Invention to be performed over the whole range claimed

EPO Case Law

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Project study

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Tiivistelmä

Erikoistyön tavoitteena oli perehtyä siihen, miten Euroopan patenttivirasto (EPO) tulkitsee keksinnön määritelmää suhteessa siihen miten se on kuvattu ja määritetty patenttijulkaisussa eli onko patenttijulkaisun pohjalta alan ammattilaisen mahdollistaa suorittaa keksintö vaatimusten määrittelemässä koko laajuudessa.

EPO määrittelee yleisesti, että riittävän tuen osoittamiseksi yksi keksinnön suoritustapa patenttijulkaisussa on riittävä vain, jos se mahdollistaa keksinnön täytäntöönpanon vaatimusten koko laajuudessa eikä vain esim. joissain tietyissä valituissa rajatuissa tilanteissa. Riittävä tuki edellyttää siis, että alan ammattilainen pystyy toteuttamaan ja/tai saavuttamaan kaikki vaatimusten piiriin kuuluvat sovellusmuodot.

Tutkiessaan ja tulkitessaan patenttijulkaisun mahdollista riittävää tukea, EPO:n teknisten valituslautakuntien täytyy vakuuttua kahdesta asiasta:

1) siitä että patenttijulkaisu kuvaa alan ammattilaiselle vähintään yhden tavan toteuttaa keksintö ja
2) että keksintö voidaan toteuttaa vaatimusten koko laajuudessa.

Erikoistyössä käydään läpi EPO:n valituslautakunnan teknisiä päätöksiä ja lopussa vedetään yhteen niiden pohjalta oleelliset kohdat EPO:n tulkinnasta mahdollisuudesta suorittaa keksintö vaatimusten määrittelemässä koko laajuudessaan (selityksen riittävä tuki).

Abstract

The aim of this project study was to examine how European Patent Office (EPO) interprets the sufficiency of disclosure for inventions presented in the patent specification, specifically if a person skilled in the art is able to perform them over the whole range claimed.

EPO concludes, in general, that the disclosure of one way of performing an invention is only sufficient if it allows the invention to be performed in the whole range claimed rather than merely in some members of the claimed class to be obtained. Sufficiency of disclosure thus requires that the skilled person is able to obtain substantially all embodiments falling within the ambit of the claims.

Thus, when examining and interpreting the sufficiency of disclosure, the Boards of Appeal in EPO have to be satisfied,

1) firstly, that the patent specification places the skilled person in possession of at least one way of putting the claimed invention into practice, and
2) secondly, that the skilled person can put the invention into practice over the whole scope of the claim.

In this project, study EPO case law technical decisions related to “Invention to be performed over the whole range claimed” are disclosed and in the end, the conclusions of EPO’s points of view related to the sufficiency of disclosure are summarized.

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1 Preface

In general, a patent must contain all of the information that is necessary to a person skilled in the art to carry out the invention over the whole range claimed. The lack of some essential information leads the patent to be insufficient. Consequently, all the key information that is required, to perform the invention must be included in the patent and hence it is not allowable to leave out any information which is essential for the performance of the invention over the whole range claimed.

A patent related to e.g. a chemical process must therefore disclose the required starting materials, as well as, all essential process steps. However, the patent does not need to disclose information, which is, regarded as the general knowledge to a person skilled in the art, but on the other hand, it must not require them to be inventive either. That is, only inventions, which can realistically be put into practice, can be patented.

The requirement of sufficiency in the European patent office (EPO) can, in general, be met by describing one way of carrying out the invention. However, it is not required in EPO to describe the best way of carrying out the invention. Still, there can be particular situations where more than one way of performing the invention has to be described in order to show that the invention may be performed over the whole range claimed.

Sufficiency is a requirement for patentability in EPO (and in Finland). This means that any patent application, which is found to lack sufficiency, will not proceed to grant of patent, unless the insufficiency is corrected. This can only be done by changing, that is in general limiting, the scope of the claims, as no additional information can be added to the application after filing.

2 The European Patent Convention (EPC) Articles[1, 2]

2.1 Sufficient disclosure – Articles 83 and 84 EPC

Article 83 EPC discloses that a European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Article 84 EPC discloses that the claims shall define the matter for which protection is sought. They shall be clear and concise and supported by the description

2.2 Opposition procedures – Articles 99-105 EPC

Any person (except the patentee) may oppose the European patent within nine months of publication on the mention to grant (Article 99 EPC) on grounds of: Lack of patentability (i.e. lack of novelty, inventive step, industrial application, not regarded as an invention) Article 100(a), insufficient disclosure Article 100(b), and extension of scope, i.e. amended beyond original disclosure Article 100(c). Consequently, not on the grounds of lack of clarity or unity (Article 84 EPC).

In the event of an opposition to the European patent being filed, any third party who proves that proceedings for the infringement of the same patent have been instituted against him may, after the opposition period has expired, intervene in the opposition proceedings, if he gives notice of intervention within three months of the date on which the infringement proceedings were instituted (Article 105 EPC).

Decisions (Article 101(2)(3) EPC) after an opposition procedure are according to Article 102 EPC revocation of the patent, rejection of opposition, or maintenance in the amended form of the patent. If a European patent is

amended, the EPO shall publish a new specification of the patent (description, claims, and drawings) in the amended form (Article 103 EPC).

2.3 Appeal procedures – Articles 106-112 EPC

Decisions of the Receiving Section, Examining Divisions, Opposition Divisions, and the Legal Division may be appealed to the Boards of Appeal of EPO (Article 106 EPC). Any party to proceedings adversely affected by a decision may appeal and any other parties to the proceedings shall be parties to the appeal proceedings as of right (Article 107 EPC; ex parte cases Article 109 EPC). The notice of appeal is to be filed within two months from the notification of the decision and the grounds are to be filed with four months (Article 108 EPC). If the appeal is admissible, the Board of Appeal will examine whether the appeal is allowable (Article 110 EPC).

There are different types of Boards of Appeal in EPO, that is, 28 Technical Boards (T decisions) and one Legal Board (J decisions).

Decisions in respect of appeals are final decisions or remittal to the first instance for further prosecution (Article 111 EPC). Appeals automatically generate case law (jurisprudence). However, in principle, the board's decision applies only to the case appealed (Article 111(2) EPC).

The Enlarged Board of Appeal (EBoA) is established by Article 15(g) EPC and its duties are laid down in Article 22 EPC. The EBoA clarifies the points of law (Article 112 EPC) at the request of the Boards of Appeal or the President and decides on petitions for review (Article 112(a) EPC). The decisions of the Enlarged Board of Appeal are binding for the Boards for the appeal in question (Article 112(3) EPC), though, their purpose is also to ensure uniform application of the law (Article 112(1) EPC). Consequently, decisions of the Enlarged Board of Appeal (G decisions) generally apply to all future cases, and in practice are incorporated into the Guidelines for Examination and taken into account when amending the EPC.

2.4 Oral proceedings – Article 116 EPC

Oral proceedings related to oppositions and appeals are carried out at request of parties and are public (Article 116 EPC).

3 Boards of Appeal – Technical decisions related to "Invention to be performed over the whole range claimed"[3]

Summaries of Boards of Appeal's technical decisions (T-decisions, published in English) related to "*Invention to be performed over the whole range claimed*" disclosed in the book "*Case law of the Boards of Appeal of the European Patent Office*" 8th ed. 2016, on page 335 chapter 4.4 are presented in this chapter. No general and more binding Enlarged Board of Appeal decisions (G-decisions) related to this subject matter have been given.

This overview of the decisions is emphasized on subject-matters related to specifically "*Invention to be performed over the whole range claimed*", that is, to the decisions especially related to Articles 83, 84, and 100(b) EPC. However, the appeals in general are filed based on several grounds.

3.1 The disclosure of one way performing an invention is only sufficient if it allows the invention to be performed in the whole range claimed rather than only in some member of claimed class to be obtained

3.1.1 T 409/91 – Application no. 87308436.2 – Middle distillate compositions with reduced wax crystal size

The appellant was the applicant of the EP87308436.2 patent application. The appeal was filed against the decision of the Examining Division that had refused the European patent application.

The application was refused as the application taught merely a method to obtain fuel oil containing wax particles having a size of 1200 nm at 6.4 °C below the Wax Appearance Temperature (WAT). No information on how to obtain smaller wax particles at the temperature of 10 °C below WAT was disclosed in the application sufficiently (clearly and completely). The second reason for

refusal was that the claims as whole did not define (state all the essential elements of) the matter for which the protection was sought, that is, fuel oil, in terms of technical features.

The appellant argued that the lower limit in the present case was not an essential feature and the particle size, as well as, the boiling range of the fuel oil, and the wax content as technical features were defined in the claims. He further argued that the invention was a new principle of solving an old technical problem and was hence a real contribution to the art. Though, at the same time the appellant admitted that the description did not disclose any other method of obtaining the desired crystal size than the addition of certain additives to the fuel oil and that there was no common general knowledge of making fuel oils of this kind available to a person skilled in the art. The appellant argued that in his opinion the situation under consideration was comparable with the invention of a new chemical compound, where it was settled jurisprudence that the disclosure of only one method preparing it was sufficient to obtain product protection per se, implicitly covering all methods of preparation.

The appellant requested the decision under appeal to be set aside and the patent be granted based on the claims as filed or on the basis of auxiliary requests.

Reasons for decision

Article 83 EPC requires that the application as filed must contain sufficient information to allow a person skilled in the art, using his common general knowledge, to carry out the invention within the whole area that is claimed. With the appellant's submission that the lower limit in the present case was not essential, the Board did not agree, since the essential features of the invention, which must be used for defining the matter for which the protection is sought, are all those technical features which were necessary to define an invention which is patentable under the EPC, including any feature which is necessary to define matter which also meets the requirement of sufficient disclosure (Article 83 EPC).

According to the description, the essential constituent of the composition was a certain additive, the feature that was missing from the claims. Therefore, the claimed subject-matter did not define all the essential technical features.

The claims must be supported by the description, that is, the definitions in *claims should essentially correspond to the scope of the invention as disclosed in the description*. The claims should not extend the subject-matter which, after reading the description, would still not be at the disposal of a person skilled in the art. Hence, the essential feature of the invention must also be a part of the independent claim or claims defining the invention.

In addition, *functional definitions are allowable only if a number of alternatives capable performing the said function would be at the disposal of a person skilled in the art*, either by reading the description or on the basis of the common general knowledge. In the description, it was disclosed that the crystal size produced in identical fuel oil compositions varies substantially. Hence, in the current application the Board was not convinced that the crystal size was a clear functional definition of the claimed fuel oil compositions, that is, that a person skilled in the art could find without an undue burden, i.e. by routine testing, whether or not a certain fuel oil composition fell within the terms of the claim. In the present case, the invention extended to subject-matter not available to a person skilled in the art, since no information was given to perform the claimed invention successfully without using the structurally defined class of additives. Hence, the invention defined in the claims did not meet the requirements of Articles 83 (and 84 EPC).

