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**Datasheet for the decision
of 28 November 2008**

Case Number: T 0859/08 - 3.3.08

Application Number: 04748879.6

Publication Number: 1649280

IPC: G01N 33/48

Language of the proceedings: EN

Title of invention:

Method of conducting and interpretation of clinical trials

Applicant:

Betkowska, Anna

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 108, 122

EPC R. 136(1)(2)

Relevant legal provisions (EPC 1973):

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Keyword:

"Unsubstantiated appeal inadmissible"

Decisions cited:

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Catchword:

-



Case Number: T 0859/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 28 November 2008

Appellant: Betkowska, Anna
12/26 Bojki Street
PL-30-611 Krakow (PL)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 February 2008
refusing European application No. 04748879.6
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: L. Galligani
Members: C. Rennie-Smith
P. Julià

Summary of Facts and Submissions

- I. The appeal is against the decision of the Examining Division dated 11 February 2008 which refused the European patent application No. 04748879.6 entitled "The method of conducting and interpretation of clinical trials of investigational products (substances' molecules) operating in the receptor mechanism as exogenous ligands".
- II. The Examining Division refused the application for the following reasons (the numbering being that of paragraphs of the decision under appeal).
2. The application did not meet the requirements of Articles 83 and 84 EPC with regard to sufficiency of disclosure, clarity and support as the language of the description is substantially theoretical rather than a technical description of an invention in practice. The drafting of the application lead to obscurity and difficulties in interpreting the meaning of the claims. The lack of clarity and support was compounded by a total lack of technical features in the claims and the absence of any worked examples.
3. The invention did not meet the requirements of Article 56 EPC. The Examining Division identified a problem to be solved by reference to the cited prior art documents D1 to D5 and considered the solution offered in the claims was to construct a trial protocol or perform a statistical analysis. Notwithstanding whether such a solution actually constituted a technical solution, the mere application of statistical methods in the design of trial protocols fell within

the knowledge and ability of the skilled person and was not considered to represent an inventive step.

4. It was not apparent from the application how the alleged invention, a design protocol for clinical trials, might be made or used in a technological sense as required for industrial applicability and therefore the requirements of Article 57 EPC were not met.

5. The subject matter of the claims related solely to a mathematical theory which constituted excluded subject matter by virtue of Article 52(2) EPC.

6. The applicant's response to the Examining Division's communication (in her letter dated 24 October 2007 received on 31 October 2007) did not present any arguments or make any *bona fide* attempt to overcome the substantive deficiencies. Insofar as the response could be understood, it only labelled the opinions in the prior art documents as "senseless".

7. Although Article 94(3) EPC allowed the Examining Division to invite an applicant to file observations as often as necessary it considered that, in view of the applicant's response to its communication, there was no reasonable objective prospect of reconciling the conflicting views of the applicant and the Examining Division which therefore exercised its discretion not to issue any further such invitations and to refuse the application.

III. The appellant (the applicant) filed a notice of appeal, in the form of a letter dated 30 March 2008 which was received at the EPO on 8 April 2008 and with which was

enclosed copies of the cover pages of the decision under appeal (Form 2007) and of the appellant's letter of 24 October 2007 to the Examining Division. No separate written statement of grounds of appeal was filed.

IV. The sum of €390 was paid as appeal fee on 11 April 2008, a shortfall of €675. A letter from the Board's registrar of 8 May 2008 informed the appellant that the fee had not been paid in full and that accordingly the appeal was deemed not to have been filed pursuant to Article 108, second sentence, EPC. The appellant paid the balance of €675 on 5 June 2008 and put forward her explanation for the underpayment in a letter dated 5 June 2008 and received at the EPO on 12 June 2008.

V. The Board sent a first communication dated 9 July 2008 regarding two matters, namely the non-payment in time by the appellant of the full appeal fee and the apparent absence of a written statement of grounds of appeal.

As regards the underpaid appeal fee, the communication stated that the appellant should file an application for re-establishment of rights pursuant to Article 122 EPC by at the latest 4 August 2008; that, if no such application was filed or, if filed but unsuccessful, then the appeal would be deemed not to have been filed and the entire appeal fee of €1065 would be refunded to the appellant; and that, if an application for re-establishment of rights was successful, the Board would then have to consider the admissibility of the appeal.

In that regard, in the apparent absence of a statement of grounds of appeal, the Board had to consider whether the letter giving notice of appeal dated 30 March 2008 contained anything which could be considered as the statement of grounds of appeal and the Board's provisional opinion was that it did not. Thus, even if the appeal should not be deemed not to have been filed by reason of the appeal fee not having been paid in time, the appeal would then in all probability be dismissed as inadmissible for non-filing of a statement of grounds of appeal, in which event the appeal fee would not be refunded.

