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

Case Number: T 1281/08 - 3.3.04

Application Number: 03380136.6

Publication Number: 1384790

IPC: C12Q 1/68

Language of the proceedings: EN

Title of invention:

Labeling of objects to be identified consisting of at least one DNA fragment

Applicant:

S.I.G. Sistemas de Identificación Genética, S.A.

Headword:

Labeling of objects/SIG

Relevant legal provisions:

EPC Art. 108, 111(1)

Keyword:

"Admissible appeal (yes)"

"Remittal to the department of first instance (yes)"

Decisions cited:

T 0063/86

Catchword:

-



Case Number: T 1281/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 3 November 2008

Appellant: S.I.G. Sistemas de Identificación Genética,
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 February 2008
refusing European patent application
No. 03380136.6 pursuant to Article 97(2) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: B. Claes
R. Moufang

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application 03 380 136.6 having the title "*Labeling of objects to be identified consisting of at least one DNA fragment*".
- II. The decision under appeal was based on claims 1 to 19 according to the then pending request submitted with letter of 22 September 2006. Claims 1, 6 and 19 of this request were independent claims. These claims read:
- "**1. A marker of objects to be identified** that comprises one or a plurality of fragments of DNA included in a solution provided with some means for detection of said marker, characterized in that each one of said fragments of DNA included in said solution is a polymorphic DNA fragment of the type of microsatellites (STR) or of the type of single nucleotide polymorphisms (SNP) microencapsulated and bound to a system of detection selected from a group comprising magnetic microspheres; pigments; and a fluid with electrical properties, and/or fluorescent to ultraviolet and/or infrared radiation." (emphasis added by the board)
- "**6. Procedure for the incorporation of the marker of claim 1 in the object to be identified**, that starting from a biological sample belonging to a selected living being, comprises:
- (first step) extracting the DNA from the biological sample;
- (second step) liberating the DNA extracted into a solution compound, and purifying the DNA;

(third step) amplifying DNA polymorphic fragments of the type STR and / or SNP using PCR process;

(fourth step) concentrating the DNA by ultracentrifugation, dissolving the solution containing the polymorphic DNA in a solvent and a polymer, introducing a resulting mix in a non-solvent in a relation solvent/non-solvent of between 1/40 up to 4/200 and microencapsulating of the amplified DNA polymorphic fragments of the type STR and / or SNP into a polymer by means of the phase inversion technique;

(fifth step) incorporating the microcapsules into a solution with UV or IR 10 radiation sensitive substances;

(sixth step) determining and correcting the degree of fluidity and concentration of the solution containing the microencapsulated DNA polymorphic fragments of the type STR and / or SNP;

(seventh step) incorporating the solution in an applicator and marking the object to be identified."
(emphasis added by the board)

"19. Method for identifying the objects marked with the marker as in Claim 1, and obtained from the procedure described in Claim 6, comprising:

(first step) detecting an object to be identified, which is carried out by means of a filter for visualizing at least one of the pigments and elements incorporated into the marker, and by detecting at least one type of radiation such as the wavelength, magnetism, and/or conductivity incorporated with at least one radiation sensitive substance, magnetic particles, and the characteristics of conductivity of the solution, the method being characterized in that additionally comprises:

(second step) revealing a key of the individual DNA polymorphic fragments of the type STRs and SNPs fragments included into the marker; and
(third step) authenticating the marked object by detecting the selected marking STRs and SNPs with specific primers that flank the polymorphic region by using PCR for the identification of every polymorphic DNA fragment in the marked object and, finally, DNA Typing of the amplified fragments and determining the real allelic variants therein." (emphasis added by the board)

III. In its decision, the examining division held that the subject-matter of claims 1, 6 and 19 contravened the requirements of Article 123(2) EPC, that claim 1 did not meet the clarity requirement of Article 84 EPC and that the subject-matter of product claim 1 and its dependent claims 2 to 4 lacked novelty pursuant to Article 54 EPC.

IV. The appellant has requested that the decision under appeal be set aside and a patent be granted on the basis of a new set of 14 claims filed with the statement of the grounds of appeal dated 18 June 2008. In this new set of claims, claims 1 and 12 are independent claims and read:

"1. A procedure for labelling an object to be authenticated characterized in that the procedure comprises:

extracting a sample containing DNA from a selected live being wherein the extracting includes liberating the DNA in a solution with Tris-HCL, 10 mM-EDTA 0.1mM, SDS to 20% (weight/volume) and Proteinase K 10mg/ml.,

and purifying the DNA with Phenol/Chloroform 10/9 (volume/volume);

selecting at least one polymorphic fragment of said DNA sample wherein the selecting includes flanking at least one polymorphic fragment selected from microsatellites and single nucleotides polymorphisms in the extracted DNA;

amplifying the selected at least one polymorphic fragment to produce amplified polymorphic DNA fragments, said amplifying being performed using polymerase chain reaction in a thermocycler with a concentration between 6 pgr and 0.05 microgr of the extracted DNA sample in a PCR Buffer solution 10X, dNTP 10X, primers that flank the polymorphic region 10X of the at least one polymorphic fragment and Taq polymerase of 5000 units per ml;

microencapsulating the amplified DNA polymorphic fragment, wherein the microencapsulating includes concentrating the amplified polymorphic fragments of said DNA by ultracentrifugation, dissolving the polymorphic fragments of said DNA in a solvent and a polymer in a concentration of between 0.25 and 10% (weight/volume), mixing the dissolved polymorphic fragment, solvent and polymer into a non-solvent in a relation solvent/non solvent of between 1/40 up to 4/200 and removing the solvent to microencapsulate the concentrated polymorphic fragments of said DNA ; and

labelling the object with microencapsulated DNA polymorphic fragment so that the DNA polymorphic fragments in the microencapsulated DNA polymorphic fragment can be analyzed to authenticate the object."