The appeal was dismissed (i.e. the application was refused).

3.1.2 T 435/91 Application no. EP85301297.9 – Detergent compositions

The appeal was filed against the Opposition Division decision to maintain the European patent in amended form.

The Opposition Division had concluded that the requirement of sufficient disclosure was met, since the description and the claims contained sufficient information to select suitable components for the desired compositions and during the preparation of the mixture, a person skilled in the art would have easily recognized the point at which a gel as claimed was formed.

The appellant (opponent) argued that it followed from the specification of the patent, as well as, of documents 1 and 3 that the concentration ranges where the desired hexagonal gel phase existed were very narrow and depended

strongly on the chemical nature of the components. Thus, the appellant concluded that the majority of compositions containing components according to claim 1 in the concentration ranges specified therein would not be able to form a hexagonal gel phase, so that it was not possible to obtain gels falling within the broad definitions of claim 1, other than those described in the worked examples, without the an undue burden of performing an excessive number of experiments, or without further inventive activity.

The respondent (patentee) argued that the subject-matter of claim 1 was sufficiently disclosed in the description in order to be carried out by a person skilled in the art who was capable to perform some routine experimentation. In particular, the patent contained several examples, which demonstrated how the desired hexagonal gel phase could be obtained. In addition, the respondent argued that it was not possible, without the loss of adequate protection, to describe the invention without "functional" definitions, since the concentration ranges for obtaining the hexagonal phase were defined by irregular areas in the phase diagram and depend strongly on the chemical nature of the components. The respondent argued that the question whether or not further invention was necessary in order to carry out the invention in some areas covered by the claim but outside the area of the worked examples was not relevant, or, in other words, the possibility to make selection inventions did not impair the sufficiency of the disclosure.

The appellant requested the decision under appeal to be set aside and the patent revoked. The respondent requested the patent be maintained on the basis of the main request or on the basis of auxiliary requests.

Reasons for decision

The main issue that was argued was whether the patent disclosed the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

There was no dispute that a person skilled in the art can establish whether or not a surfactant composition exists in the hexagonal liquid phase. Furthermore, the feasibility of the worked examples, in which the "additive" is either urea or sodium toluenesulfonate, remained unchallenged. Thus, it was clear that the patent disclosed at least one way to carry out the invention and that it was possible to determine whether or not any particular composition met the

definition on the invention as disclosed in claim 1. There was a dispute; however, as to whether or not *the subject-matter of claim 1 as a whole could be carried out by a person skilled in the art*, as one of its essential features, the "additive", was defined only by its function.

In the Board's judgment, the criteria for determining the sufficiency of the disclosure are the same for all inventions, irrespective of the way in which they are defined, be it by the structural terms of their technical features or by their function. In both cases the requirement of sufficient disclosure can only mean that the whole subject-matter that is defined in the claims, and not only part of it, must be capable of carried out by a person skilled in the art without the burden of an undue amount of experimentation or the application of inventive ingenuity.

The peculiarity of a "functional" definition of a component of a composition of matter resided in the fact that this component is not characterized in structural terms, but by means of its effect. Thus, this mode of definition does not relate to a tangible component or group of components, but comprises an indefinite and abstract host of possible alternatives, which may have quite different chemical compositions, as long as they achieve the desired result. Consequently, *they must all be available to a person skilled in the art if the definition, and the claim of which it forms a part, is to meet the requirements of Article 83 or 100(b) EPC*. This approach is based on the general legal principle that the protection covered by a patent should correspond to the technical contribution to the art made by the disclosure of the invention described therein, which excludes that the patent monopoly be extended to the subject-matter which, after reading the patent specification, would still not be at the disposal of a person skilled in the art.

There cannot be a clear-cut answer to the question of how many details in the specification are required in order to allow its reduction to practice within the comprehensive whole ambit of the claim, since this question can only be decided on the basis of the facts of each individual case. Nevertheless, it is clear that the available information must enable a person skilled in the art to achieve the envisaged result within the whole ambit of the claim containing the respective "functional" definition without an undue difficulty, and that therefore the description with or without the relevant common general

knowledge must provide a fully self-sufficient technical concept as to how this result is to be achieved.

Therefore, it had to be established whether or not the present specification disclosed a single embodiment or a technical concept fit for generalization which made available to a person skilled in the art the host of variants encompassed by the respective "functional" definition of the said claim. In this respect, the respondent had admit during the oral proceedings that it was not possible to identify, *on the basis of the information contained in the patent specification and taking into account the common general knowledge*, other compounds than those specifically mentioned, i.e. "hydrotropes", which could reasonably be expected to bring about the desired effect.

Thus, it was clear that the definition of the "additive" was no more than an invitation to perform a research program in order to find other "additives" which met the "functional" requirement set out in claim 1. Through the definition of claim 1 the respondent tried to claim not only the solution of the technical problem of providing surfactant compositions in the form of a hexagonal liquid crystal gel phase made available to a person skilled in the art by the disclosure in the patent specification, but, in addition, all other possible solutions to this problem which were based on the "principle" of mixing the surfactant composition as defined in claim 1 with a "suitable additive" and water, without giving any or any useful technical guidance as to how obtain, with a reasonable expectation of success, further suitable "additives" which were not "hydrotropes". *Neither the patent specification nor the relevant common general knowledge* provided guidance as to how further additives might be traced out or according to which criteria they might be selected. Therefore, the Board held that the patent did not disclose a self-sufficient technical concept, which adequately corresponded to the "functional" definition used for the "additive" in claim 1.

The respondent had referred to several earlier decisions of the Boards of Appeal, which in his opinion, supported the legal proposition that the requirement of Article 100(b) EPC would always be satisfied by the disclosure of only one way of carrying out the invention (e.g. one worked example). However, the decisions referred did not support such a broad proposition, since the respondent had not relied on the whole content of these decisions but only selected parts of them.

Therefore, in the Board's judgement there was no conflict between these decisions, since the description did not contain adequate instructions, which would have allowed a person skilled in the art to perform random experiments with an acceptable statistical expectation of success. On the contrary, these decisions were all based on the common ground that the disclosure of an invention is only sufficient if a person skilled in the art can reasonably expect *that substantially all embodiments of a claimed invention which this person skilled in the art would envisage on the basis of the corresponding disclosure and the relevant common general knowledge can be put into practice*. That is, only exceptional failures can be tolerated. In the present case, however, the possibility of failure was far from being exceptional. Thus, the respondent's submission that he was entitled to a broader protection because the knowledge of the disputed patent would provide an incentive for those skilled in the art to entertain further research activities which might lead to the discovery of further suitable compositions, had no basis in the EPC, nor it was supported by the cited jurisprudence of the Boards of Appeal.

In the auxiliary request, claim 1 was limited in such a way that the "additive" was selected from a limited list of individual chemical compounds, which were structurally very similar to the "additives" used in the worked examples. The Board held that in respect of the subject-matter now claimed the requirements of Articles 83 and 100(b) EPC were met.

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.1.3 T 172/99 Application no. 90303267.0 – Styrene-based resin composition

The appeal was made against the decision of Opposition Division to revoke the European patent. The Opposition Division held that the patent did not comply with the requirements of Article 83 EPC and that novelty and/or inventive step of the claimed subject-matter could not be assessed. The decision was based on the reason that one of the three essential parameters used in Claim 1, to define the particles of the rubbery polymer, the so called "peripheral parameter" ("C_i"), which was admittedly a newly formulated parameter, was neither defined nor explained in such a way that a person skilled in the art received all information necessary to carry out the polymerization by

means of process features which led clearly and unambiguously to the predetermined values of the said parameter.

The appellant argued that the peripheral parameter "C_i" was clearly defined in the patent specification (value obtained from transmission electron microscope photograph, i.e. result of rubber particles L in a unit area A given in unit μm^{-1} divided by the content of rubbery polymer in the composition given as wt-%). The appellant believed that "C_i", as well as, the other two parameters in claim 1, could be controlled by the method in the specification.

The respondents disclosed the patent in suit did not contain a clear and unambiguous description of "C_i" (how large is the size of the area A, which particles has been taken into account, which "image analyzer" has been used, how C_d is determined). In summary, a person skilled in the art was not able to ascertain from the patent what to do in order to obtain a "peripheral parameter C_i" within the required range.

The respondents requested that the appeal be dismissed. The objections raised by the respondents were twofold: 1) a person skilled in the art could not properly evaluate whether a given product fell within the scope of the claim and 2) it was not clear from the specification which process features were to be carried out in order to provide a product meeting all requirements defined in claim 1.

The appellant requested that the decision under appeal to be set aside and the patent to be maintained (claims 1-6) based on the main request or the first auxiliary request.

Reasons for decision

The three auxiliary requests submitted, differed from each other merely in the limits of the ranges of two parameters, but not with the respect of the parameters as such. The decision under appeal focused on the sole question whether the "peripheral parameter" is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC). The claim 1 referred to the description rather than defining the methods of determination of the parameters. The Board concluded that *there is an inconsistency in the definition of area A used in the calculation of C_i, as between*

the disclosure of the patent itself and Declaration II offered by the appellant in response to criticism by respondents.

The Board disclosed that in the case of newly formulated parameters, such as C_i, the patentee has a duty of making the full and fair disclosure of his invention to the public (Article 83 EPC) and is under particular obligation to disclose all the information necessary reliably to define the new parameter not only (i) in the formally correct and complete manner such that its values can be obtained by a person skilled in the art without an undue burden, but also (ii) in a manner which reliably retains the validity of the parameter for the solution of the technical problem for the application or patent as a whole in the sense that the values routinely obtained will not be such that the claimed subject-matter covers variants incapable of providing the relevant effect or, therefore, of solving the associated technical problem. The second conditions of these was not in the view of Board's view fulfilled in the current patent. This as, due to complete freedom of choice of particle population and therefore L and A, the value of C_i generated by any sample composition was essentially unrestricted. That is, any sample containing rubber particles can evidently generate, depending on the population of rubber particles chosen, a series of values for C_i, some of which fall within and some outside the claimed for this parameter in claim 1.

Therefore, the absence of an essential piece of information regarding the conditions for measuring the parameter C_i meant that the ranges routinely obtained will be such that *the claimed subject-matter inevitably covers variants which are incapable of providing the promised effect*. Consequently, the disclosure of patent was insufficient and the patent in suit did not comply with the requirements of Article 83 EPC and therefore in accordance with Articles 100(b) and 102(1) EPC none of the requests of the appellant was successful.

