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Datasheet for the decision of 20 February 2025

Case Number: T 1629/23 - 3.3.08

Application Number: 18186518.9

Publication Number: 3456844

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Language of the proceedings: EN

Title of invention:
Resolving genome fractions using polymorphism counts

Patent Proprietor:
Verinata Health, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:
Resolving genome fractions/VERINATA HEALTH

Relevant legal provisions:
EPC Art. 56, 87, 113(1)
RPBA 2020 Art. 12(3), 12(5), 13(2)

Keyword:
Main request - priority (no)
Main request - inventive step (no)
Auxiliary requests - admittance (no)

Decisions cited:
T 2598/12, T 0694/15, T 0816/16, T 2115/17, T 0261/19, T 1220/21, T 2360/19, T 1006/21, T 1919/17, T 1913/19

Catchword:
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Case Number: T 1629/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 20 February 2025

Appellant: (Opponent)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Respondent: (Patent Proprietor)	Verinata Health, Inc. 5200 Illumina Way San Diego, California 92122 (US)
Representative:	Cooley (UK) LLP 22 Bishopsgate London EC2N 4BQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 July 2023 rejecting the opposition filed against European patent No. 3456844 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	T. Sommerfeld
Members:	B. Claes
	R. Winkelhofer

Summary of Facts and Submissions

I. The appeal lodged by the opponent (appellant) lies from the opposition division's decision rejecting the opposition against European patent No. 3 456 844 granted on the basis of European patent application No. 18 186 518.9, which is a divisional application of European patent application No. 16 158 103.8, which in turn is a divisional application of European patent application No. 12 716 939.9, filed as an international application published as WO 2012/142334. The patent claims priority from US 201161474362 P filed on 12 April 2011 ("priority document").

II. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and Article 100(b) EPC.

III. With the appeal, the appellant contested priority, novelty and inventive step in the context of the claims as granted.

IV. The patent proprietor (respondent) replied to the appeal and maintained the three auxiliary requests which had been filed in the opposition proceedings.

V. The parties were summoned to oral proceedings to be held on 7 March 2025 and subsequently, in a communication pursuant to Article 15(1) RPBA, the board expressed the preliminary opinion, *inter alia*, that the priority was not valid for the subject-matter of claim 1 of the main request (patent as granted), meaning that the relevant date was thus the filing date, and document D9 was accordingly part of the state

of the art under Article 54(2) EPC. While the board further held in this communication that the subject-matter of claim 1 was not anticipated by the disclosure in document D9 (Article 54 EPC), it also held that it lacked inventive step (Article 56 EPC) when starting from the disclosure of example 6 of document D9, which represented the closest prior art. The board also held that claim 1 of each of the auxiliary requests on file was not allowable.

VI. In response to the board's communication, the respondent further defended their patent, announced that they would not be represented at the oral proceedings and requested "*a decision to be issued in our absence on the file as it stands*" (section 6 of respondent's response dated 27 January 2025).

VII. The board cancelled the oral proceedings.

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

D8: Chu T. *et al.*, Prenatal Diagnosis, 2010, 30: 1226-9

D9: WO 2012/019200

IX. The parties' submissions and arguments on appeal, insofar as they are relevant for the decision, are taken into consideration in the reasons for the decision by the board set out below.

X. The parties' requests which are relevant for the decision on substance are as follows:

The appellant requests that the decision under appeal be set aside and amended such that the patent be

revoked.

The respondent requests that the appeal be dismissed (main request, patent as granted), or alternatively, that the patent be maintained with the set of claims in one of auxiliary requests 1 to 3 filed on 4 April 2023.

Reasons for the Decision

Decision in written proceedings

1. The respondent's announcement that they would not attend oral proceedings was equivalent to a withdrawal of their request that oral proceedings be held (see Case Law of the Boards of Appeal, 10th edition, "CLBA" in the following, III.C.4.3.2 and the decisions cited in it). Furthermore, the respondent requested that "a decision be issued on the file as it stands". On the other hand, revocation of the patent complies with the appellant's request.