"12. **Method for authenticating an object marked with a mixture of polymorphic fragments of DNA** comprising identifying an object to be authenticated, obtaining identification of a mixture of polymorphic fragments of DNA in the marked object and authenticating the marked object by detecting fragments using polymerase chain reaction with primers flanking the polymorphic region".

V. The appellant's arguments in the statement of the grounds for appeal were the following:

"The invention concerns a procedure for labeling [sic] an object to be authenticated wherein the marking material includes one or more polymorphic fragments extracted from a live being, amplified and microencapsulated. While it is known that DNA from a live being can be used as a marker for objects to be identified, such markers do not contain an amplified concentration of polymorphic fragments extracted from the DNA of a live being. Extraction and amplification of polymorphic fragments, such as STR and SNP, occur during authentication of the marker, not during the manufacture of the marker prior to applying to an object. The prior art describe artificially generated nucleic acid strings and amplification of such strings is part of such manufacture. Generally DNA containing fluids from a living being are rich enough in DNA not to need amplification for use in a marker.

Therefore, applicant respectfully traverses the arguments from the Examiner, regarding Article 123(2) EPC, Article 84 EPC and Article 54 EPC, for the rejection of the application and is now amending the

current set of claims in such a form that applicant believes the claims are now in condition for allowance.

Applicant, as part of this Appeal, is filing a newly amended set of 14 Claims. Applicant states that no new matter has been introduced in the amended set of claims now filed. Basis for the amended claims can be found in the original description as filed.

In view of the foregoing reasons, Applicant respectfully requests a favourable decision granting the present application."

Reasons for the Decision

The grounds for refusal of the application and the new request

1. In its decision, the examining division held that the subject-matter of claims 1, 6 and 19 of the pending request submitted with letter of 22 September 2006 before them (see section II above) contravened the requirements of Article 123(2) EPC, that claim 1 did not meet the clarity requirement of Article 84 EPC and that the subject-matter of product claim 1 and its dependent claims 2 to 4 lacked novelty pursuant to Article 54 EPC.
2. The appellant no longer defends the set of claims that was pending before the examining division but has instead filed with its statement of the grounds of appeal a new set of claims with two independent claims 1 and 12, both method claims, which are concerned with a procedure for labelling an object to

be authenticated and a method for authenticating an object marked with a mixture of polymorphic fragments of DNA, respectively. Accordingly, none of the claims pending before the examining division and on which the refusal of the application was based are now pending before the board.

Admissibility of the appeal

3. The board notes that the request now on file no longer contains product claims. Hence, the objections of the examining division under Article 54 and 84 EPC no longer apply to the claims of this request. Furthermore, the two method claims in the request before the board no longer contain features to which the examining division has objected under Article 123(2) EPC.
4. It is established case law of the boards of appeal that as an exception to the general principle that the statement of the grounds for appeal should specify the legal or factual reasons why the decision is alleged to be incorrect, an appeal can already be admissible if new claims are put forward which overcome the objections of the department of the first instance (see Case Law of the Boards of Appeal of the European Patent Office, 2006, VII.D.7.5.1 and 7.5.2, in particular 7.5.2(a) and (d)). Following this case law the board is satisfied in the present case that the statement of the grounds of appeal complies with the requirements of Article 108, third sentence, EPC.
5. Since the appeal meets also the further admissibility criteria as set out in Articles 106 to 108 EPC and Rule 99 EPC, the appeal is admissible.

Remittal to the first instance department

6. The new independent claims 1 and 12 contain substantial amendments to the appellant's case as it follows from a comparison of their wording with that of independent claims 6 and 19 before the examining division (see sections II and IV). Neither of these new claims, which are concerned with a procedure for labelling an object to be authenticated and a method for authenticating an object marked with a mixture of polymorphic fragments of DNA, respectively, have been formulated before the examining division let alone been the subject of examination in the first instance. Furthermore, as already noted in point 3, the new independent claims 1 and 12 no longer contain features to which the examining division has objected under Article 123(2) EPC. The new claims therefore generate a fresh case not yet addressed in examination proceedings and requiring further examination.

7. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case for further prosecution.

8. In a case such as the present one where substantial amendments have been proposed which require a substantial further examination in relation to both the formal and substantial requirements of the EPC, the board, following the established case law of the boards

of appeal (see Case Law of the Boards of Appeal of the European Patent Office, 2006, VII.D.9, in particular decision T 63/86, OJ EPO 1988, 224) and with a view to secure the applicant's right to appeal to a second instance, considers it appropriate that such further examination should be carried out by the first instance department.

9. Under these circumstances, the board has decided to exercise its discretion under Article 111(1) EPC to remit the case to the first instance department for further prosecution on the basis of the patent application documents on file including the documents filed with the statement of the grounds of appeal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar

The Chair

P. Cremona

U. Kinkeldey