- VI. The appellant, in three letters dated 31 July 2008 and 1 August 2008 (both sent by fax on 1 August 2008, the 1 August 2008 letter being in both handwritten and typed versions) and of 3 August 2008 (sent by fax on 4 August 2008), filed a request for re-establishment of rights. She subsequently filed further copies with a letter dated "August 12-18 2008" and received by post on 22 August 2008.
- VII. The Board sent a second communication dated 26 August 2008 together with a summons to oral proceedings. In this communication the Board indicated that, in its provisional view and with reference to the matters set out at paragraphs 1 to 3 below, the request for re-establishment of rights appeared to be admissible and allowable. However, after again explaining the admissibility issue and referring to the previous communication of 9 July 2008, it still appeared to the Board that within the time limit in Article 108 EPC (which expired on 23 June 2008) the appellant had neither filed a written statement of grounds of appeal

nor explained in her notice of appeal and the copy documents enclosed with it how the Board should ascertain the appellant's case as to why the decision under appeal was wrong.

Oral proceedings had been appointed to allow the appellant to present her case on these matters and the discussion at those oral proceedings would be limited to those matters. In the event that the Board was persuaded that the appeal was admissible - which appeared extremely unlikely - the proceedings would thereafter be continued in writing for the consideration of the substantive issues of allowability. If the Board was not so persuaded then, depending on the outcome of the discussion, it appeared that the appeal would either be deemed not to have been filed or be dismissed as inadmissible.

The communication concluded by encouraging the appellant to obtain advice from, and representation at the oral proceedings by, a patent professional.

VIII. In reply to that communication the appellant sent a letter dated "October 4-27, 2008". Since it appeared from that letter that the appellant did not entirely understand the Board's position, the Board sent a third communication, both by courier on 10 November 2008 and by post on 13 November 2008, to make clear that the only decision to be made at the oral proceedings was whether, before the time limit expired on 23 June 2008, the appellant had filed a written statement which, by reference to the reasons in the decision under appeal, presented her case why she considered that decision to be wrong; that the only documents filed in the appeal

proceedings before 23 June 2008 had been the appellant's letter dated 30 March 2008 and its enclosures; and that at the oral proceedings the appellant had to explain to the Board why she considered that these documents presented a case why the decision under appeal was wrong. Copies of that decision, the appellant's letter of 30 March 2008 and its enclosures were enclosed with this communication which stated that those were the **only** documents which were relevant for the oral proceedings, that reference to any other documents would **not** be necessary, and that any other document the appellant might produce would **not** be admissible in these oral proceedings.

- IX. The appellant's arguments in support of her request for re-establishment of rights were as follows.

In her letter dated 5 June 2008, the appellant explained that she paid only €390 as an appeal fee because that was the sum she had been told was the fee when she telephoned the EPO. She had made telephone calls to The Hague and Munich on 7 and 8 April 2008 and been given this information by the Munich office of the EPO on 8 April 2008. She filed a copy of her telephone bill showing calls were made to the numbers of those EPO offices on those dates. The letter from the Board's Registrar of 8 May 2008 was received by her on 2 June 2008.

- X. The appellant's relevant arguments regarding the admissibility of the appeal were as follows.

In her letter of 30 March 2008 (the notice of appeal), the appellant stated that the members of the Examining

Division and the authors of the principal prior art document D5 were "very strong ignorants", that her submissions of 24 October 2007 were not taken into consideration, and that D5 if correctly interpreted shows the appellant's method of conducting clinical trials according to her patent application works. She also referred to her "Statement under Article 19(1)" filed with WIPO and a second pending patent application, stated that her patent applications are worth billions of Euros, and that the Examining Division should have consulted a competent statistician to explain D5. The enclosed copy letter of 24 October 2007 also stated that the authors of D5 had misinterpreted their own findings and the resulting incorrect information had been spread by the authors of the other citations. The opinions in all the cited documents were therefore "senseless". The appellant also referred here to the statement filed with WIPO and her second patent application, both of which she said provided more information about the present patent application.

Those arguments were partially repeated in some of the appellant's other letters filed in the course of the appeal proceedings which also contained extensive submissions on matters of no apparent relevance.

At the oral proceedings held on 28 November 2008, the appellant (who appeared in person and was not represented) again argued that the authors of document D5 had incorrectly interpreted their own findings and that it required a knowledge of statistics to appreciate the full significance of her claimed invention. Otherwise, she argued that it was obvious

that she disagreed with the reasons given for its decision by the Examining Division and she referred again to her statement filed with WIPO and her second patent application.

- XI. No request was specified in the notice of appeal but by clear implication the appellant requested that the decision under appeal be set aside and that a patent be granted. As regards the decision to be made at the oral proceedings on 28 November 2008, the appellant requested re-establishment of rights as regards her late-paid appeal fee and, although not expressly stated, requested that her appeal be found admissible.

Reasons for the Decision

Request for re-establishment of rights

1. The Board finds the re-establishment request admissible. As regards the appellant's submission that the Registrar's letter of 8 May 2008 was received by her on 2 June 2008, the deemed date of delivery would be 18 May 2008 unless it reached the appellant at a later date (see Rule 126(2) EPC). The appellant has clearly said in her letter of 5 June 2008 that she received the letter on 2 June 2008 and it then becomes incumbent on the EPO to establish the date of delivery (see also Rule 126(2) EPC). In the absence of any other evidence, the only date that can be relied on is 2 June 2008 and accordingly that must be treated as the date of delivery. That is therefore also the date when the cause of the appellant's non-compliance with Article 108 EPC (by not paying the full appeal fee in

- time) was removed and her re-establishment request (contained in her various faxes of 1 and 4 August) was filed within two months thereafter as required by Rule 136(1) EPC. The two month period ended on 4 August 2008 as 2 August 2008 was a Saturday (see Rule 134(1) EPC).
2. The omitted act was completed (that is, the outstanding part of the appeal fee was paid) and the fee for re-establishment was also paid within that two month time limit as also required by Rule 136(1) EPC. The appellant's faxes of 1 and 4 August 2008 do not themselves state the grounds and set out the facts on which the request is based (see Rule 136(2) EPC) but those facts were set out in her earlier letter of 5 June 2008 (see paragraph IX above) and the Board accepts the submissions in that earlier letter as the grounds and facts of the re-establishment request. That request is therefore admissible.
 3. As regards the allowability of the re-establishment request, the appellant's account of events (see paragraph IX above) is plausible. That she called the EPO on 8 April 2008 is evidenced by copies of extracts from her telephone bill. That she was then given incorrect information, namely that the appeal fee was €390, seems quite possible because €390, which is in fact the fee for an appeal under Articles 19 and 27 of the Regulation on the European Qualifying Examination, is described just as "Fee for appeal" on page 7 of the current OJ Fees Supplement, while the higher fee for an appeal (such as the present) under Articles 106 to 108 EPC is also described just as "Fee for appeal" on page 5 of that Supplement. The Board considers it

possible that someone dealing with a telephone inquiry could turn to the wrong page and give the wrong information. Accordingly, the Board finds the re-establishment allowable. That means that the entire appeal fee will be treated as having been paid within the correct time limit and the appeal is not deemed not to have been filed.

Admissibility of the appeal

4. Article 108, third sentence, EPC provides that, within four months of the notification of the decision in question, an appellant must file a statement setting out the grounds of appeal. In the present case the decision under appeal was dated 11 February 2008, the notification was deemed to be delivered ten days later, and the four month period from then ended not on 21 June 2008, which was a Saturday when the EPO filing offices were closed, but on Monday 23 June 2008 (see Rules 126(2) and 134(1) EPC). Rule 99 EPC requires an appellant to indicate in that statement the reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based. The case-law of the Boards of Appeal has consistently interpreted these provisions as requiring an appellant to file a statement which in itself presents the Board with the appellant's case, made by reference to the reasons in the decision under appeal, why it considers that decision to be wrong (see generally "Case Law of the Boards of Appeal of the European Patent Office", 5th edition 2006, Section VII.D.7.5 "Statement of grounds of appeal", pages 621 to 625). Since the appellant filed no separate statement of grounds of appeal, those

grounds must be in her letter of 30 March 2008 or its enclosures for the appeal to be adequately substantiated.

5. The decision under appeal gave reasons for rejecting the appellant's European patent application on a number of grounds namely lack of an inventive step, lack of disclosure, lack of clarity and support, lack of industrial applicability and excluded subject-matter (see paragraph II above). In the decision each of those grounds is explained by reference to the patent application, in the case of lack of inventive step by reference to the prior art considered in the examination proceedings, and by reference to the relevant provisions of the EPC (Articles 56, 83, 84, 57 and 52(2) EPC respectively).

