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Datasheet for the decision of 14 October 2016

Case Number: T 1634/15 - 3.3.08

Application Number: 99965030.2

Publication Number: 1135530

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:
MULTIPLEX AMPLIFICATION OF SHORT TANDEM REPEAT LOCI

Patent Proprietor:
PROMEGA CORPORATION

Opponents:
Qiagen GmbH
Life Technologies Corporation

Headword:
CODIS core STR loci forensic human identification/PROMEGA

Relevant legal provisions:
EPC Art. 100(a), 54, 112a(1)

Keyword:
Main and sole request (claims as granted) - novelty (no)
Referral of question to the Enlarged Board of Appeal (no)

Decisions cited:

T 0772/89, T 0348/94, T 0386/94, T 0607/93, T 0086/95, T 1208/97, T 1212/97, T 0890/02, T 0151/05, T 0452/05, T 2264/09, T 0412/09, T 1347/11, T 2168/11, T 2487/12

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1634/15 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 14 October 2016

Appellant: (Patent Proprietor)	PROMEGA CORPORATION 2800 Woods Hollow Road Madison, WI 53711-5399 (US)
Representative:	Brasnett, Adrian Hugh Mewburn Ellis LLP City Tower 40 Basinghall Street London EC2V 5DE (GB)
Respondent: (Opponent 1)	Qiagen GmbH Qiagen Str. 1 40724 Hilden (DE)
Representative:	CH Kilger Anwaltspartnerschaft mbB Fasanenstrasse 29 10719 Berlin (DE)
Respondent: (Opponent 2)	Life Technologies Corporation 5791 Van Allen Way Carlsbad, CA 92008 (US)
Representative:	Roques, Sarah Elizabeth J A Kemp 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 June 2015 revoking European patent No. 1135530 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	B. Stolz
Members:	P. Julià
	D. Rogers

Summary of Facts and Submissions

I. The appeal lies against the decision of the opposition division to revoke European patent No. 1 135 530, which is based on European patent application No. 99 965 030.2 (published as International patent application WO 00/31306) claiming the priority date of 25 November 1998 from the document US 199 542. The opposition division decided that the main and sole request (the claims as granted) did not fulfil the requirements of Article 100(a) EPC (Article 56 EPC) and, accordingly, revoked the patent.

II. With the statement setting out the grounds of appeal, the patent proprietor (appellant) requested that the decision under appeal be set aside and the patent be maintained as granted.

III. Acceleration of the appeal proceedings was requested by opponent 02 (respondent II), which provided evidence of the payment of royalties under license agreement between opponent 02/respondent II and the patent proprietor/appellant.

IV. The request for acceleration of the appeal proceedings was granted by the board.

V. Both, opponent 01 and 02 (respondents I and II, respectively), replied to the statement of grounds of appeal and requested to dismiss the appeal. Respondent I further requested that, if the board decided that the patent was entitled to the claimed priority date, four questions of law be referred to the Enlarged Board of Appeal.

VI. The appellant replied to respondent I's submissions on the entitlement to the claimed priority rights and the request for a referral to the Enlarged Board of Appeal.

VII. The parties were summoned to oral proceedings and, in a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, they were informed of the board's preliminary, non-binding opinion on the issues of the case.

In particular, the board stated that respondent I's arguments about the entitlement to the priority rights appeared to have been filed only in appeal proceedings. Thus, they were new in the proceedings and late-filed. The board was unlikely to admit a fresh case in appeal proceedings based on these arguments. The board further stated that, taking into account only prior art available before the claimed priority date, the appellant's main and sole request, namely the claims as granted, did not fulfil the requirements of Articles 54 and 56 EPC.

VIII. In reply to the board's communication, respondent II confirmed its request that the appeal be dismissed and requested furthermore that the decision under appeal be upheld without a referral to the Enlarged Board of Appeal.

IX. The appellant withdrew its request for oral proceedings, informed the board of its intention not to be represented at these proceedings, and maintained its main and sole request, namely to set aside the decision under appeal and to maintain the patent as granted, without making any substantive submissions.

X. Both, respondents I and II, requested the board to hold the scheduled oral proceedings and informed the board of their intention to attend these proceedings.

XI. Oral proceedings were held on 14 October 2016 in the absence of the appellant.

XII. Claim 1 of the **main request** (claims as granted) reads as follows:

"1. A method of simultaneously identifying the alleles present in a set of loci of from one or more DNA samples, comprising:

(a) providing a DNA sample to be analyzed,

(b) selecting a set of loci of the DNA sample, comprising short tandem repeat loci D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D21S11, HUMCSF1PO, HUMFIBRA, HUMTH01, HUMTPOX, and HUMvWFA31;

(c) co-amplifying the loci in the set in a multiplex amplification reaction, wherein the product of the reaction is a mixture of amplified alleles from each of the co-amplified loci in the set; and

(d) evaluating the amplified alleles in the mixture to determine the alleles present at each of the loci analyzed in the set within the DNA sample;

wherein the multiplex amplification reaction is a polymerase chain reaction."

Claims 2 to 6 are directed to preferred embodiments of the method of claim 1.

XIII. The following documents are cited in this decision:

D2: WO 97/39138 (publication date: 23 October 1997);

D8: J.W. Schumm *et al.*, "Pentanucleotide Repeats: Highly Polymorphic Genetic Markers Displaying Minimal Stutter Artifact", early 1999, pages 100 to 111;

D9: E.A. Amiott *et al.*, "Incorporating High Quality Genetic Markers into Forensically Useful Multiplexes", early 1999, pages 2 to 6;

D10: "Meeting Report on The Ninth International Symposium on Human Identification, October 8-10, 1998", Profiles in DNA, GenePrint™, early 1999, page 13;

D20: B. Budowle *et al.*, "CODIS and PCR-Based Short Tandem Repeat Loci: Law Enforcement Tools", pages 73 to 88 (published after the priority date claimed by the patent);

D26: N.J. Oldroyd *et al.*, "A highly discriminating octoplex short tandem repeat polymerase chain reaction system suitable for human individual identification", Electrophoresis, 1995, Vol. 16, pages 334 to 337;

D35: Extract from "Forensic DNA Typing", pages 97 and 98 (published after the filing date of the patent);

D36: C. Kimpton *et al.*, "Evaluation of an automated DNA profiling system employing multiplex amplification of four tetrameric STR loci", Int. J. Leg. Med.,

1994, Vol. 106, pages 302 to 311;

D37: P. Gill *et al.*, "Automated short tandem repeat (STR) analysis in forensic casework - a strategy for the future", Electrophoresis, 1995, Vol. 16, pages 1543 to 1552.

XIV. In the statement of grounds of appeal, the appellant provided only arguments relating to Article 100(a) EPC in conjunction with Article 56 EPC, the sole article of the EPC and ground of opposition for which the patent was revoked (cf. point I *supra*). No substantive submissions relating to Article 100(a) EPC in conjunction with Article 54 EPC were filed by the appellant, neither in reply to the respondents' objections raised under this article nor to the board's communication pursuant to Article 15(1) RPBA (cf. point VII *supra*).

XV. In reply to appellant's statement of grounds of appeal, respondent I argued that the patent was not entitled to the claimed priority date. As regards Article 100(a) EPC in conjunction with Article 54 EPC, respondent I argued that the subject-matter of granted claim 1 was anticipated by the disclosure of document D8 (an article on a lecture presented at the Ninth International Symposium on Human Identification that took place on October 8-10, 1998) which was published after the claimed priority date but before the filing date of the patent.

XVI. Respondent II argued that granted claim 1 lacked novelty over the disclosure that took place at the Ninth International Symposium on human identification on 8-10 October 1998 (thus, before the claimed priority date of the patent), as reported in document D10.

Document D10 provided a short report of what took place at this Symposium. According to the case law of the Boards of Appeal, in particular decision T 86/95 of 9 September 1997, document D10 provided an accurate report of what was disclosed at the meeting.

In the second paragraph, document D10 referred to several presentations made at this Symposium and focused on short tandem repeat (STR) analysis using multiplex systems. Two speakers, E. Amiott of Promega Corporation and S. Walsh of Perkin-Elmer/Applied Biosystems, presented data on STR multiplex systems having all 13 loci recommended by the United States Federal Bureau of Investigation (FBI) for inclusion in the Combined DNA Index System (CODIS loci), a database of DNA typing information. According to document D10, E. Amiott informed on systems for amplification of all 13 core CODIS loci in two reactions and further described a single reaction system containing 16 loci that was planned to be commercialized in the summer of 1999. In the context of this passage, it was understood that this system included the 13 CODIS loci and 3 additional loci to make up the number to 16. This was consistent with the PowerPlex™ 16 kit, identified in document D35 as having a release date of May 2000 and having 16 loci in total, including the 13 core CODIS loci. This oral presentation anticipated the subject-matter of granted claim 1.

XVII. The appellant requested that the decision under appeal be set aside and the patent maintained as granted.

XVIII. The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. By its decision not to attend the scheduled oral proceedings and not to file substantive arguments in reply to the board's communication pursuant to Article 15(1) RPBA, the appellant has chosen not to comment on the board's preliminary, non-binding opinion expressed in that communication. This has been done even though the board was of the preliminary, non-binding opinion that appellant's main and sole request, the claims as granted, did not fulfil the requirements of Article 54 EPC. Moreover, none of the respondents has filed or made further substantive submissions on Article 54 EPC in reply to the board's communication.

2. The present decision on Article 54 EPC is thus based on the board's preliminary, non-binding opinion as expressed in its communication pursuant to Article 15(1) RPBA.

Article 100(a) EPC (Article 54 EPC)

3. Documents D8 to D10, D20 and D35 have been cited under Article 54 EPC. It is not contested that "*documents D8-D10 ... were made available to the public sometime in 1999, i.e. after the priority date*" (cf. Notice of opposition filed on 20 September 2012 by opponent 01/ respondent I, point VI, pages 19 to 24; patent proprietor/appellant's reply thereto on 7 April 2014, pages 13 to 15; and page 6, point 2.3.4 of the decision under appeal). Documents D20 and D35 have also been published after the priority date claimed by the patent and after the filing date of the patent, respectively. It is necessary to assess whether "*the oral disclosures given before the priority date* [at "*The Ninth International Symposium on Human Identification,*

October 8-10, 1998"] *were identical to the disclosures of the later published reports of D8 and D9*" (cf. page 6, last paragraph of the decision under appeal).

4. Document D10, under the heading "*Meeting Report*", reports on "*The Ninth International Symposium on Human Identification, October 8-10, 1998*" and refers to the data presented "*on STR multiplex systems that provide all 13 loci recommended by the FBI for inclusion in the U.S. CODIS (Combined DNA Index Sytem) database*". Immediately thereafter, it states that "*Elizabeth Amiott provided information on the GenePrint™ PowerPlex™ 1.2 and 2.2 Systems for amplification of* ***all 13 CODIS loci*** *in two reactions and described a* ***single-reaction system containing 16 loci*** *that is planned for the summer of 1999*" (emphasis by the board). The disclosure of document D10 is also acknowledged in the patent itself when describing the background of the invention (cf. paragraphs [0011] and [0012] of the patent).

5. It is not contested that "*all 13 CODIS loci*" were known before the claimed priority. Document D20, cited also on paragraphs [0011]-[0012] of the patent, refers to a "*STR Project meeting* [held] *on November 13-14, 1997*" in which the 13 CODIS loci were agreed upon by participating laboratories (cf. page 76, right-hand column, second paragraph of document D20). Importantly, document D20 reports that "*the STR project working group decided overwhelmingly that ... samples would be typed for* ***all 13 core STR loci"*** (emphasis by the board) (cf. page 77, left-hand column, second paragraph of document D20). Thus, the set of 13 core CODIS loci (the set of loci cited in claim 1) was already defined and characterized in November **1997**. The relevance of developing "*STR multiplex systems*" for providing data

on "*all 13 core CODIS loci*" is evident from the strong support from the STR project working group for this decision.

6. In the board's view, the disclosure of document D10 must be read in the light of these considerations. In view of the common general knowledge and the particular context of the citation "*16 loci*" in document D10, these loci must be understood as comprising "*all 13 core CODIS loci*". This is in line with documents D8 and D9 (cf. page 102, right-hand column, Figures 9-12 of document D8; page 2, paragraph bridging left and right-hand columns, Figures 2-4 of document D9) which refer to GenePrint™ PowerPlex™ 1 and 2 Systems and to a GenePrint™ PowerPlex™ **16** System comprising "*all 13 core CODIS loci*". Evidence on file shows that the PowerPlex™ 16 System was released in May 2000 (cf. Table 5.3 of post-published document D35).

7. In the light thereof, the conclusion of the opposition division that "*it cannot be determined with* ***certainty*** *whether the actual lectures only mentioned the number of loci (16) or if they also specified the identities of the loci*" (cf. page 7, first paragraph of the decision under appeal) is considered to be untenable, since the identities of "*all 13 core CODIS loci*" were known to the skilled person who was also well-aware of the interest to have all of them "*incorporated in a single-reaction system*" (cf. page 7, first and second paragraphs of the decision under appeal). Indeed, this is also in line with appellant's argument in the context of Article 56 EPC as to the constraints faced by the skilled person not being free to choose any combination of loci but, contrary to the case underlying the decision T 2264/09 of 25 March 2014, being limited to the "*13 core CODIS loci*".

8. In the board's view, the evidence on file is appropriate and credible to overcome any possible doubt. The board is certain beyond reasonable doubt that the information concerning the "*16 loci*" - and comprising "*the 13 core CODIS loci*" - was made available to the public at "*The Ninth International Symposium on Human Identification*" which took place before the claimed priority date (cf. T 86/95 of 9 September 1997, point 3 of the Reasons; T 348/94 of 21 October 1998, point 3.2 of the Reasons; T 1212/97 of 14 May 2001, point 2 of the Reasons).

9. According to the case law of the Boards of Appeal, for a disclosure to destroy novelty, this disclosure must be reproducible and enabling, that is to say, the information provided by the disclosure must be sufficient to enable a skilled person, at the relevant date of said disclosure, to carry out the technical teaching of the disclosure, taking also into account the general common general knowledge at that time in the field (cf. "Case Law of the Boards of Appeal of the EPO", 8th edition 2016, I.C.4.11, page 113).

10. There is no evidence that the oral disclosure of the GenePrint™ PowerPlex™ **16** System comprising "*all 13 core CODIS loci*" included more specific technical information such as specific primer sequences or the reaction conditions of the single multiplex PCR (mPCR) amplification. It is therefore necessary to assess whether the mere disclosure of the "*16 loci*" enabled a skilled person to carry out the method disclosed at "*The Ninth International Symposium on Human Identification*" (cf. T 1212/97, *supra*, point 2 of the Reasons).

11. The method of claim 1 is not limited to the use of specific primer sequences and concentrations, mPCR conditions, etc. In line with the established case law of the Boards of Appeal (cf. *inter alia*, T 607/93 of 14 February 1996, points 2.2 and 2.3 of the Reasons, T 1208/97 of 3 November 2000, points 4(a) to 4(c) of the Reasons, and T 2487/12 of 27 October 2015, point 1.13 of the Reasons), none of these features has to be taken into account when assessing novelty.