The appeal was dismissed (i.e. the patent remained revoked).

3.2 Skilled person is able to obtain substantially all embodiments falling within the scope of the claims

3.2.1 T 0418/91 Application no. 83303910.0 – Hair conditioning preparation

The appellant filed an opposition against the granted European patent. The Opposition Division rejected the opposition, considering that the disclosure

of the patent was sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 and 100(b)). The appellant filed an appeal against the decision of the Opposition Division.

The patent disclosed compositions that contain an ionized polymer together with an ionic surfactant of opposite charge. The polymers and surfactant interact to form a complex, which separates on dilution to form a lyotropic liquid crystal phase.

The respondent argued that the test to determine the presence of a lyotropic liquid crystal was relatively simple.

The appellant argued that although claim 1 specifies the molar ratio of tenside (T) to ¨the polymer (P) and the total weight concentration T+P, it remained unclear how one would obtain a lyotropic liquid crystal phase. The appellant further argued that a large number of polymers were disclosed and considerable experimentation would be necessary to determine which combination led to a liquid crystal phase. The term "neutral surfactant" was obscure and "charge density" was not adequately defined.

The respondent's main request was the maintenance of the patent as granted. The appellant requested that the decision of the Opposition Division to be set aside and the patent to be revoked.

Reasons for the decision

The patent listed the suitable cationic polymers and examples of specific anionic and cationic surfactants, in addition, the specification contained 13 worked examples, which indicated the suitable combinations of materials relating to both cationic and anionic polymers complexed respectively with anionic and cationic surfactants. At the oral proceedings, the appellant indicated that experiments had shown that no fewer than five polymer/surfactant complexes selected from the lists of the patent had failed to yield a lyotropic crystal phase. In an opposition procedure, including an opposition appeal, the burden of proof lies within the opponent. The Board considered that the subject matter of claims to be well within the degree of trial and error deemed to satisfy the Article 83 EPC. In order to satisfy the requirements of Article 83

EPC substantially any embodiment of *the invention, as defined by the broadest claim, must be capable of being realized on the basis of disclosure. Thus, the appellant's statement was regarded as an unsubstantiated allegation.*

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.2.2 T 19/90 Application no. 85304490.7 – Method for producing transgenic animals

The patent application was refused by the Examining Division, due to the fact that the application did not meet the requirements of Articles 53(b) and 83 EPC. The question of reproducibility (Article 83 EPC) has been concluded to be satisfied (according to T 226/85) only, if any embodiment of the invention, as defined in the broadest claim, could be carried out on the basis of specific disclosure. Consequently, the Examining Division concluded that it could not be assumed that the sole example described in the application – that of mice – could be extended to all other mammals. Thus, it was unlikely that the same genetic manipulation could be successfully performed on other animals without inventive skill.

The appellant appealed against the decision to refuse their application and filed four sets of claims: the main request and three auxiliary requests. The appellant argued that the scope of the terms used was a reasonable extrapolation from the experiments actually performed, and set out in detail in the description. Mammals' genetic systems were broadly similar and although there were differences, they were not decisive. The appellant further argued that the EPC did not require the description of every possible embodiment, which might be covered by a general broad claim. The techniques were relatively straightforward and employed at a level where from that point of view little distinction could be drawn between the different species of mammals.

Reasons for the decision

The mere fact that the claim is broad is not in itself a ground for considering the application as not complying with the requirement for sufficient disclosure (Article 83 EPC). Only if there are serious doubts, substantiated with verifiable facts, may application be objected to for lack of sufficient disclosure. *The application clearly indicated how a person skilled in the art can*

achieve a chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammal, by disclosing an activated mouse myc gene introduced into a suitable plasmid and then micro-injected into mouse eggs at a given stage of cellular development. Hence, *this ensured that the invention can be reproduced* on mice and secondly, it might be assumed that a person skilled in the art is aware of other suitable mammals on which the invention can be likewise successfully performed. Consequently, there was no reason why the application should be refused on the ground that it involves an extrapolation from mice to mammals in general and in the Board´s view, the invention was sufficiently disclosed (Article 83 EPC).

The decision of the Examining Division was set aside and the case was remitted to the Examining Division.

3.2.3 T 0548/91 Application no. 81108348.4 – Carboxyalkyl dipeptides, process for their production and pharmaceutical compositions containing them

The European patent had been granted and three oppositions were filed against the granted patent. The Opposition Division maintained the patent (as novel and involving an inventive step) on the basis of claims submitted during oral proceedings. The Examining Division took further the view that the objection related to insufficient disclosure had not been sufficiently substantiated by the opponents.

Appeals against the decision of the Opposition Division were made. Appellant 01 requested the limitation of the patent to examples 8-17 and 48-49 on the grounds of insufficient disclosure (Article 83 EPC), thus, the sufficiency of the disclosure was questionable at least for a part of the claimed subject-matter. Appellant 02 requested the revocation of the patent. The disclosure of the patent was insufficient since the process to be used in order to prepare some of the necessary starting products was missing and since some of the claimed compounds contained specific groups associated by a person skilled in the art with pharmaceutical activities different from the intended activities.

The respondent (the patentee) submitted an amended set of claims, limiting claim 1. During the oral proceedings of appeal new claims set was filed. Con-

sequently, the respondent requested that the appeal by appellant 01 be rejected, the appeal by appellant 02 be dismissed and the patent be maintained on the basis of claims 2-11.

Reasons for decision

The Board concluded that appellant 01 may not introduce an appeal on new grounds for opposition, i.e. insufficient disclosure. The appeal of appellant 01 was inadmissible but the appeal of appellant 02 was admissible. In addition, the Board expressed doubts concerning the amended claim 1 in both amended sets submitted (Articles 123(2) and 123(3) EPC).

The disclosure of the limited ways of performing the invention can be considered to be sufficient within the meaning of *Article 83 EPC if it allows a person skilled in the art to perform the invention in the whole range claimed*. The question whether the disclosure of one way of performing the invention covers *the whole claimed range is a question of fact that must be answered on the basis of available evidence and on the balance of probabilities* in each individual case. The burden of proof in order to establish that the invention cannot be reproduced lies with the opponents.

The present invention related to carboxyalkyl dipeptides, their production, and pharmaceutical compositions containing them. The dipeptides were defined by their chemical formula and by the lists of the corresponding chemical groups. *The description of the patent generally disclosed the process* to be used in order to prepare the claimed compounds. Specific examples were disclosed to illustrate the methods of preparation and to provide chemical and physical data on some of the dipeptides obtained.

The appellants though failed to provide any concrete evidence of unsuccessful laboratory attempts to prepare some of the claimed compounds. The mere argument that some of the claimed compounds possessed some structural elements, which would automatically confer to the corresponding compounds some desirable properties, was considered not relevant, since the common general knowledge in this technical field was that some compounds with a complex structure exhibit simultaneously different pharmaceutical activities. Thus, in the present case, *the appellants failed to provide either "literature" or "experimental" evidence in order to challenge the sufficiency of disclosure* of the newly limited but still exceptionally broadly claimed subject-matter.

Consequently, the Board considered that the subject-matter according to the disputed patent satisfies the requirements of Article 83 EPC.

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.2.4 T 0923/92 Application no. 83302501.8 – Human tissue plasminogen activator, pharmaceutical compositions containing it, processes for making it, and DNA and transformed cell intermediates thereof

The European patent was granted and seven parties filed opposition against the patent. Revocation of the patent was requested. The patent was maintained in amended form.

The Opposition Division observed that the respondents had been the first to disclose the nucleotide and amino acid sequence of t-PA and decided that the disclosure of the patent was enabling since it provided a person skilled in the art all the information which was necessary for the expression of a protein with a human tissue plasminogen activator (t-PA) function, for its purification, and for the preparation of its "derivatives". Although t-PA has several functions, a person skilled in the art would have taken the notion of "function" in a large sense and would have included therein the already known immunologic function of t-PA.

Appeals were filed by three appellants against the decision of the Opposition Division. The respondents filed a response to the statements and filed six subsidiary claim requests in replacement of the existing subsidiary claim requests. However, the Board of Appeal expressed in their preliminary opinion that only the main request, namely the claims as maintained by the Opposition Division, could be admitted into the proceedings. The respondents submitted still three new subsidiary claim requests in the substitution of all previous subsidiary requests.

The appellants considered that none of the requests complied with requirements of Article 84 EPC (unclear expressions of "human plasminogen activator function" and "derivative") and argued that the patent did not satisfy the requirements of Article 83 EPC either. In particular, the embodiments related to t-PA derivatives and the expression of human t-PA in *E. coli* were disputed.

The respondent argued that the "function" of t-PA was known in the art and a person skilled in the art would have taken it in a large sense to include the known immunological function. The term "derivative" was qualified in the relation to the function and also as the nature of the derivative and hence it was clear enough in the context. Concerning the reproducibility of the invention the respondent argued that Article 83 EPC required the reproducibility of the invention, not of the examples, and further argued that in any case the specification sufficiently demonstrated the first cloning and expression of human t-PA in *E. coli* and its production in mammalian cells. The patent provided detailed information about the structure and properties of the molecule and the work therein had found confirmation worldwide.

The appellants requested that the decision under appeal to be set aside and the patent be revoked. The respondents requested as the main request the appeal to be dismissed and as auxiliary requests 1-3 that the decision under appeal be set aside and the patent be maintained on the basis of one of the new subsidiary claim requests 1-3 submitted at the oral proceedings.

Reasons for decision

The appellants argued that: (i) The Bowes melanoma cell line was not generally available to the public, (ii) shown by the experimental reports submitted by the appellants, the examples concerned with the expression of *E. coli* were not workable, (iii) the description of the patent specification did not contain enough information with respect to the fibrin-binding and immunological assays which are important for the distinguishing human t-PA from urokinase, (iv) the information in respect of probe (iii) of claim 1 was misleading, and (v) not a single example of a functional derivative was provided in the description.

The Boards view was that: (i) a large body of evidence showed that Bowe melanoma cells were generally available and freely exchanged in the scientific community, (ii) the question under Article 83 EPC was not whether or not a specifically described example was exactly repeatable, but *whether the overall teaching of a patent in respect for claimed embodiment can reliably lead a person skilled in the art to put it into practice*. The issue in the current case was whether the teaching of the patent was sufficient in order to achieve expression of human t-PA in *E. coli* at any level. In this respect, the evidence

was rather confirmatory and even if the example was not exactly repeatable as shown by the experimental reports, it did not invalidate the teaching of the patent as a whole. *This must be seen from the wider perspective of the overall disclosure*, not merely from the narrow angle of a single experiment. Hence, the Board's view was that a person skilled in the art, given the stated sequence information and the results of its expression in a mammalian host, did not have to apply inventive skills or an undue experimentation in order to achieve the expression in the *E. coli* system. (iii) Immunological and fibrin-binding assays were part of the state of the art at the priority date and therefore needed not to be disclosed in detail in the description. (iv) Irrelevant point with respect to the insufficiency of disclosure. (v) When given a basic molecular structure and an activity to be tested, a person skilled in the art can be expected to be able to prepare without application of inventive skill or an undue experimentation generic functional derivatives of the molecule.

In summary, the requirements of Article 83 EPC were met by the patent.

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.2.5 T 1727/12 Application no. 06076929.6 – Tape drive and printing apparatus

The appeal was filed by the patentee against the interlocutory decision of the Opposition Division on the amended form in which the European patent could be maintained. The third auxiliary request had been found to satisfy the requirements of EPC. In addition, the opponent filed an appeal against the decision of the Opposition Division but the appeal was withdrawn. A third party intervention was also filed during the appeal proceedings and subsequently withdrawn. Consequently, the patent proprietor was the sole remaining appellant.

The appellant requested that the decision to be set aside and patent to be maintained as granted and no auxiliary requests were filed.

Reasons for decision

The Opposition Division had distinguished between "classical insufficiency" and "Biogen insufficiency". It had found the invention as exemplified in the

patent specification to be disclosed in the manner sufficiently clear and complete for it to be carried out a person skilled in the art. However, related to the subject-matter of claim 1 "a person skilled in the art would not be able to carry out the invention without using the tension monitoring disclosed in claims 3 and 5". Due to this lack of "Biogen sufficiency" ("to hold a patent invalid on the substantive ground that the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification" Biogen vs. Medeva 1997 RPC 1) the Opposition Division concluded that claim 1 did not meet the requirements of Article 100(b) and 83 EPC.

The principle of EPO proceedings is that the party who raises an objection bears the burden of proving it. The application of this principle to opposition proceedings leads to the conclusion that the burden of proof in respect of the grounds for opposition raised by an opponent lies on the opponent. Opposition Division may (Article 114(1) EPC) of its own motion raise a ground for opposition not covered by the notice of opposition or raise new arguments in respect of a ground for opposition covered by the notice of opposition, but if it does so, it has to bear the burden of proof for its objections. In addition, by date the concept on "Biogen sufficiency" was not part of the established jurisprudence of the boards of appeal of the EPO and was not commonly used in EPO proceedings. However, the concept is well known in the U.K.

When using this concept, the Opposition Division should have, however, at least explained what exactly was meant, namely that the extent of the monopoly claimed ought not to exceed the technical contribution to the art made by the invention as described in the specification. The Opposition Division appeared to have considered that claim 1 could not be said to be sufficiently disclosed within the whole scope of the claim as the only invention disclosed in the specification corresponded to the combination of claims 1 and 3-5. The Opposition Division justified its dismissal of the main request by concluding that "the patent only discloses how to the monitor the tension in the tape by monitoring the power supplied to the motors by monitoring the magnitude of current using a regulated power supply since the patent does not give any technically enabling disclosure to use another method to monitor the tension in the tape and since claim 1 is claiming a controller operative to monitor tension of the tape without monitoring the power supplied to the motors". Consequently, a person skilled in the art would not be able to carry out the

invention without using the tension monitoring disclosed in claims 3-5. Moreover, there was no hint in the available prior art how to maintain the tension without contacting the tape. Thus, the subject matter of claim 1 of the main request did not meet the requirements of articles 100(b) and 83 EPC.

The Board of Appeals was not persuaded by this reasoning as claim 1 was directed at a tape drive comprising a controller. Claim 3 added that the power supplied to at least one of the stepping motors was monitored and used to calculate an estimate of the tension of the tape. Claim 4 added that the monitoring of the power was itself indirect and according to claim 5 a constant voltage was supplied to the stepper motor and what was monitored was the magnitude of the current supplied. Hence, claim 1 did not comprise any disclaimer related to that the tension in the tape was monitored without monitoring the power supply etc. Claim 1 did not state how the tension was monitored. The *statement of Opposition Division that "a person skilled in the art would not be able to carry out the invention without using the tension monitoring disclosed in claims 3-5" may have been correct but was not sufficient to justify the conclusion* that a person skilled in the art was thus hindered from carrying out the invention. The Opposition Division had presumed the existence of alternatives and the impossibility to a person skilled in the art to carry out them. Hence, the *objection appeared to be purely speculative and therefore unfounded*. In addition, the same applied for the argument according to which there was no hint in the available prior art how to maintain the tension without contacting the tape. The mere fact that a person skilled in the art is aware of only one way of maintaining the tension did not justify an objection under Article 100(b) EPC.

In conclusion, the Board concluded that the Opposition Division had not established that of claim 1 of the main request failed to comply with the requirements of Article 100(b) EPC.

The decision under appeal was set aside and the case was remitted to the Opposition Division for further prosecution.

3.3 Acceptable if all alternatives are available and achieve the desired result

3.3.1 T 1121/03 Application no. 96944758.0 – Process employing indicator ligands

The appellant (the patentee) filed an appeal against the decision of the Opposition Division revoking the European patent. The opposition requesting revocation of the patent was filed on the ground of lack of novelty and inventive step (Article 100(a) EPC) and insufficient disclosure (Article 100(b) EPC).

The decision under appeal was based on the main request consisting of the claims as granted and four auxiliary requests. The Opposition Division had decided that the patent according to all pending requests did not disclose the invention in the manner sufficiently clear and complete. Thus, the Opposition Division held that the two functional features additionally defining the sterically hindered organophosphorus ligand: (i) had a coordination strength with respect to the metal of the said metal-organopolyphosphite ligand complex catalyst less than the organophosphate ligand of the said metal-organopolyphosphite ligand complex catalyst and (ii) when complexed with the metal to form a metal-sterically hindered organophosphorus ligand complex catalyst, provided a reaction rate of at least 25 percent of the reaction rate provided by the metal-organopolyphosphite ligand complex catalyst, were insufficiently disclosed. No methods for measuring either the coordination strength or the reaction rate were disclosed. In addition, with regard to the former parameter, no reliable method for its measurement was available in the prior art either, and with regard to the latter parameter, the patent was silent about the conditions under which it should have been measured. Hence, it had been concluded that a person skilled in the art would not be able to carry out the invention without an undue experimentation.

The appellant submitted the main request and auxiliary requests 1-7 superseding any previous request.

The appellant argued that the invention defined in claim 1 was sufficiently disclosed related to definition “a reaction rate of at least 25%...” Based on common general knowledge and simple preliminary experiments, such as examples 1-5 in the description, the skilled person could measure the reaction rate and conclude whether the sterically hindered ligand met feature (ii) or

not. However, the appellant submitted during the proceedings that the reaction rate was dependent on the catalyst metal, operation time, temperature, and concentration of the reactants of the rhodium metal, and of the ligands. The appellant further submitted that the limits of the suitable sterically hindered ligand were defined once the organopolyphosphite ligand was chosen.

The respondent (the opponent) argued that the amended claim 1 disclosing a feature "under the same reaction conditions" was not clearly and unambiguously derivable from the application as filed. The respondent further submitted that the invention was insufficiently disclosed with respect to feature (ii) as the patent was silent how the reaction rate should be determined. The reaction rates are dependent on reaction conditions (metal, time, temperature, concentrations) and different reaction conditions result in different reaction rates and hence different reaction rate ratios. Consequently, a person skilled in the art was invited to conduct a research program in order to figure out which sterically hindered ligand may be used with which organopolyphosphite ligand.

The appellant requested the decision under appeal to be set aside and the patent to be maintained on the basis of the main request or, subsidiarily on the basis of any of the auxiliary requests. The respondent requested the appeal to be dismissed.

Reasons for decision

The appellant objected in particular to the finding of the Opposition Division that the subject-matter of claim 1 as whole could not be carried out by a person skilled in the art as the sterically hindered organophosphorus ligand was defined by means of inadequate functional features.

It is the established jurisprudence of the Boards of Appeal that the requirements of *sufficiency of disclosure are only met if the invention as defined in the independent claim could be performed by a person skilled in the art in the whole area claimed* without an undue burden, using common general knowledge and having regard to further information given in the patent in suit. This principle applied to any invention irrespective of the way in which it is defined, be it by way of a functional feature or not. The peculiarity of the functional definition of a technical feature resides in the fact that it is defined by means of its effect. That is, that mode of definition comprises an indefinite

and abstract host of possible alternatives, which is acceptable, as long as all alternatives are available and achieve the desired result. Consequently, it had to be established whether or not the patent in suit disclosed a technical concept fit for generalization which made available to a person skilled in the art the host of variants encompassed by the functional definition of the technical feature in that claim.

The patent aimed at providing an indication when the organopolyphosphite ligand in a hydroformylation reaction had become depleted and at overcoming the problem of the metal of the metal-organopolyphosphite complex becoming intractable. The means were indicated in claim 1. The definition of the indicator ligand in claim 1 contained two parts: the result to be achieved and the indication of a structural requirement to be met in order to obtain the result (steric hindrance). However, the structural definition comprised a practically unlimited number of individual ligands, since apart from the indication that the organophosphorus ligands should be sterically hindered, their structure remained completely undefined. Though, not all sterically hindered organophosphorus ligands would necessarily satisfy at the same time all the functional features defined in the patent, which indicated that "certain" sterically hindered organophosphorus ligands had been found to be suitable ligands to use as indicators, "provided that the chosen sterically hindered organophosphorus ligand met the criteria set forth herein". Hence, the appellant admitted that a person skilled in the art needed to select an indicator ligand from among the sterically hindered ligands which met the criteria (i)-(iv) disclosed in the patent. All in all, this structural definition of the indicator ligand comprised a host of possible chemical compounds which might or might not have led to the required minimum indicator: the primary ligand reaction rate ratio.

And in order to pick from that host chemical compounds which satisfied the functional feature of reaction rate (ii), a person skilled in the art was confronted with the fact that the resulting reaction rate ratio was affected by a number of operational variables (reaction system and/or reaction conditions) unrelated to the structure of the indicator ligand. Consequently, there was no necessary correlation between the structural definition of the indicator ligand and the further functional requirement (ii) in claim 1. The reaction rate ratio defined in claim 1 necessarily varied unsystematically and unpredictably without any conclusive interdependency. Neither did the common general

knowledge nor the patent provide any technical guidance related to this. Consequently, a person skilled in the art did not have at his disposal any information leading necessarily and directly towards success through the evaluation of initial failures. Thus, the functional definition of the indicator ligand given in claim 1 was no more than an invitation to perform a research program in order to find a suitable ligand. In the Board's judgement, the invention as defined in claim 1 *could not be performed by a person skilled in the art within the whole area claimed without an undue burden*. The Board concluded that it was possible to a person skilled in the art to determine two separate reaction rates and calculate therefrom a reaction rate ratio, though, in the present case the decisive fact was that whilst being able to measure two separate reaction rates, a person skilled in the art cannot carry out the invention without an undue burden, since the functional definition of an indicator ligand in claim 1 merely invites him to perform a research program due to lack of any technical guidance disclosed in the patent. Therefore, the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art pursuant to Article 100(b) EPC.