2. The present decision can therefore be handed down in the written proceedings and no oral proceedings before the board need to be held (Article 116(1) EPC and Article 12(8) RPBA).

Main request (patent as granted) - independent claim 1

3. Claim 1 of the patent as granted reads as follows:

"1. A method of estimating the fraction of fetal DNA in DNA obtained from a bodily fluid of a pregnant individual, the method comprising:

(a) extracting DNA from a sample of the bodily fluid under conditions that extract DNA of both a maternal genome and a fetal genome present in the bodily fluid;
(b) sequencing the extracted DNA with a nucleic acid sequencer under conditions that produce DNA segment sequences containing one or more polymorphisms;
(c) aligning or otherwise mapping the DNA segment sequences derived from sequencing the DNA in the bodily fluid to one or more designated polymorphisms on a reference sequence, wherein the mapping is performed using a computational apparatus programmed to map nucleic acid sequences to the one or more designated polymorphisms;
(d) determining allele frequencies of the mapped DNA segment sequences for at least one of the designated polymorphisms;
(e) classifying the at least one designated polymorphism based on a combination of the zygosity of the pregnant individual and the zygosity of the fetus; and
(f) estimating the fraction of fetal DNA in the DNA obtained from the pregnant individual using the allele frequencies determined in (d) in conjunction with the classification of zygosities from (e),
wherein (d)-(f) are performed on one or more processors running under program instructions for the determining, classifying and estimating; and
wherein the classifying in (e) classifies the at least one designated polymorphism into one of the following combinations: (i) the pregnant individual is homozygous and the fetus is homozygous, (ii) the pregnant individual is homozygous and the fetus is heterozygous, (iii) the pregnant individual is heterozygous and the fetus is homozygous, and (iv) the pregnant individual is heterozygous and the fetus is heterozygous."

Entitlement to the claimed priority (Article 87 EPC)

4. In accordance with Article 87 EPC a European patent application is only entitled to priority in respect of "the same invention" as was disclosed in the previous application. As established by decision G 2/98 of the Enlarged Board of Appeal (OJ 2001, 413), the requirement for claiming priority of "the same invention" means that priority of a previous application in respect of a claim in a European patent application is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole. The subject-matter of the claim defining the invention in the European application has to be understood as "the specific combination of features present in the claim".

5. The appellant reiterated here that, contrary to the conclusions reached in the decision under appeal, step (a) of claim 1 ("extracting DNA from a sample of the bodily fluid under conditions that extract DNA of both a maternal genome and a fetal genome present in the bodily fluid") was not directly and unambiguously derivable from the disclosure in the priority document.

6. This is not persuasive. It is undisputed that the priority document does not literally disclose step (a) of claim 1, and in particular not the expression "extracting DNA".

7. In the decision under appeal (see point 3.2), the opposition division held that the passage on page 6, lines 8 to 10 of the priority document, read in

conjunction with Figure A, provided disclosure of step (a) of claim 1. Said passage reads as follows: "*An example process flow for implementing some of the disclosed embodiments is provided in attached Figure A*", and in lines 31 to 33, it reads "*Finally, as illustrated at block 107, the method uses the combination of zygosity case allele frequency at one or more of the polymorphisms to estimate the fractional amount of fetal component in the DNA from the maternal sample*". Figure A discloses step 101, "*Collect DNA from maternal blood*". Furthermore, claims 1 and 11 of the priority document refer to "*fetal DNA in DNA obtained from a bodily fluid of a pregnant individual*" and page 2, lines 14 to 15, "*Certain disclosed embodiments involve analyzing DNA taken from a pregnant female's blood*", discloses conditions that ensure that DNA of both a maternal genome and a fetal genome present in the bodily fluid (the maternal blood) is extracted.

8. Accordingly, in coming to their positive decision on priority, the opposition division held that the notions "collecting DNA from a sample of bodily fluid" and "extracting DNA from a sample of bodily fluid" were technically equivalent and interchangeable.

9. On appeal, the respondent agreed with this decision and additionally referred to the disclosure on page 6, lines 7 to 33, also referred to by the opposition division (see point 7. above), and on page 2, lines 14 to 16, disclosing analysis of DNA "*obtained from a bodily fluid of a pregnant individual*" (preamble of claim 1).

10. The board, however, agrees with the appellant that the disclosure referenced by the opposition division and the respondent in the priority document broadly refers

to the technical step of "collecting" or "obtaining" DNA; however, such a technical step does not have the same technical informational content as a technical step of "extracting" DNA. Indeed, the expression "extracting DNA" in step (a) implies that DNA of a maternal and fetal genome is *isolated* from a sample, i.e. is separated from other components of the sample, such as proteins, lipids, etc., thus involving separation. By contrast, the expressions "collecting DNA" and "DNA obtained from" do not necessarily imply such isolation or separation. These expressions are thus indeed not technically equivalent and interchangeable. Consequently, the skilled person would not directly and unambiguously derive the feature "extracting DNA from a sample of bodily fluid" from the disclosure of the notion "collecting DNA from a sample of bodily fluid".

11. The board furthermore agrees with the appellant that the feature of extracting DNA from a sample of a bodily fluid cannot be interpreted as an implicit technical requirement for the subsequent sequencing step (b) ("sequencing the extracted DNA with a nucleic acid sequencer under conditions that produce DNA segment sequences containing one or more polymorphisms"). Indeed, for example, a PCR may be performed directly on the sample to amplify the DNA contained in it for sequencing. Whilst the quality of the PCR may improve if the template DNA is extracted before the PCR, such an extraction step is not technically mandatory.

12. To conclude from the above considerations, the skilled person would not directly and unambiguously derive step (a) of claim 1 from the disclosure of the priority document. Consequently, the subject-matter of claim 1

is not entitled to claim the priority date as the effective filing date (Article 87 EPC).

Inventive step (Article 56 EPC)

Closest prior art

13. Since the opposition division held that the subject-matter of claim 1 was entitled to the priority date, document D9 was considered to be comprised in the state of the art pursuant to Article 54(3) EPC only, and was consequently not to be drawn upon in the assessment of inventive step pursuant to Article 56 EPC. For their assessment of inventive step, the opposition division started from the disclosure in document D8, a document pursuant to the state of the art according to Article 54(2) EPC, as representing the closest prior art, and concluded that the claimed subject-matter involved an inventive step.

14. On appeal, the appellant maintained that the claimed subject-matter lacked an inventive step when starting from the disclosure in example 6 of document D9 (entitled "Determination of Percent Fetal DNA using Tandem Ligation"), which represented the closest prior art. Like the patent, document D9 disclosed methods for estimating the fraction of fetal DNA in DNA obtained from a bodily fluid of a pregnant individual, and was thus a suitable starting point for the assessment of inventive step.

15. The board agrees with the appellant that document D9, and in particular its example 6, is such a suitable starting point for the discussion of inventive step. The respondent's arguments that the opposition division had correctly considered the disclosure in document D8

to represent the closest prior art and that the disclosure in document D9 was not suitable as the closest prior art are not convincing for the following reasons.

16. Although assessing inventive step from only one "closest" prior-art disclosure may constitute a suitable approach for addressing the situation in which multiple similar disclosures are presented as starting points for the assessment of inventive step, it is not an appropriate approach if the alternative starting points likewise represent (alternative and different) routes to the invention, as document D8 and D9 do in the case in hand. In such a situation, each starting point needs consideration because, under Article 56 EPC, in order for an inventive step to be acknowledged, the claimed invention must not be obvious to a skilled person having regard to the (complete) state of the art, i.e. any prior-art disclosure excluding documents under Article 54(3) EPC (see e.g. decisions T 694/15, points 13 to 15 of the Reasons, T 816/16, point 3.7.1 of the Reasons and T 261/19, point 2.5 of the Reasons).

Difference between the claimed subject-matter and example 6 of document D9

17. In the context of the assessment of novelty (Article 54 EPC) the opposition division held that the subject-matter of claim 1 differed from the disclosure of example 6 of document D9 by requiring that the classification step (e) and the estimation step (f) of the claimed method "*are performed on one or more processors running under program instructions for the determining, classifying and estimating*", and the board agrees.

18. On appeal, the respondent reiterated that the claimed subject-matter further differed in that the classification step in example 6 of document D9 did not make use of all polymorphisms in the four combinations (i) to (iv) identified at the end of claim 1 (see point 3.) for the classification step (e):

"(i) the pregnant individual is homozygous and the fetus is homozygous,
(ii) the pregnant individual is homozygous and the fetus is heterozygous,
(iii) the pregnant individual is heterozygous and the fetus is homozygous, and
(iv) the pregnant individual is heterozygous and the fetus is heterozygous".

19. This is not persuasive. On the contrary, the appellant is correct that example 6 of document D9 discloses the use of all four zygosity classes for determining the fetal fraction.

20. Indeed, paragraph [000272], which is part of example 6, provides for two separate metrics in the last sentence, and reads as follows:
"*The purified PCR product was sequenced on 6 lanes of a single slide on an Illumina HiSeq™ 2000. The sequencing run gave rise to 384M raw reads, of which 343M (89%) mapped to expected genomic loci, resulting in an average of 3.8M reads per sample across the 37 samples, and 8K reads per sample per locus across the 480 loci. The mapped reads were parsed into sample and locus counts, and two separate metrics of percent fetal DNA were computed as follows*." (emphasis added by the board)

21. Paragraph [000274] explains the determination of the fetal fraction when SNPs are used which map only to the autosomes, i.e., when the 144 SNPs were used. This paragraph reads as follows:
"*Percent fetal DNA detected by polymorphic loci corresponds to the proportion of reads derived from non-maternal versus maternal alleles at loci where such a distinction can be made. First, for each identified locus, the number of reads for the allele with the fewest counts (the low frequency allele) was divided by the total number of reads to provide a minor allele frequency (MAF) for each locus. Then, loci with an MAF between 0.075% and 15% were identified as informative loci. The estimated percent fetal DNA for the sample was calculated as the mean of the minor allele frequency of the informative loci multiplied by two, i.e., computed as 2X average (MAF) occurrence where 0.075%<MAF<15%.*" (emphasis added by the board)

22. Paragraph [000274] hence discloses that the allele frequency for each of the 144 SNPs under consideration was measured, but that not each of the 144 loci turned out to be informative, i.e. where "*a distinction can be made*" between maternal and fetal alleles, thus belonging to the combination (ii) or (iii) scenario.

23. However, by the same token, when determining allele frequencies for informative SNPs for the determination of the fetal DNA fraction, based on the measured signal, an SNP has been categorised either as informative and thus belonging to the combination (ii) or (iii) scenario, or as non-informative and thus belonging to the combination (i) or (iv) scenario.

24. No distinction can be made between a minor and major allele in the combination (i) and (iv) scenarios (in

the combination (i) scenario there is one allele and in the combination (iv) scenario both alleles are present at the same frequency); however, a distinction has further been disclosed between the informative SNPs of the combination (ii) or (iii) scenario. By setting thresholds for the minor allele frequency of >0.075% and <15%, example 6 excludes informative SNPs of Case 3 and performs the estimation of the fetal fraction using only the SNPs of Case 2 which are retained by the set threshold values of 0.075% and 15%. The threshold settings of example 6 ensure that only allele frequencies which are indicative SNPs of the Case 2 scenario are retained, and that all allele frequencies which would indicate Case 1, 3 and 4 scenarios are omitted. Even though the Case 1, 3 and 4 scenarios were thus excluded for estimating the fetal fraction, the skilled person understood that they had been considered as part of the analysis.

25. In view of the above considerations, the skilled person would directly and unambiguously derive from example 6 of document D9 that all four zygosity classes for determining the fetal fraction were used.

26. Following on from the above considerations, example 6 of document D9 differs from the claimed subject-matter solely on account of the requirement in claim 1 that the classification step (e) and the estimation step (f) "*are performed on one or more processors running under program instructions for the determining, classifying and estimating*".

Technical effect and objective technical problem

27. The technical effect of the computer implementation of the methods is that the claimed estimation method is

automated. Accordingly, the technical problem can be formulated as submitted by the appellant, namely that of providing an automated procedure for estimating the fetal fraction in maternal samples.

Obviousness

28. The respondent submitted that document D9 failed to *disclose* the implementation of program instructions adapted to classify polymorphisms into any of the four possible zygosity cases (i)-(iv), and that it failed to disclose the implementation of program instructions for estimating the fraction of fetal DNA in DNA obtained from a pregnant individual using determined allele frequencies in conjunction with the classification of zygosities. Furthermore, such program instructions could not be *suggested* by document D9, either, since the calculations performed in the method in D9 to "classify" the loci and "estimate the fraction of fetal DNA" amounted to simple maths. There was thus no reason why such simple calculations would have prompted the skilled person to consider using "one or more processors running under program instructions for the … classifying and estimating" as specified in claim 1.

29. This is not persuasive either. On the contrary, the appellant is correct that, considering the number of data points and the workflow disclosed in document D9, the skilled person, on the relevant date, would have taken computer implementation as an obvious route for improvement.

30. To conclude, the subject-matter of claim 1 does not involve an inventive step. The main request is thus not allowable.

Auxiliary requests

Article 12(3) and (5) RPBA

31. In its reply to the appeal, the respondent maintained auxiliary requests 1 to 3, all filed in the opposition proceedings prior to the final date set pursuant to Rule 116(1) EPC for making written submissions.

32. Article 12(3) RPBA provides that the statement of grounds of appeal and the reply shall contain a party's complete appeal case and that, accordingly, they should set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the requests, facts, objections, arguments and evidence relied on. This provision reflects that it is not for the board to speculate as to the intentions underlying the party's submissions (see decisions T 2115/17, point 6.1.3 of the Reasons, and T 1220/21, point 4.3.1 of the Reasons) or to further investigate the submissions made before the department of first instance.

33. The substantiation for maintaining the auxiliary requests provided by the respondent in the reply to the appeal in the context of inventive step was limited to referring to
(i) the inventive-step arguments submitted on appeal in the context of the main request which were considered to apply, *mutatis mutandis*, to the claimed subject-matter of the auxiliary requests, and to
(ii) their written submissions on the auxiliary requests that were filed on 4 April 2023 in the opposition proceedings.

34. With respect to reference (i), the reply to the appeal fails to present dedicated arguments as to why any of the sets of claims in the auxiliary requests would be responsive to and could overcome the inventive-step objections having regard to the disclosure in document D9 as the closest prior art. In their reply to the appeal, the respondent thus failed to provide any substantiation for the auxiliary requests in this respect. Moreover, even if the amended requests had been considered self-explanatory, this would not have met the standard as set out in Article 12(3) RPBA, because an implicit argument does not meet the requirement that the party should specify expressly the arguments relied on (see decisions T 2598/12, point 1.10 of the Reasons and T 1220/21, point 4.3.2 of the Reasons).

35. With respect to reference (ii), the respondent only relied on the facts and evidence put forward in the opposition proceedings; however, such a passing reference to the facts and evidence put forward in opposition proceedings does not fulfil the requirements of Article 12(3) RPBA (see CLBA, V.A.2.6.3.f) and V.A. 2.6.5). In fact, it is not for the board to identify the issues that may still be a matter of dispute among those raised in each and every submission in the previous proceedings, or to identify the arguments as to why the objections do not apply. It is for the parties, though, to put forward, in the grounds of appeal and in the reply, their line(s) of argument and all the facts and evidence on which they rely in appeal proceedings.

36. Therefore, in the reply to the appeal, the respondent failed to present the necessary substantiation with regard to auxiliary requests 1 to 3, contrary to

Article 12(3) RPBA. Consequently, these auxiliary requests could not be taken into account pursuant to Article 12(5) RPBA.

Article 13(2) RPBA

37. In the board's communication pursuant to Article 15(1) RPBA, and after essentially opining that the auxiliary requests were not substantiated, the following was further stated (see points 31. to 36. above and the board's communication, points 24 and 25):

> "*26. Nevertheless and for the sake of completeness, there are no particular arguments from the side of the respondent why any of the set of claims of auxiliary requests would be responsive to and overcome the inventive step objections having regard to the disclosure in document D9 as closest prior art (see above)*"
>
> *27. Accordingly, none of the auxiliary requests is allowable either.*"

38. In response to the board's communication, the respondent filed a further submission (see section VI.), which included dedicated arguments that the subject-matter of claim 1 of auxiliary request 1 involved an inventive step starting from the disclosure of example 6 of document D9, which represented the closest prior art. The respondent further considered features in claim 1 of auxiliary requests 2 and 3 to be disclosed in document D9.

39. This response is governed by Article 13(2) RPBA, which provides that any amendment to a party's appeal case made after notification of a communication under

Article 15(1) RPBA will, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

40. The respondent argued that the further submission was in direct response to a statement made by the board in its communication "*that the subject matter claimed in Auxiliary Requests 1-3 lacks an inventive step in the light of D9 as the closest prior art*." (response dated 27 January 2025, point 1.3.) The negative opinion in the board's communication was the first time in the opposition and appeal proceedings that inventive step in respect of the auxiliary requests was considered. The respondent thus had to be given an opportunity to respond to this new objection by the board, otherwise their right to be heard under Article 113 EPC would have been infringed. This new objection by the board had thus created exceptional circumstances, justified with cogent reasons, for the further submissions to be admitted and taken into account by the board (Article 13(2) RPBA).

41. This is not persuasive. As a matter of principle, Articles 12 and 13 RPBA 2020 serve to take account of changes in the facts or the subject-matter of appeal proceedings ("amendments" within the meaning of Articles 12(4) and 13(1) and (2) RPBA), within narrow limits (T 2360/19, point 1 of the Reasons, T 1006/21, point 25 of the Reasons, with reference to T 1919/17, point 25 of the Reasons, and T 1913/19, points 10 and 16 of the Reasons).

42. Moreover, in *inter partes* appeal proceedings, the parties have a particular obligation to conduct the proceedings diligently and expeditiously, for reasons

of fairness towards the other party, but also to bring the proceedings to a conclusion within a reasonable period of time. Article 13(2) RPBA sanctions this obligation, i.e. in particular the obligation in the case in hand to submit any arguments as to why the claimed subject-matter of the auxiliary requests involves an inventive step starting from the disclosure of example 6 of document D9, which represents the closest prior art, as early as with the reply to the appeal, or at least after having been summoned to oral proceedings (see Article 13(1) RPBA).

43. In the case in hand, however, the respondent only submitted the substantiation of auxiliary request 1 after the board's remarks in point 26 of its communication under Article 15(1) RPBA that it had not seen any dedicated arguments from the respondent as to why any of the sets of claims in the auxiliary requests would be responsive to and overcome the inventive-step objections having regard to the disclosure in document D9 as the closest prior art. The fact that a board notes the absence of dedicated arguments from a party in a communication under Article 15(1) RPBA naturally cannot create exceptional circumstances justifying that the party can provide such arguments in response.

44. Furthermore, the fact that the board, in point 27 of the communication under Article 15(1) RPBA, expressed the preliminary opinion that the auxiliary requests would not be allowable in the absence of dedicated inventive-step arguments cannot justify the submission of substantive arguments for the first time in the proceedings, either. Indeed, the board's statement in point 27 did not go beyond indicating the procedural consequences of the absence of dedicated arguments from

the respondent for the auxiliary requests. Naturally, such an indication cannot create exceptional circumstances for providing such dedicated arguments in response, either.

45. Lastly, and as a matter of principle, Article 13 RPBA mainly serves to allow account to be taken of changes of fact or changes to the subject-matter of the appeal proceedings, within narrow limits. It does not allow the subsequent submission of essential elements of the appeal and the requests filed with them (cf. T 1913/19, point 16. of the Reasons).

46. In view of the above considerations, the amendment to the respondent's appeal case, i.e. the substantive arguments submitted with the further submission by the respondent, could not be taken into account for the decision either (Article 13(2) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

C. Rodríguez Rodríguez T. Sommerfeld

Decision electronically authenticated