12. As regards the common general knowledge of a person skilled in the art, although it has been defined by the Boards of Appeal as normally being represented by encyclopedias, handbooks and dictionaries on the subject in question, the Boards have also acknowledged that, in several cases, scientific publications may also be considered as forming part of this common general knowledge, in particular, when a field of research is so new that this research has not yet found its way into textbooks (cf. *inter alia*, T 890/02, OJ EPO 2005, page 497, point 2 of the Reasons; T 1347/11 of 29 October 2013, point 4 of the Reasons; T 772/89 of 18 October 1991, point 3.3. of the Reasons), or when a plurality or a series of publications provides a consistent picture that a particular technical procedure was generally known and belonged to the common general knowledge in the art at the relevant date (cf. *inter alia*, T 412/09 of 9 May 2012, point 2.1.3 of the Reasons; T 452/05 of 30 August 2006, point 2.4.1, paragraph (b)(ii) of the reasons; T 151/05 of 22 November 2007, point 3.4.1 of the Reasons).

13. In the present case, the patent itself provides information on this common general knowledge in the section "*Background of the Invention*" by reference to a large body of prior art concerned with multiplex

systems, mPCR amplification of STRs, and co-amplification of several STRs in a single reaction (cf. paragraphs [0007] to [0012] of the patent). This whole body of prior art is also acknowledged in the documents from the prior art on file such as, for instance documents D36 and D37, which identify the factors and conditions most relevant for successfully performing mPCR amplification in a single reaction.

14. Indeed, this prior art reports the application of mPCR amplification in a single reaction for some of the STR loci cited in claim 1. Example 23 of document D2, a prior art document cited in paragraph [0010] of the patent, discloses a single mPCR amplification of 8 core CODIS loci (CSF1PO, TPOX, TH01, VWA (HUMvWFA31), D16S539, D13S317, D7S820, D5S818) present in the PowerPlex™ Systems with release dates of January 1997 and September 1998 (versions 1.1 and 1.2, respectively), as shown in Table 5.3 of post-published document D35. Document D35 also shows that two STR multiplexes with more than 8 loci were already commercially available before the claimed priority date. One of them, the AmpF/STR® Profiler Plus™ with a release date of December 1997, had 5 core CODIS loci (D3S1358, FGA (HUMFIBRA), D8S1179, D21S11 and D18S51) not cited in document D2, showing thereby that these other 5 CODI loci were also amenable to a single mPCR amplification and, indeed, in a set of 10 loci which comprised some of the other core CODIS loci used in Example 23 of document D2 (VWA (HUMvWFA31), D5S818, D13S317 and D7S820). Likewise, document D26 reports a single mPCR amplification system based on 8 loci, 5 of which are core CODIS loci (D21S11, D18S51, HUMvWFA31/A, HUMTH01 and HUMFIBRA). Whilst 3 of these loci are used in Example 23 of document D2 (HUMvWFA31/A, HUMTH01,

HUMFIBRA), 2 are not cited in document D2 (D21S11, D18S51).

15. In the light of this common general knowledge of a person skilled in the art, the board is convinced that the information concerning the "*16 loci*" (which comprise "*the 13 core CODIS loci*") made available to the public at "*The Ninth International Symposium on Human Identification*", enabled the skilled person to carry out a method of simultaneously identifying the alleles present in a set of loci from a DNA sample with all the features of claim 1.

16. Thus, the main request does not fulfil the requirements of Article 54 EPC.

Referral of questions of law to the Enlarged Board of Appeal

17. Respondent I's request to refer four questions of law to the Enlarged Board of Appeal concerned issues relating, only and exclusively, to the entitlement to priority rights. The request was made conditional upon a possible decision of the board acknowledging the priority rights claimed by the patent (cf. point V *supra*).

18. Since the board could decide on the question of novelty of the main request on the basis of disclosures made available to the public before the claimed priority date, the question whether priority is validly claimed can be left unanswered. Consequently, the precondition of respondent I's request for referring any questions of law to the Enlarged Board of Appeal is not met.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

A. Wolinski B. Stolz

Decision electronically authenticated