The appeal was dismissed (i.e. the patent remained revoked).

3.3.2 T 0369/05 Application no. 97100106.0 – Products having anti-microbial activity

The appellant filed an appeal against the interlocutory decision of the Opposition Division which found that the European patent could be maintained in amended form. Opposition had requested the revocation of the patent as granted entirely. The decision under appeal was based on the set of amended claims.

Opposition Division had concluded that the invention was disclosed in a manner sufficiently clear to be carried out by a person skilled in the art. The Opposition Division found that the patent specification contained several examples teaching which type of polymeric material and which type of anti-microbial agent should be used and which concentration of the anti-microbial agent should be applied. Consequently, a person skilled in the art had sufficient information to carry out the invention.

The appellant argued that the invention defined the anti-microbial agent to be anti-microbially effective against any type of micro-organism. Hence, in order to be able to carry out the invention a person skilled in the art had to identify the micro-organism to be tested. Consequently, only then he would be in a position to determine whether the tested anti-microbial agent was releasable in anti-microbially effective amounts for at least three days. The appellant further argued that the releasability was influenced by various other operation parameters (level of humidity, type of polymeric material, concentration). According to variation of these parameters, the results obtained varied as well, but in an unpredictable manner. Thus, a failure concerning the tested combinations of parameters did not put a person skilled in the art in a position to derive any guidance thereof for achieving future success. The appellant argued that the patent did not give any evaluation criteria for the results obtained leaving a person skilled in the art in doubts as to whether the obtained results were falling within the meaning of an "anti-microbially effective amount" or not. Therefore, the patent did not contain sufficient information to carry out the invention, but a person skilled in the art had to exercise inventive skills in order to carry out the invention within the whole scope claimed.

The respondent argued that the patent contained sufficient information to a person skilled in the art to carry out the claimed invention. Concerning the type of micro-organism to be tested a person skilled in the art would certainly have had used those tested in the examples of the specification of the patent. Concerning the influence of polymeric material on the anti-microbially effective amounts he argued that some variation of the level of growth inhibition was of no relevance, since in any case some inhibition was achieved, which fulfills the criterion of being anti-microbially effective.

The appellant requested the decision under appeal to be set aside and the patent be revoked and the respondent requested that the appeal to be dismissed and the patent maintained in amended form according to the main request or subsidiarily the patent be maintained upon the basis of any of the auxiliary requests.

Reasons for the decision

The appellant objected in particular to the finding of the Opposition Division that the subject-matter of claim 1 could be carried out by a person skilled in the art within the whole area claimed, because the amine salt to be used was defined by means on inadequate functional features, namely being "releasable in anti-microbially effective amounts within the period of at least three days". Hence, this clear and unambiguous wording made plain that the functional definition of being releasable from the polymeric material in effective amounts over a specific period of time related and determined exclusively the anti-microbial agent to be used in the claimed product. Therefore, the respondent's argument that this functional definition rather referred to the claimed product itself was at variance with the facts. Furthermore, the term "releasable" specified that what the anti-microbial agent must be able to do. Thus, the functional definition disclosed in claim 1 indicated an ability to be satisfied by the anti-microbial agent and, contrary to respondent's submission, was not a property to be attributed to the claimed product.

It is established jurisprudence of the Boards of Appeal that requirements of *sufficiency of disclosure are only met if the invention as defined in the independent claim can be performed by a person skilled in the art in the whole area claimed* without an undue burden, using common general knowledge and having regard to further information given in the patent. This principle applies to any invention irrespective of the way in which it is defined. The peculiarity of the functional definition of a technical feature resides in the fact that it is defined by means of its effect. That mode of definition comprises an indefinite and abstract host of possible alternatives, which is acceptable as long as all alternatives are available and achieve the desired result. That is, is the technical concept fit for generalization.

The definition of an anti-microbial agent in claim 1 contained two parts: 1) result to be achieved and 2) an indication of a structural requirement to be met in order to obtain the desired result, i.e. amine salt. However, this structural definition comprised a practically unlimited number of compounds since apart from being "amine salt" the structure remained completely undefined. Thus, the structural definition in claim 1 covered any chemical compound as long as it comprised an amine salt group. However, the respondent had stated during oral proceedings that not all amine salts were suitable for effectively

inhibit growth of micro-organisms for the required release period of at least three days. Therefore, a person skilled in the art was confronted by the fact that the anti-microbial effective amount and the release period of at least three days were affected by a number of variables unrelated to the structure of the agent. That is, the polymeric material used, operating conditions of the test, and the concentration of the amine salt used all affected. Therefore, there was no necessary correlation between the structural definition of the anti-microbial agent, being an amine salt, and the functional requirement, that the said anti-microbial compound is releasable from said polymeric material in anti-microbially effective amounts for a period of at least three days. That is, the releasability in anti-microbially effective amounts necessarily varied unsystematically and unpredictably without any conclusive interdependency with the exact structure of the anti-microbial agent. *Neither the common general knowledge nor the patent provided any technical guidance to the identifying of suitable an amine salt to a person skilled in the art without an undue effort*. Therefore, the invention as defined in claim 1 could not be performed by a person skilled in the art within the whole area claimed without an undue burden. That is, claim 1 failed to meet the requirement of clarity imposed by Article 84 EPC.

The decision under appeal was set aside and the patent was revoked.

3.4 Lacking generalizable teaching acceptable within the scope of the claims (beyond the specific examples)

3.4.1 T 1051/09 Application no. 98964923.1 – Process to reduce the AOX level of wet-strength resins by treatment with base

The appeal was filed by the patentee against the decision of the Opposition Division revoking the European patent. The decision under appeal was based on the claims of the patent as granted (main request) and three sets of auxiliary requests. The decision held that the patent did not meet the requirements of Article 83 EPC as it did not teach beyond the specific examples given how to carry out the base treatment in order to meet the requirements of the claims pertaining to conversion of a tertiary aminohalohydrin present in the starting resin into an epoxide (i.e. the adsorbable organic halogen AOX content), the azetidinium content (AZE), and wet strength. On the contrary, a person skilled in the art could only establish by trial and error involving a large number of experiments whether a particular combination of parameters (temperature, type and amount of base, pH, reaction time, resin concentration) would

yield the required treated resin. This constituted an undue burden. Consequently, the patent was revoked.

The appellant filed nine more amended sets of claims. Claim 1 of all sets of claims contained a feature relating to the resin treatment step, analogous to that in claim 1 of the patent as granted. The appellant argued that the key contribution of the patent was the recognition that by adapting a moderate base treatment it was possible to achieve the dual effects of 1) removing AOX whilst 2) retaining azetidinium ions or wet strength which was reflected in claim 1 by three conditions 1) 90% of tertiary aminohalohydrin in the starting material was converted to epoxide, 2) the level of azetidinium was to be substantially unchanged, and 3) the effectiveness of the resin at imparting wet strength was at least as great as that of the starting material. Considering the nature of the treatment, it was only possible to formulate the claims by the way of object to be achieved. The description and examples showed how to select appropriate treatment conditions for various resin types and explained why some examples gave better results than others did. The extensive teaching, in particular the large number of examples, of the patent showed that it was necessary to adopt moderate conditions. In description, it was disclosed that various factors affected the harshness of base treatment (temperature, time, pH). Whilst there were multiple permutations of parameters, the examples provided sufficient teaching as to how these could be selected for various resins. In addition, the appellant argued that the wet-strength requirement was only to be seen as an explanatory feature (in known base treatments the wet-strength was lost, that was not the case with the present base treatment).

The respondent (the opponent) argued that great many factors affected the outcome making it necessary to carry out a large number of experiments to identify appropriate conditions. The respondent further argued that the examples of the patent were inconsistent as some met the requirements set out in the claims and others did not. The claims were not limited to any particular resin, thus a person skilled in the art should achieve the necessary results with any water-soluble wet-strength resin. However, this was not the case.

The appellant requested the decision under appeal to be set aside and the patent be maintained on the basis of auxiliary request 3 as filed at the oral proceedings or on the basis of the auxiliary requests submitted earlier. The respondent requested that the appeal to be dismissed.

Reasons for decision

The claimed process was defined in a functional manner, i.e. by its outcome. Since the claimed subject-matter was not limited to particular water-soluble wet-strength resins, the question was whether the way to achieve that outcome for any possible water-soluble wet-strength resin *was disclosed in the patent in such a manner that it was fit for generalization beyond the specific examples disclosed*. The only general information relating to the nature of the resin was provided in the description where it was stated that the amount of base varies widely from resin to resin and taught that this was dependent on: resin type, amount and type of aminochlorohydrin, the amount of epi by-products, the amount of stabilization acid in the resin, and the condition used to activate the resin. However, no further explanations, analyses, or discussions of any of these factors, their interrelationship and how they affected the outcome was disclosed. This *did not amount to the provision of a teaching of a concept fit for generalization*. The sum of total of the general teaching disclosed in the patent was that it was necessary to select conditions that were neither "too mild" nor "too harsh" but are "moderate" or "just right" and that the conditions have to adapted to the resin and the list of factors which influenced the reaction (in line with the argumentation of the appellant).

The patent did indeed contain a great number of examples, however, the outcome of these was variable. The Board also noted that the teaching of the patent with respect to the requirement of claim 1 of maintenance of the effectiveness of the resin at imparting wet-strength properties was also insufficient. This was shown also in many examples disclosed in the patent ("should be at least" that imparted by the starting resin was not fulfilled).

Consequently, the only conclusion that could be drawn was *that the conditions necessary to meet the varying requirements of the resin, cannot be generalized* but need to be adapted for each starting resin to be treated. *The patent provided no indication or teaching to a person skilled in the art* on how starting from a given resin it was possible in a directed and structured manner to identify an appropriate set of conditions. *Nor did the patent provide any indication or guidance to assist a person skilled in the art* in evaluating the outcome of unsuccessful trials to identify modifications need to be made in order to progress towards conditions which give the desired result. The technical teaching of the patent amounted to a little more than a report that it has been

found possible to provide optimized conditions enabling the various competing requirements to be met and some examples of special cases in which this had been achieved.

What was lacking was a generalizable teaching applicable within the scope of the claims, i.e. beyond the specific examples. The patent did not therefore meet the requirements of Article 83 EPC and was refused.

The appeal was dismissed (i.e. the patent remained revoked).

3.5 More than one example may be necessary to support claims of broad scope – One way of implementing invention over whole scope of claim

3.5.1 T 0612/92 Application no. 84200792. 4 – A process for the incorporation of foreign DNA into the genome of monocotyledonous plants

The European patent was granted and a notice of opposition was filed requesting the revocation of the patent. By the interlocutory decision, the Opposition Division maintained the patent in amended form. It was determined that the description of the patent disclosed the invention enabling manner. No scientific arguments existed to conclude that members of other monocotyledonous families were so much different from the ones exemplified that the invention could not be performed.

The appellants (the opponents) filed an appeal against the decision of the Opposition Division. During the oral proceedings, the respondent (the patentee) filed auxiliary requests.

The appellant argued that the patent specification was not enabling in three respects: 1) the description did not approach the problem of incorporating Ti DNA into the genome of monocytoledonous plants other than *Liliaceae* and *Amaryllidaceae*, 2) the patent did not show that T-DNA incorporated into the plant genome of even *Liliaceae* and *Amaryllidaceae*, and 3) the process of claim 1, which had to be interpreted as the provision of transgenic monocytoledonous plants, could not be carried out as insufficient information had been given how to perform the regeneration of wounded cells or protoplasts.

The respondent replied that the patent specification was enabling as 1) the specification provided the examples of the inoculation of *Agrobacterium* into

two monocytoledonous species families *Amaryllidaceae* and *Agaraceae*, followed by the introduction and the expression of Ti DNA in the plant cells, 2) there was no reason to believe that the differences in the experimental conditions used in documents 10 or 18 an in the patent would have any influence on the T-DNA incorporation into the plant genome, and 3) the specification left no doubts that the techniques generally in use for the regeneration of dicotyledons were likewise applicable to monocytoledonous plants.

The appellants requested the decision under appeal to be set aside and the patent to be revoked. The respondent requested that the appeal to be dismissed and the patent to be maintained on the basis of main request or the auxiliary requests.

Reasons for decision

The claimed invention was defined as a process for the incorporation of foreign DNA into the genome of monocytoledonous plants. The patent did not disclose a technique new in itself, but rather made the suggestion that a technique already known for the incorporation of foreign DNA into the genome of dicotyledonous plants, worked also for monocytoledonous plants. Hence, the contribution to the state of the art by the patent was the suggestion of a new application for a known technique. Thus, it must be of particular relevance for the assessment of sufficiency of disclosure that the process could indeed *be carried out over the whole range of the claimed application*, and that a person skilled in the art did not find himself in a situation where despite having used reasonable endeavors, he could not carry out the process in relation to the particular monocytoledonous plant he was interested in.

The established case law of the European Patent Office disclosed that "*an invention is sufficiently disclosed if at least one way is clearly indicated enabling a person skilled in the art to carry out invention*. Consequently, any non-availability of some particular variants of functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to a person skilled in the art through the disclosure or common general knowledge, which provide the same effect for the invention. The disclosure needs not to include specific instructions as to how all possible component variants within the functional definition should be obtained".

However, it is necessary that a person skilled in the art is given sufficient guidance *for performing the invention in the whole range claimed without an undue burden*. The mere fact that a claim is broad is not in itself a ground for considering the application as not complying with the requirement for sufficiency of disclosure under Article 83 EPC. Only if there are serious doubts, substantiated with verifiable facts, may an application be objected to for lack of sufficient disclosure.

The issue of the patent in suit was concerned with applying a known method to a new area of applications, defined as monocytoledonous plants. This was not a feature defined in functional terms, for which one variant, which can be carried out by a person skilled in the art, may be sufficient in some circumstances. The feature in the claim now under consideration related to known plants, and the novelty of the process was applying known methods to these plants. But then the information in the patent and common general knowledge at the priority date must enable a person skilled in the art to carry out the method throughout the novel field of application claimed. There was no justification for allowing the claim to cover the application of the process to monocytoledonous plants which a person skilled in the art could not with the information in the patent transform using a Ti-plasmid achieve. Therefore, the claim did not comply Article 83 EPC if the appellant could show that for one type of monocytoledonous plant the process could not be carried out on the basis of the information in the patent and common general knowledge.

The Board noticed that the class of the monocytoledonous regroups 53 widely diversified families. The specification of the patent never mentioned the need for adapting the claimed process to each specific monocytoledonous species. Thus, neither did it suggest which parameters should be changed. Consequently, *to obtain all needed information substantial amount of work was needed*. The Board found that this work would amount to an undue burden of experimentation. It was also clear that as late as 1990, the transformation of cereal plants could not be achieved.

The Board concluded on the basis of facts presented, that *the information in patent was insufficient to allow the invention be carried out with the majority of monocytoledonous plants*. Hence, the main request was refused under the provisions of Article 83 EPC for lack of sufficient disclosure.

The decision under appeal was set aside and patent was revoked.

3.5.2 T 0694/92 Application no. 8432533.9 – Plant gene expression

The European patent was granted and an opposition was filed against the grant of the patent by eleven parties all requesting its revocation in part or in whole. The Opposition Division issued an interlocutory decision in which the patent was maintained in amended form.

Six parties filed an appeal against the decision of Opposition Division and the respondents (the patentees) filed a response to the statements of the grounds of the appellants. After the Board's preliminary analysis of the case, the respondents filed four auxiliary requests and asked the Board to refer two questions to the Enlarged Board of Appeal in case it was minded to refuse the main request, i.e. for the maintenance of the patent in amended form. During the oral proceedings, the respondents filed three new auxiliary requests to replace the four previous.

The appellants argued that the patent contained no technical features other than a reference to the result to be achieved ("such that the expression of the protein encoded by the said plant structural gene is detectable in said plant cell" in claim 1). The description failed to indicate the technical measures, which had to be taken in order to successfully achieve, without an undue burden, the desired effect over the whole area claimed. The appellants further argued that the patent specification contained only the example of the expression in the plant cells of a phaseolin gene containing its own promoter, something that had already been suggested in the prior art. The appellants argued that the scanty description with its reference to a series of intended experiments, which had never been carried out, did not provide a disclosure sufficient to a person skilled in the art to obtain the technical effect of expression in any plant. Broad claims that failed to recite the critical technical features which truly distinguished the claimed subject-matter over the known from the prior art should not be allowed.

The respondents argued that fair protection had to be granted to inventions, which provided a real progress in the art. The patent in situ demonstrated a method which allowed the expression of plant genes in plant cells and in plants and plant tissue derived therefrom under the control of a plant promoter. The respondents further argued that before the patent in suit, there

were neither indications nor expectations in the prior art that this could be achieved. Hence, the disclosure of the patent opened a previously closed door by providing the first demonstration that transcription and translations of a plant structural gene could be achieved. The specification illustrated in the examples that a plant promoter could be used to achieve a detectable level of expression of a plant structural gene. Consequently, fair protection had to be granted and this could be done only in the basis of general claims, which contained all the essential technical features of the invention, and provided instructions clear enough for testing whether the functional definition had been met. None of the appellants had provided evidence nor could it be argued that it was unclear what fell under the scope of the claims.

The appellants requested the decision under appeal to be set aside and the patent revoked. The respondents requested the appeals to be dismissed or that the decision under appeal to be set aside and the patent be maintained according to the auxiliary requests

Reasons for decision

Article 84 EPC requires that the matter for which protection is sought be defined in the claims in a clear and concise manner and that the claims are supported by the description. That is, all the essential features of the claimed invention have to be indicated in the claim. The essential features may be also be expressed in general functional terms, if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the claim, and if these features provide instructions which are sufficiently clear to a person skilled in the art to reduce them to practice without an undue burden.

Article 83 EPC requires an invention to be *disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*. The extent to which an invention is sufficiently disclosed is highly relevant when considering the issue of support within the meaning of Article 84 EPC, because both these requirements reflect the same general principle: the scope of a granted patent should correspond to its technical contribution to the state of the art.

Therefore, despite *being supported by the description* from a purely formal point of view, claims may not be considered allowable if they encompass

subject-matter which in the light of the disclosure provided by the description can be performed only with an undue burden or with application of inventive skill. Technical details needed is a matter which depends on the correlation of the facts if each particular case. In certain cases, a description of one way of performing the claimed invention may be sufficient to support broad claims with functionally defined features (new technique disclosed with the essence of the invention and disclosed one way of carrying out the invention enables the same effect in a broad area). In other cases, more technical details and more than one example may be necessary in order to support claims of broad scope (serious doubts exist). *The guiding principle is that a person skilled in the art should after reading the description be able to perform the invention over the whole area claimed* (without an undue burden and inventive skills).

In summary, the art of genetically modifying plant cells so as to achieve detectable levels of expression of a transferred foreign gene was not very well established at the priority date of the patents and was faced by a number of uncertainties and problems. By providing a single example of successful expression, the patent in suit did not generally remove these problems and uncertainties. The patent did not make it plausible that the same effect would be obtained routinely in any plant cell with any combination of any plant structural gene with any plant promoter. In addition, later publications showed that the expression of the transferred gene under its own signals were largely empirical and thus involved a large amount of trial and error with high risk of failure.

Consequently, the Board decided *that the experimental evidence and technical details in the description of the patent were not sufficient* to a person skilled in the art to reliably achieve without an undue burden the technical effect of expression in any plant cell of any plant structural gene under the control of any plant promoter and that, therefore, they did not provide sufficient support for a claim.

In the third auxiliary request the respondents had limited claim 1 to a *dicotyledonous* plant cell into which a phaseolin promoter with a phaseolin structural gene is transferred and hence the subject-matter of this claim complied the requirements of Articles 83 and 84 EPC.

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.5.3 T 0187/93 Application no. 84305909.8 – Vaccines based on membrane bound proteins and process for making them

The European patent was granted and an opposition was filed. The Opposition Division issued an interlocutory decision whereby the patent was maintained on the basis of claims filed at oral proceedings.

The appellants (the opponents) filed an appeal against this decision and the respondents (the patentees) filed counterarguments.

The Board expressed its provisional view that the respondent's arguments in support of the inventive step (Article 56 EPC) might be in conflict with those submitted in favor of a broad claim 1, directed to a process for making a vaccine comprising a truncated glycoprotein from any viral pathogen (Articles 83 and 84 EPC), since a person skilled in the art could not apparently predict with certainty whether the truncation of glycoproteins from a virus different from the exemplified *Herpes simplex* virus (HSV) might have deleteriously affected the conformation of the secreted viral glycoprotein in such a way as to destroy the epitopes responsible for immunoprotection *in vivo*.

The respondents submitted a further subsidiary claim request in addition to previous two auxiliary requests. The claims of the main request correspond to the claims of patent as maintained by the Opposition Division.

The appellants argued that claim 1 of the main request was directed to a process for producing any viral glycoprotein from any virus. In the auxiliary requests, claim 1 was limited to a process for producing a polypeptide derivative of either any *Herpes* virus polypeptide or any *Herpes simplex* virus polypeptide or any *Herpes* virus gD protein or any *Herpes simplex* virus gD protein. However, the patent failed to provide any guideline as to which immunogen was likely to confer immunoprotection *in vivo*. No prediction of the immunoprotective action could be made based on the patent. Hence, claim 1 had to be restricted to the particular exemplified relating to gD-1.

The respondents argued that the discovery by the present inventors that truncated, a membrane-free derivative of gD of HSV conferred immunoprotection, gave rise to a reasonable expectation that the system would be successful

with other pathogens. These expectations arose because the successful results produced in the HSV model demonstrated that all the technical problems leading to successful vaccine had been overcome.

The appellants requested the decision under appeal to be set aside and the patent to be revoked. The respondents requested that the appeal is dismissed or that the patent is maintained on the basis of auxiliary requests.

Reasons for decision

Claim 1 as granted comprised the essential technical feature that the truncated polypeptide produced by the method claimed should have exposed antigenic determinants "capable of raising neutralizing antibodies against a pathogen". During the opposition procedure, said technical feature had become "capable of raising neutralizing antibodies and provides protection in an immunized subject against *in vivo* challenge by a viral pathogen". In the context of inventive step, the respondents argued that this additional technical effect was an exceptional one that went many steps beyond the mere induction of neutralizing antibodies. The Board agreed that this conferring immunoprotection by an immunogen is a far more demanding task than merely eliciting neutralizing antibodies. In view of this, whether this technical effect can be arrived at without an undue burden by a person skilled in the art within the whole range of viral polypeptides of claim 1 became relevant question.

The respondent argued that before the earliest priority date of the patent, a person skilled in the art could not have reasonably predicted that a vaccine based solely on the truncated viral glycoprotein that was associated with its membrane domain, would have exhibited the property of immunoprotection *in vivo*. This property was linked with the conformation of the secreted truncated protein and with the host's T-cell response. Thus, a person skilled in the art could not predict in advance their role upon immunoprotection *in vivo*.

However, since slight changes in the three-dimensional conformation may have unpredictable effects in the host's immune response, the Board concluded that a person skilled in the art must experience the same uncertainty in relation to any other truncated membrane-bound polypeptide from any virus, having no amino acid homology with gD from HSV. This, as no two membrane glycoproteins from unrelated viruses are the same. Furthermore, there was no common technical feature automatically turning up as a result

of the truncation process, which common feature was of necessity capable of producing or preserving the epitope(s) responsible for *in vivo* immunoprotection, the said feature being valid for any membrane glycoprotein from any virus. Therefore, *a person skilled in the art could not predict with certainty* whether the truncation of glycoproteins from a virus different from the exemplified gD from HSV might deleteriously affect the conformation of the secreted viral glycoprotein in such a way as to destroy the epitopes responsible for immunoprotection *in vivo*. Consequently, the results relating to gD from HSV could not be extrapolated to glycoproteins from the whole range of all other viruses. Thus, it could reasonably be expected that a person skilled in the art when trying to obtain the same technical effect with a glycoprotein from a viral pathogen different from HSV, *would experience the same lack or predictability as in the case of gD from HSV, which led to an undue burden and/or possible failures (Article 83 EPC)*.

Thus, claim 1 did not fulfill the requirements of Articles 83 and 84 EPC and the main request was refused.

The amendments in fourth auxiliary request limited the membrane-bound viral polypeptides to glycoproteins gD of *Herpes simplex* virus. Therefore, claim 1 of the fourth auxiliary request satisfied the requirements of Articles 83 and 84 EPC.

The decision under appeal was set aside and the patent was maintained on the basis of the amended claims.

3.5.4 T 0792/00 Application no. 89910702.3 – Generation and selection of recombinant varied binding proteins

The European patent was granted and two opponents opposed the patent. The Opposition Division revoked the patent on the ground that the specification did not disclose the invention in a sufficiently straightforward manner or it to be carried out by a person skilled in the art (Article 83 EPC).

The Opposition Division concluded that in order to overcome prejudice in the prior art, it was not sufficient to simply state that the prejudice was false or merely to give a hypothetical example. The patent specification should rather demonstrate that the prejudice has been overcome, or at least teach the invention in a direct and straightforward manner. This was not the case for the

present Example I as it had not been shown that the specific teaching of this example led to success but merely that something different not derivable from the description had to be done.

The patentee filed an appeal against the decision of the Opposition Division and the respondents (the opponents) filed submissions in reply asking the appeal to be dismissed. The appellant (the patentee) filed four auxiliary requests and further submissions and evidence.

The appellant argued that, the invention was a concept invention relating to the display of proteinaceous binding domains and the prejudices against this at the priority date were not based on any reported failed experiments but on a generalized belief in the art. The appellant further argued that the decision under appeal was based on unsubstantiated allegations by the opponents and an incorrect application of the legal principles of the EPO, as the opponents had not provided any experimental evidence of the inoperability or insufficiency of the patentee's claimed methods. The appellant argued that the fact that the patent did not include a worked example was irrelevant, as this was not required for sufficiency of disclosure under Article 83 EPC. All that was required was that a person skilled in the art could put the invention into practice without an undue burden of experimentation, and the patentee's general disclosure and hypothetical example met this requirement. The appellant argued that the burden of proof was on the opponents.

The respondents argued that for the sufficiency there must be a technical basis for predicting success. Here there was no "contribution to the art" by the patentee, which allowed the subject matter of the claims to be achieved. There was a mere hope to succeed, while the description referred to numerous possible problems and failure was clearly envisaged. The respondents argued that the disclosure of an invention must demonstrate the successful achievement of the claimed subject-matter. The respondents further argued that demonstration of a successful achievement of the patent was mandatory when there was, a technical prejudice based on the results of experiments defining an area of unpredictability. Thus in these cases, expectations of success must be based on the patent disclosure rather than common general knowledge as the latter leads to an expectation of failure. The patent gave no precise guidance to a person skilled in the art but actually aimed at covering all the possibilities to

neutralize every source of failure. Therefore, the patent was incitement to embark on a research program.

The appellant requested the decision under appeal to be set aside and the patent to be maintained on the basis of the claims granted or on the basis of the auxiliary requests. The respondents requested the appeal to be dismissed.

Reasons for decision

The Board have to be satisfied firstly that the patent specification puts a person skilled in the art in possession of at least one way of putting the claimed invention into practice and secondly that *the skilled person in the art can put the invention into practice over the whole scope of the claim*. If the Board was not satisfied on the first point that one way exists, the second point needs not to be considered.

Of a special legal significance for this case was also that all parties agreed and was accepted by the Board that what was claimed, was something, which according to prevailing technical opinion at the priority date would not be possible. In such a case, *it becomes critical that the patent specification describes the invention in such a way that the Board is satisfied* that a person skilled in the art will succeed in putting at least one form of it into practice. If by following the only example(s) in the patent specification a person skilled in the art does not succeed, and this is the result he would expect according to prevailing technical opinion, then it is beyond what can be expected of a person skilled in the art to try further variations or research himself, which according to prevailing technical opinion would be futile. A person skilled in the art would then have been given no reasons to doubt the prevailing opinion and could not be expected to pursue research on the basis of mere hope expressed in the patent. An invention, which goes against prevailing technical opinion, may be considered particularly meritorious, if it is told how to put in into practice, but if the patentee has failed to give a single reproducible instance, it would amount to an undue burden to a person skilled in the art. The fact that the patent specification may contain numerous suggestions as to other ways trying to succeed cannot make up for the lack of even a single example that works. Rule 27(1) (e) EPC states that the description shall describe in detail at least one way of carrying out the invention claimed using

examples where appropriate. While the case law does not consider the requirement for an example as an absolute necessity, *for inventions, which are contrary to prevailing technical opinion, in the absence of an example that works as described, the recognition of sufficiency is unlikely*.

A technical prejudice as used in the jurisprudence or Boards of Appeal refers to a prevailing technical opinion, which is so widely established as to appear in textbooks and the like, and which is shown later to be erroneous. However, for the issues considered in this decision it did not matter whether the prevailing technical opinion was well enough established or not to be considered as a "prejudice": it was solely of importance that it was the prevailing technical opinion at the priority date.

The general rule is that he who asserts something positive has the burden of proof. In the special situation where an opponent accepts that the invention can be carried out as stated in examples, but alleges that there are other circumstances where something falling under the claim cannot be carried out, *the Boards of Appeal would normally expect the opponent to provide concrete evidence of this*. However, this was not the situation here. Where as in patent in suit, the only example was explicitly described as a hypothetical experimental protocol, and the experiment had clearly not been actually carried out, the burden of proof was on the appellant (the patentee) to show that what is described works. The critical question for deciding whether the example can be relied to support sufficiency, is whether in the example the experimental protocol as stated leads to an embodiment of the invention or not. It is the experimental protocol as stated that a person skilled in the art can be expected to follow. If the only evidence is that something deviating from the experimental protocol as stated works, the Board has no experimental evidence that a person skilled in the art would achieve success, and is likely to be able to rely on the example as the evidence of sufficiency.

Claim 29 used very general language to describe the invention. Thus, claim 29 by itself provided no teaching that a person skilled in the art could reproduce relying only on his general knowledge. Referring to description, a person skilled in the art, found a single example and the example emphasized throughout that in only gave a hypothetical example of a protocol. From reading the example alone the skilled reader could not derive any certainty that the invention claimed in claim 29 can be got to work according to protocol.

The appellant had provided experimental evidence with somewhat varied protocol compared with the hypothetical protocol of an example. The respondent challenged whether even these experiments showed that the varied protocol allowed one to achieve success. The experimental protocol followed in this additional experimental evidence differed in several respects from the teaching of the patent. Furthermore, although the patent mentioned in several instances possible sources of problems and ways which might solve them, when the protocol does not work as described, the Board cannot assume that the variations are routine. In the absence of evidence that the protocol as stated succeeds, the Board must assume that by following the protocol as stated a person skilled in the art would fail. Thus, given that failure was the result he would be in any case expecting from prevailing technical opinion, any further efforts of a person skilled in the art would amount to embarking on a research program with no expectation of success.

Though, *since every element of the solution proposed in the patent might be according to the patent a potential source of failure, the patent in suit did not provide a person skilled in the art with real guidance to perform* the claimed subject-matter but on the contrary, in the Board's view, offered nothing else to a person skilled in the art than an outline of a research program. An invention, however, is supposed to relate to a solution to a technical problem. The conclusion was that the patent specification did not contain sufficient information to carry out the subject matter of claim 29, if this could be carried out at all. That is, the subject matter of claim 29 was not sufficiently described to meet the requirements of Article 100(b) EPC.

The appeal was dismissed (i.e. the patent remained revoked).

3.6 Common general knowledge or not

3.6.1 T 0553/10 Application no. 06834277.3 – Lithium nickel manganese cobalt composite oxide and lithium rechargeable battery

The appellant filed an appeal against the decision of Examining Division to refuse the European patent application. Examination Division held that the patent did not meet the requirements of clarity (Article 84 EPC) and in addition, raised doubts as to whether the requirement of sufficiency of disclosure was met.

The Board informed in its preliminary opinion that the requirement of sufficiency of disclosure was not met. In the preparation of oral proceedings, the appellant filed four auxiliary requests.

The appellant argued that the question needed to be answered was whether a person skilled in the art could prepare lithium nickel manganese cobalt composite oxides falling within the present claims. Methods of preparing oxides was disclosed in the description and in examples there. Based on X-ray diffraction alone, the layered structures of the crystal structure in the both examples and the comparative examples appeared to be equivalent. But, according to the invention, it was possible to differentiate a structure that improved the battery characteristics, and a structure that did not. This could be done on the basis of the intensity ratio of the Raman spectrum. Therefore, the application disclosed an extra step which ascertained whether or not an oxide produced fell within the claims. The general manufacturing method for manufacturing a precursor and the range required for obtaining a layered structure were indicated in the application as filed, and it was shown that within these ranges the formation of oxides having the claimed Raman spectrum was possible. Hence, a person skilled in the art would be able to determine whether an oxide would fall within the ambit of claim 1 or not.

The appellant requested the impugned decision to be set aside and that the patent to be granted on the basis of the main request, i.e. the claims as originally filed, or, in the alternative, on the basis of the auxiliary requests.

Reasons for decision

Statutory law and jurisprudence of the Boards of Appeal discloses that a *European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC)*. The requirement of sufficiency of disclosure is met only if the invention as defined in the independent claim can be performed by a person skilled in the art *within the whole area claimed* without the burden of an undue amount of experimentation, *taking into consideration the whole information content of the patent and common general knowledge*. The requirement of sufficiency of disclosure is not met in particular if the patent lacks guidance and this lack of guidance cannot be overcome by drawing to common general knowledge.

According to the description, the lithium nickel manganese cobalt composite oxides of the invention were obtained by the same process as the composite oxides of the comparative examples, i.e. those which were not according to the invention. The structure of the oxides of the comparative examples was a layered structure as was the structure of the oxides according to the examples of the invention. The oxides according to the invention thus differed from those of the comparative examples only in their Raman spectra. The application as filed failed to disclose a process step that would have been needed to allow a person skilled in the art to prepare oxides having the properties as required by claim 1. The appellant argued that according to the invention, in comparison with the comparative examples, there was a further step, namely taking the Raman spectrum of the lithium nickel manganese cobalt oxides produced.

The Board was not convinced by these arguments. An additional step required when seeking to prepare oxides falling within the ambit of claim 1 was missing, however. It was true that the application disclosed as an additional step the taking of Raman spectra, this however did not amount to the process step, which would be required to prepare the oxides in question, but rather only served the purpose of determining their presence.

Even if it were conceded that, as submitted by the appellant, the disclosure of the application as filed enabled a person skilled in the art to determine whether or not an oxide fell within the ambit of claim 1, a person skilled in the art would still have been at a loss when wishing to actually prepare an oxide falling within the ambit of claim 1, i.e. to reproduce the oxides according to the examples and not according to the comparative examples.

There was no evidence on file that would have shown that this lack of guidance, i.e. the missing process step for obtaining the claimed oxides, could be overcome by drawing on common general knowledge. Nor had the appellant provided arguments in this respect.

Thus, *the application lacked guidance* and this could not be overcome by drawing on common general knowledge. Therefore, the requirement of sufficiency of disclosure set forth in Article 83 EPC was not complied with. The Board did not admit the auxiliary requests into the proceedings.

The appeal was dismissed (i.e. the application was refused).

4 Summary

In summary, Article 83 EPC requires that the application as filed must contain sufficient information to allow a person skilled in the art, using his common general knowledge, to carry out the invention within the whole area that is claimed. The disclosure of the limited ways of performing the invention can be considered to be sufficient within the meaning of Article 83 EPC if it allows a person skilled in the art to perform the invention in the whole range claimed. The question whether the disclosure of one way of performing the invention covers the whole claimed range is a question of fact that must be answered on the basis of available evidence and on the balance of probabilities in each individual case. The requirement of sufficiency of disclosure is not met in particular if the patent lacks guidance and this lack of guidance cannot be overcome by drawing to common general knowledge.

However, the mere fact that a claim is broad is not in itself a ground for considering the application as not complying with the requirement for sufficiency of disclosure under Article 83 EPC. Only if there are serious doubts, substantiated with verifiable facts, may an application be objected to for lack of sufficient disclosure. The principle of EPO proceedings is that the party who raises an objection bears the burden of proving it. The application of this principle to opposition proceedings leads to the conclusion that the burden of proof in respect of the grounds for opposition raised by an opponent lies on the opponent.

Thus, Article 83 EPC requires an invention to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. This extent to which an invention is sufficiently disclosed is also highly relevant when considering the issue of support within the meaning of Article 84 EPC, because both these requirements reflect the same general principle: the scope of a granted patent should correspond to its technical contribution to the state of the art.

Article 84 EPC requires that the matter for which protection is sought be defined in the claims in a clear and concise manner and that the claims are supported by the description. That is, all the essential features of the claimed invention have to be indicated in the claim. The essential features may be also be expressed in general functional terms, if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the claim, and if these features provide instructions which are sufficiently clear to a person skilled in the art to reduce them to practice without an undue burden.

Thus, based on the common ground that the disclosure of an invention is only sufficient if a person skilled in the art can reasonably expect that substantially all embodiments of a claimed invention which this person skilled in the art would envisage on the basis of the corresponding disclosure and the relevant common general knowledge can be put into practice, i.e. only exceptional failures can be tolerated.

Functional definitions in claims are allowable in EPO but only if a number of alternatives capable performing the said function would be at the disposal of a person skilled in the art, either by reading the description or on the basis of the common general knowledge. The description with or without the relevant common general knowledge must provide a fully self-sufficient technical concept as to how this result is to be achieved. The peculiarity of a "functional" definition of a component of a composition of matter resides in the fact that this component is not characterized in structural terms, but by means of its effect. Thus, this mode of definition does not relate to a tangible component or group of components, but comprises an indefinite and abstract host of possible alternatives, which may have quite different chemical compositions, as long as they achieve the desired result.

The general legal principle in EPO is that the protection covered by a patent should correspond to the technical contribution to the art made by the disclosure of the invention described therein, which excludes that the extent of the monopoly claimed ought not to exceed the technical contribution to the art made by the invention as described in the specification. This criterion for determining the sufficiency of the disclosure is the same for all inventions, irrespective of the way in which they are defined, be it by the structural terms of their technical features or by their function. In both cases, the requirement of

sufficient disclosure means that the whole subject-matter that is defined in the claims, and not only part of it, must be capable of carried out by a person skilled in the art without the burden of an undue amount of experimentation or the application of inventive ingenuity (to meet the requirements of Article 83 or 100(b) EPC). Though, the question if there is disclosed a single embodiment or a technical concept fit for generalization made available to a person skilled in the art, the host of variants encompassed by the respective "functional" definition of the said claim, can only be decided on the basis of the facts of each individual case. For example, invention is sufficiently disclosed if at least one way is clearly indicated enabling a person skilled in the art to carry out invention. Consequently, any non-availability of some particular variants of functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to a person skilled in the art through the disclosure or common general knowledge, which provide the same effect for the invention. That is, the disclosure does not need to include specific instructions as to how all possible component variants within the functional definition should be obtained.

However, in certain cases, a description of one way of performing the claimed invention may be sufficient to support broad claims with functionally defined features (new technique disclosed with the essence of the invention and disclosed one way of carrying out the invention enables the same effect in a broad area). In other cases, more technical details and more than one example may be necessary in order to support the claims of broad scope (serious doubts exist). The guiding principle is that a person skilled in the art should after reading the description be able to perform the invention over the whole area claimed (without an undue burden and inventive skills). Technical details needed is a matter which depends on the correlation of the facts if each particular case.

An invention, which goes against prevailing technical opinion, may be considered particularly meritorious, if it is told how to put in into practice, but if the patentee has failed to give a single reproducible example, it would amount to an undue burden to a person skilled in the art. The fact that the patent specification may contain numerous suggestions as to other ways trying to succeed, cannot make up for the lack of even a single example that works. Rule 27(1) (e) EPC states that the description shall describe in detail at least one way of carrying out the invention claimed using examples where appropriate.

While the EPO case law does not consider the requirement for an example as an absolute necessity, for inventions, which are contrary to prevailing technical opinion, in the absence of an example that works as described, the recognition of the sufficiency is unlikely.

In general, related to sufficiency of disclosure the Boards of Appeal in EPO had to be satisfied

- firstly that the patent specification puts a person skilled in the art in possession of at least one way of putting the claimed invention into practice and
- secondly that the skilled person in the art can put the invention into practice over the whole scope of the claim.

If the Board is not satisfied on the first point that one way exists, the second point needs not to be considered.

In conclusion, the basic principles of interpreting the sufficiency of disclosure (Article 83 EPC) in the EPO case law decisions was relatively straightforward. However, the implementation of principles related to Articles 83 and 84 EPC, into each appeal case, is in each case highly depended on the correlation of the facts presented in this particular case.

5 Conclusion

All in all, three main points for the EPOs principles related to the interpretation of the sufficiency of the disclosure and "*Invention to be performed over the whole range claimed*" based on the EPO case law T-decisions summarized in this study, can be concluded:

- The principle of EPO proceedings is that the party who raises an objection bears the burden of proving it. That is, *the burden of proof* in respect of the grounds for opposition raised by an opponent *lies on the opponent.*
- Functional definitions in claims are allowable but, *the whole subject-matter* that is defined in the claims, and not only part of it, *must be capable of carried out* by a person skilled in the art.
- *The description (specification) is essential* when interpreting the subject-matter disclosed in the claims.

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