6. The only argument of the appellant in her letter of 30 March 2008 or its enclosures which deals at all with the substance of the decision under appeal is the assertion that the authors of document D5 misinterpreted their own findings and that, if correctly interpreted, D5 shows the appellant's method of conducting clinical trials according to her patent application works. However, it appears clear that the Examining Division recognized that this was the solution offered by the appellant but then further decided that, notwithstanding whether such a solution actually constituted a technical solution, the mere application of statistical methods in the design of trial protocols was not an inventive step. That reason for finding a lack of inventive step clearly goes beyond any views one might have about the interpretation or significance of D5. The Board can

find no explanation in the appellant's letter of 30 March 2008 or its enclosures why she disputes this general finding of no inventive step. It is true that the appellant said in writing that the Examining Division should have used a statistician and at oral proceedings that a knowledge of statistics was needed to understand her claimed invention fully. However, assuming there is some merit in that, she has provided no indication in her letter of 30 March 2008 of what a statistician would appreciate and how that might overcome the Examining Division's objection. Thus, as regards the finding of lack of inventive step, there is no coherent case against the reasons for that finding.

7. Otherwise, as regards both that finding of no inventive step and all the other findings of the Examining Division, the appellant has argued only that the Examining Division did not take her submissions of 24 October 2007 into consideration, that it was obvious that she disagreed with the reasons given by the Examining Division and that her statement filed with WIPO and her second patent application provided more explanation about her present patent application. The statement was filed under Article 19(1) PCT which allows an applicant, when filing amended claims with the International Bureau (as the appellant did in April 2005), to file a brief statement explaining the amendments. While no copy was filed with the letter of 30 March 2008, the Board has seen and considered the statement which is in the EPO file and notes that it contains no more than a further and partial expression of her proposed clinical trial protocol, apparently related to the amended claims she filed with the statement. Those amended claims were the claims

subsequently considered by the Examining Division and thus, at the very least by implication, it found the content of that statement insufficient to lead to any other decision than the one it made. The Board has never seen, and has no means of obtaining, the appellant's second patent application. Moreover, no copies of either the statement or the second patent application were enclosed with the letter of 30 March 2008 and by no stretch of imagination could it be said their contents were incorporated by the mere reference to them.

8. As regards the appellant's contention that her submissions of 24 October 2007 were not considered, it is abundantly clear that the Examining Division did in fact take these into account. Its decision refers to the receipt of those submissions on 31 October 2007 (see paragraph IV of the "Summary of Facts and Submissions" in the decision) and further says those submissions did not present any arguments or make any *bona fide* attempt to overcome the substantive deficiencies and that, insofar as the response could be understood, it only labelled the opinions in the prior art documents as "senseless" (see paragraph 6 of the "Reasons for the Decision"). The record shows that the Examining Division received and read the appellant's submissions but did not entirely understand them. Having itself read those submissions, which are largely irrelevant and where relevant largely imprecise, the Board is quite satisfied the Examining Division did its best to take account of them.
9. As regards the appellant's argument that it was obvious that she disagreed with the reasons given by the

Examining Division, the Board can only agree. Such disagreement was apparent from the notice of appeal, and indeed previously noted by the Examining Division whose decision mentioned the conflicting opinions of the applicant and itself (see paragraph 7 of the "Reasons for the Decision"). It is in any event inherent in the act of appealing that an appellant disagrees with the decision under appeal. As a matter of law, an appellant must be adversely affected by a decision in order to be able to appeal (Article 107 EPC); since that means that an appellant's case must have been rejected at least in part, it is self-evident that an appellant disagrees with the decision. But such self-evident disagreement does not mean that the appellant's reasons why that decision should be reversed or amended on appeal are also self-evident. However emphatic, the expression of disagreement *per se* is clearly not enough to satisfy the requirement that an appeal must be substantiated.

10. After a thorough consideration of the appellant's letter of 30 March 2008 and the copy documents enclosed with it, the Board can find no relevant statement, beyond bare disagreement, as to why any one or more of the actual reasons in the decision under appeal for the refusal of her patent application are wrong. Nor is the Board able, either from that letter and enclosures and/or from the appellant's arguments at the oral proceedings, to place any interpretation or construction upon her notice of appeal and enclosures so as impute to them any substantive reasons why the appellant considered the decision under appeal should be set aside or amended. Even if, in the case of an unrepresented appellant with little or no experience of

Board of Appeal procedure, a lower standard of substantiation could be accepted than in most cases, it would none the less be unfair to other appellants generally to accord admissibility to an appeal in which not even a coherent *prima facie* case against the first instance decision could be ascertained from the written submissions filed before the expiry of the time limit. Accordingly the Board sees no alternative but to dismiss the appeal as inadmissible.

Order

For these reasons it is decided that:

1. The request for re-establishment of rights is granted.
2. The appeal is dismissed as inadmissible.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani