable therefrom. This specific section of the J1 HCV isolate was just one coding region among other possible coding regions indicated in Figure 16. However, none of these regions was ever singled out or individualised as a special or preferred coding region. Thus, the feature "*from nucleotides 5095 to 5266 of Figure 16*" contravened the requirements of Article 123(2) EPC. Moreover, since this region was not mentioned in the granted claims, its introduction in claim 1 of the main request represented an extension of the protection conferred too (Article 123(3) EPC).

- Similarly, the omission of the feature "said J-1 HCV isolate having at least 90% nucleotide sequence homology with the J-1 sequence of any one of Figures.." in claim 1 of the main request when compared to claim 1 as granted represented an extension of the protection conferred (Article 123(3) EPC). Whereas in claim 1 as granted the subject-matter related to a very specific

subgroup of J1 HCV isolates - namely, J1 HCV isolates having at least 90% nucleotide sequence homology with the J1 sequence of any one of the indicated Figures - from which the nucleotide sequence of at least 15 nucleotides was to be obtained, claim 1 of the main request did not contemplate such a limitation. In claim 1 of the main request the nucleotide sequence of at least 20 nucleotides could be obtained from any J1 HCV isolate including J1 HCV isolates having much less than 90% homology with the J1 sequences shown in the figures indicated in the claim. Claim 1 of the main request comprised nucleotide sequences derived from J1 HCV isolates that were excluded in claim 1 as granted (i.e. nucleotide sequences from J1 HCV isolates with a degree of homology lower than 90%). Therefore, there was an extension of the protection conferred (Article 123(3) EPC).

- The term "antigenic determinant" of claim 4(b) was not present *expressis verbis* in the application as originally filed. The presence in the application as filed of many similar terms - antigenic active regions, antigens, antigenic or immunogenic regions, epitopes, etc. - demonstrated the ambiguity of this term and the absence of a single commonly accepted meaning. Since there was no commonly accepted meaning that could provide a possible basis for this term, an implicit disclosure could not be accepted. In fact, the term was not equivalent to "epitope" since it could be understood as comprising one epitope only or a collection of (multiple) epitopes as well. When drafting the application, the applicant had a right to choose the definitions and to have its own lexicon. However, after this choice, new terminology could not

be introduced arbitrarily. Thus, the term "*antigenic determinant*" contravened the requirements of Article 123(2) EPC.

The same objections applied to the main request for the Contracting State Spain too.

XIII. As main request the appellants (patentees) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims filed during the oral proceedings for all Contracting States except Spain and the claims of the main request filed for Spain with letter dated 19 April 2005. As auxiliary requests 1 to 13, the appellants requested that the patent be maintained on the basis of any of auxiliary requests I to XIII, taken in their numerical order, filed with the same letter.

XIV. The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

*Main request for all Contracting States except Spain
Article 123(2) EPC*

1. Article 123(2) EPC requires that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. In accordance with the established case law of the Boards of Appeal, the content of an application comprises the **whole disclosure** that is directly and unambiguously derivable

from the application including information which a person skilled in the art reading the application would consider to be implicitly present. In this respect, a clear distinction must be made between what has been directly and unambiguously **made available** by the application as filed, either explicitly or implicitly, and what can be merely rendered obvious by the content of the application as filed (cf. "Case Law of the Boards of Appeal of the EPO", 4th edition 2001, III.A.3.3, pages 218 to 221 and *inter alia* decision T 823/96 of 28 January 1997, point 4.5 of the reasons).

The feature "from nucleotides 5095 to 5266 of Figure 16" in claim 1

2. The application as originally filed discloses two Japanese isolates of hepatitis C virus (HCV), namely J1 and J7, which comprise specific nucleotide and amino acid sequences distinct from the corresponding sequences of the American HCV isolate HCV-1 known from the prior art (document D1). The technical contribution that the application as a whole makes over this prior art consists in the provision of these specific J1 HCV fragments that are distinct from the corresponding HCV-1 fragments for the purpose of improving the diagnosis of HCV.

3. The application as filed refers to the genomic organization of the HCV-1 isolate (core (C), envelope (E) and non-structural regions (NS1 to NS5), Figure 11) and to the nucleotide and amino acid sequences of the HCV-1 isolate (from nucleotide -267 to nucleotide 8866, Figure 12) as a "prototype" for all HCV isolates, i.e. similar genomic organization and sequences are expected

to be present in the Japanese HCV isolates (cf. page 5, lines 1 to 11, 19 to 26 and 33 to 51 of the application as published). The teachings of the application - i.e. the identification of J1 HCV fragments distinct from the corresponding HCV-1 fragments - are to be applied along the "*complete viral polypeptide*" (claim 3 as originally filed), particularly, along the length of the J1 regions C/E ("*from amino acid 116 to amino acid 350*"), E/NS1 ("*from amino acid 351 to amino acid 651*"), NS2/NS3 ("*from amino acid 1007 to amino acid 1650*") and NS3/NS4/NS5 ("*from amino acid 2100 to the end of the coding sequence*") (claims 5 to 8 as originally filed).

4. Moreover, in order to put these teachings into actual practice, the application provides the skilled person with full information on how to achieve these specific J1 HCV fragments distinct from the corresponding HCV-1 fragments. Figure 7 shows the homology of the J1 E consensus sequence with the nucleotide sequence of the same domain from HCV-1 (193 amino acid residues corresponding to amino acids 138 to 330 in Figure 12), Figure 8 shows the homology of the J1 E/NS1 consensus sequence with the nucleotide sequence of the same domain from HCV-1 (117 amino acid residues corresponding to amino acids 325 to 433 in Figure 12), etc. The comparison of these J1 consensus sequences with the corresponding HCV-1 sequences - as shown in the figures of the application as filed - allows the skilled person to identify, in a simple and easy manner, "*nucleotide sequences of at least 20 bp from a J-1 HCV isolate ... distinct from the nucleotide sequence of the HCV isolate HCV-1*" along the disclosed regions of the J1 HCV genome. These J1 HCV genomic regions - for which a straight comparison with the corresponding

- HCV-1 sequences is provided - are **made available** to the skilled reader as suitable tools for the production of the claimed polynucleotide molecules.
5. Figure 16 shows the nucleotide and amino acid sequences of the J1 HCV and HCV-1 isolates in the NS3/NS4 genomic region, particularly in the C200 region that encompasses the section encoding the 5-1-1 polypeptide (cf. page 21, lines 22 to 25 and page 23, lines 5 to 10 of the application as published). However, the comparison of the J1 and HCV-1 sequences is not complete along the full-length of the C200 region; in this case, only three sub-regions are disclosed, namely from nucleotide 3799 to 3941, 4133 to 4316 and 5095 to 5266 (cf. Figure 16 of the application as published). The 5095-5266 sub-region corresponds to part of the 5-1-1 sequence as seen by comparison with the HCV-1 sequence disclosed in the prior art (cf. Figure 1 of document D1). These three C200 sub-regions are **made available** in a straightforward manner to the skilled reader as suitable tools for the production of nucleotide sequences "*of at least 20 nucleotides ... distinct from the nucleotide sequence of HCV isolate HCV-1*" along the NS3/NS4 region.
6. The question as to whether the fragment 5095-5266 as such has actually been cloned and as to whether this clone corresponds to the clone 5-1-1 referred to on page 23 of the application as published (cf. page 23, lines 21 to 23) is considered not to be relevant by the board since, for the reasons explained above, this specific 5095-5266 sub-region referred to in the claim has been made available in a straightforward manner in

Figure 16 to the skilled person in the application as filed.

7. For these reasons, the board considers that there can not be objection under Article 123(2) EPC to the introduction of this feature in the claim.

The feature "antigenic determinant" in claim 4(b)

8. The application as originally filed defines an "epitope" as "*an antibody binding site usually defined by a polypeptide, ... An epitope could comprise 3 amino acids in a spatial conformation which is unique to the epitope, generally an epitope consists of at least 5 such amino acids, and more usually, consists of at least 8-10 such amino acids*" (cf. page 9, lines 3 to 6 of the application as published).
9. Said definition corresponds exactly to what common general knowledge understands as an "*antigenic determinant*", i.e. a single antigenic site recognized by an antibody on a complex antigenic molecule. No evidence has been provided, nor is the board aware of any, supporting a different meaning, in particular the meaning given by the respondent, namely an antigenic region comprising a collection of (multiple) epitopes.
10. Thus, the terms "*epitope*" and "*antigenic determinant*" are alternative and interchangeable. Although the term "*antigenic determinant*" is not found in the application as filed, a formal basis is found therein for the term "*epitope*". This basis is considered to support the alternative term "*antigenic determinant*" too. Since this term is the one present in the claims as granted,

the board - in these circumstances - sees no reason for changing it back to "epitope".

Article 123(3) EPC

Omission of the feature "J-1 HCV isolate having at least 90% nucleotide sequence homology with the J-1 sequence of any one of Figures..." in claim 1

11. According to Article 123(3) EPC the claims of the European patent may not be amended during opposition proceedings in such a way as to extend the protection conferred. Thus, for assessing whether the omission of the feature "J-1 HCV isolate having at least 90% nucleotide sequence homology with the J-1 sequence of any one of Figures..." involves an extension of the protection conferred, it is necessary to compare the protection conferred by the products of both claim 1 as granted and claim 1 of the main request.

Claim 1 as granted

12. The polynucleotide of claim 1 as granted is characterized only and exclusively by comprising "a nucleotide sequence of at least 15 nucleotides from a J-1 HCV isolate". There are no other requirements, elements or features characterizing this polynucleotide, which is (except for the presence of said nucleotide sequence of at least 15 nucleotides from the J1 HCV isolate) undefined, i.e. it might have any other possible nucleotide sequences and be of any possible length above 15 nucleotides.
13. The "nucleotide sequence of at least 15 nucleotides" is characterized by the following features: (a) its

- minimal length, (b) it is derived from a J1 HCV isolate, which is itself characterized by having at least 90% nucleotide sequence homology with the J1 sequences of any one of Figures 7 to 10 or 13 to 18, and (c) it is distinct from the nucleotide sequence of the HCV isolate HCV-1 (cf. section II *supra*). This "*nucleotide sequence from at least 15 nucleotides*" is not, however, limited to nucleotide sequences comprised in the regions of the J1 HCV isolate shown in any one of the figures mentioned in claim 1 but it might well be derived from other regions of the said J1 HCV isolate.
14. If, however, the "*nucleotide sequence of at least 15 nucleotides*" is selected from the regions shown in any one of these figures, claim 1 as granted does not require this nucleotide sequence to have any particular degree of homology with the J1 sequences indicated in these figures since the requirement of "*at least 90% nucleotide sequence homology*" applies only to the J-1 HCV isolate as a whole. This requirement does not exclude, however, J1 HCV isolates having a lower degree of homology in regions other than the ones indicated in the figures referred to in claim 1 and/or in all of these regions except for one. Moreover, J1 HCV isolates having an unevenly distributed degree of homology within these regions (i.e. comprising fragments with homology greater than 90% and fragments with lower homology) are not excluded from claim 1 as granted.
15. It follows from the above considerations that the "*nucleotide sequence of at least 15 nucleotides*" might be a nucleotide sequence having a degree of homology as high as 100% - or much lower than 90% - with the sequences shown in the figures referred to in claim 1

as granted but it might also be a nucleotide sequence from a region of an J1 HCV isolate (as defined in the claim) other than the regions shown in these figures. A mandatory requirement is that the "*nucleotide sequence of at least 15 nucleotides*" be distinct from the nucleotide sequence of HCV isolate HCV-1.

Claim 1 of the main request

16. The polynucleotide of claim 1 of the main request is also characterized only and exclusively by the presence of "*a nucleotide sequence of at least 20 nucleotides from a J-1 HCV isolate*". However, the said nucleotide sequence of at least 20 nucleotides is now limited to sequences having 100% nucleotide sequence homology with the J1 sequence of any one of Figures 7, 8, 15 or from nucleotides 5095 to 5266 of Figure 16 and being distinct from the nucleotide sequence of HCV isolate HCV-1. Thus, there is no extension of the protection conferred both in respect of feature (a), which now requires a longer minimal length in comparison to claim 1 as granted ("*at least 20 nucleotides*" versus "*at least 15 nucleotides*"), and of feature (c) of claim 1 as granted (cf. point 13 *supra*).

17. The respondent argues that the J1 HCV isolate from which the "*nucleotide sequence of at least 20 nucleotides*" is derived (feature (b) in point 13 *supra*) is no longer characterized in claim 1 of this request and thus, said nucleotide sequence may be derived from J1 HCV isolates other than the ones defined in claim 1 as granted, which were J1 HCV isolates having at least 90% nucleotide sequence homology with the J1 sequence of any one of Figures 7 to 10 or 13 to 18 (cf. section

- XII *supra*). However, feature (b) was a "process feature" which related only to the source of the "nucleotide sequence of at least 15 nucleotides", i.e. a feature concerning only the method of producing the said nucleotide sequence.
18. According to the established case law of the Boards of Appeal, a method of production might be relevant for the examination and, thus, for the scope of a product claim only if it confers distinct differences in the properties of the claimed product (cf. "Case Law", *supra*, I.C.3.2.7 and II.B.6, pages 72 and 172 to 175, respectively). In the present case, since the complete structure of the "nucleotide sequence of at least 20 nucleotides" (i.e. the actual nucleotide sequence) is completely defined as having 100% nucleotide sequence homology with the J1 sequence of any one of Figures 7, 8, etc. and distinct from the nucleotide sequence of the HCV isolate HCV-1, no other characteristics can be conferred by the source wherefrom this nucleotide sequence is derived (the J1 HCV isolate, feature (b) *supra*), which thus becomes irrelevant.
19. In this regard, claim 1 of the main request now requires the "nucleotide sequence of at least 20 nucleotides", which is comprised in the claimed polynucleotide, to have 100% nucleotide sequence homology with the J1 sequences of any one of the figures indicated in claim 1 (cf. section VIII *supra*). Since a degree of 100% homology cannot be achieved if the length of the nucleotide sequence is greater than the length of the corresponding nucleotide sequence shown in these figures, an upper limit to the length of the "nucleotide sequence of at least 20 nucleotides" is

- implicitly set out in claim 1 of the main request. Thus, the presence of additional undefined regions within this nucleotide sequence is excluded by the required degree of homology and, as stated in point 18 *supra*, the structure of the "*nucleotide sequence of at least 20 nucleotides*" is completely defined.
20. Although additional undefined regions are clearly excluded from the "*nucleotide sequence of at least 20 nucleotides*", such regions might well be comprised within the claimed polynucleotide, which is itself (except for the presence of the "*nucleotide sequence of at least 20 nucleotides*") undefined (cf. point 16 *supra*). The presence of other nucleotide sequences, either from related or non-related J1 HCV isolates or from any other possible source, within the claimed polynucleotide is not excluded. Nevertheless, exactly the same applies for the polynucleotide of claim 1 as granted too (cf. point 12 *supra*).
21. It follows from all the above that, as far as the scope of protection is concerned, which is defined by the characteristics of the "*nucleotide sequence of at least 20 nucleotides*" having 100% homology with the J1 sequences of the figures referred to in claim 1 of the main request, the J1 HCV isolate from which this nucleotide sequence is obtained is not relevant and thus, the omission of a feature characterizing this J1 HCV isolate does not represent an extension of the protection conferred.

The feature "from nucleotides 5095 to 5266 of Figure 16" in claim 1

22. This feature represents a limitation to a sub-region out of three sub-regions made available to the skilled person for obtaining J1 nucleotide sequences of at least 20 nucleotides distinct from the corresponding nucleotide sequences of the HCV isolate HCV-1. Since in claim 1 as granted the nucleotide sequence of at least 15 nucleotides was not required to be selected from any specific region (or sub-region) of the J1 HCV isolate, a limitation to one of these three sub-regions - as in claim 1 of the main request - cannot be seen as an extension of the protection conferred.

Main request for the Contracting State Spain (ES)

23. No objections other than the ones raised against the main request for all Contracting States except Spain have been raised against the main request of the Contracting State Spain (cf. section XII *supra*). The reasons given above for the main request for all Contracting States except Spain apply also, in principle, for the Contracting State Spain.
24. However, claim 1 of the main request for the Contracting State Spain is a method claim and thus, the omission of the feature "*said J-1 HCV isolate having at least 90% nucleotide sequence homology*" might have a possible relevance under Article 123(3) EPC (cf. point 18 *supra*). In claim 1 as granted this feature, however, only defines the product (polynucleotide comprising a nucleotide sequence of at least 15/20 nucleotides) resulting from the claimed method, not the

method itself, i.e. it is not required that in carrying out the claimed method a specific type of J1 HCV isolate is actually used as a physical source for the nucleotide sequence. In fact, both claims 1 and 2 as granted foresee any possible source since explicit reference is made *inter alia* to chemical synthesis (cf. section IX *supra*). Thus, the omission of the feature "*said J-1 HCV isolate having at least 90% nucleotide sequence homology*" in the main request for the Contracting State Spain does not represent an extension of the protection conferred.

Conclusion

25. In summary, in the board's judgment, none of the objections under Articles 123(2), (3) EPC pleaded by the respondent are convincing and thus, the main requests for all Contracting States except Spain and for the Contracting State Spain are considered to fulfil the requirements of Articles 123(2), (3) EPC.

26. As a violation of the provisions of Article 123(2) EPC by the claims then on file was at the origin of the revocation of the patent by the opposition division, the case is now remitted to the opposition division for further prosecution (Article 111 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution on the basis of the main request, for all Contracting States except Spain as filed during the oral proceedings, for Spain as filed with the appellants' letter dated 19 April 2005.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani