EPO DECISIONS

Notes:


Patentability (Articles 52 and 53 EPC)

G 1/04: Questions referred by the EPO President EBA Opinion of 16 December 2005 Chairman: P Messerli Members: W Moser, U Kinkeldey, A Nuss, J-C Saisset, M Seppik, and HC Thomsen

The EBA considered questions referred on 29 December 2003 by the President of the EPO concerning the breadth of the exclusion from patentability of diagnostic methods under Article 52(4) EPC. The President had made the reference pursuant to Article 112(1)(b) EPC, referring to conflicting decisions of the boards of appeal in T 385/86 and T 964/99. T 385/86 (which decision has been adopted subsequently in T 775/92, T 530/93, T 1165/97 and T807/98) construed the exclusion narrowly, requiring that all of the steps involved in making a diagnosis be included. Conversely, the board in T 964/99 held that the exclusion should not be construed as relating only to methods containing all of the required steps – Article 52(4) was meant to exclude all methods practised on the human or animal body which related to diagnosis or were of value for the purpose of diagnosis.

After considering the President’s referral and statements filed by several third parties, the EBA answered the referred questions and set out the ambit of “diagnostic methods practised on the human or animal body” under Article 52(4) as follows:

1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:

   (i) the diagnosis for curative purposes stricto sensu [i.e. in the strict sense] representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
   (ii) the preceding steps which are constitutive for making that diagnosis, and
   (iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

2. Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all
method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. Moreover, no distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it.

3. In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion “practised on the human or animal body”.

4. Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion “practised on the human or animal body” if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.

The EBA considered that the exclusion was based on socio-ethical and public health considerations. It seeks to ensure that those carrying out diagnostic methods in the treatment of humans and animals are not inhibited by patents. However, the Board recognised that under Article 4(3) EPC, the general task of the EPO is to grant patents, and although there are exceptions to patentability, the general principle by which such exceptions are construed narrowly should apply.

In the context of Article 52(4), this meant that the steps that precede the deductive phase of a diagnosis (i.e. examination, collection of data and comparing the data with standard values to identify any significant deviation) are also required for the exclusion to apply. This is because of the inherent multi-step nature of diagnostic methods, in contrast to the methods of a surgical or therapeutic nature which are also excluded by Article 52(4). Arguments that such a narrow interpretation could pose the risk of circumvention of the exclusion by missing out an essential feature of a diagnostic method were rejected. Established jurisprudence under Article 84 EPC would prevent this, since it requires that any independent claim recite all essential features necessary to clearly and completely define the invention.

The EBA did not consider that falling within the exclusion should depend on who was involved – the exclusion relates only to the method and not the person carrying it out. Further, only the steps of a method that are of a technical nature need fulfil the term “practised on the human or animal body” (it would not, for example, apply to the deductive decision phase which will normally be a purely intellectual exercise), and no specific type and intensity of interaction with the body is required.

The Board made clear that the above interpretation would apply to the exclusion of diagnostic methods under the new Article 53(c) of EPC 2000 (which is substantially equivalent to Article 52(4)) when it comes into force (expected Jan/Feb 2008).

T 1374/04: Primate embryonic stem cells / Wisconsin Alumni Research Foundation
TBA Decision of 18 November 2005 yet to be issued

In oral proceedings on 18 November 2005, the TBA considered an appeal against the Examination Division’s refusal to grant European Patent application no. 96 903 521.1 relating to a method of preparation of embryonic stem cells derived from primate blastocysts. The application describes removal of embryonic stem cells from monkeys and culturing them on feeder cells, and discloses that the same growth conditions can be used to isolate and grow human embryonic stem cells.
The patent had been refused by the Examination Division for failure to comply (in particular) with Article 53(a) EPC in conjunction with Rule 23d(c) which prevents the grant of European patents for biotechnological inventions concerning "uses of human embryos for industrial or commercial purposes". The Examination Division considered that, since use of an embryo was an indispensable part of the disclosed invention and primate (including human) embryonic stem cell cultures were claimed, the application fell foul of Rule 23d(c).

Before the TBA, the appellant requested the decision be set aside, with an auxiliary request for the matter to be referred to the Enlarged Board. The TBA took the latter course. Although at the time of writing the TBA's written decision setting out precise details of the referral is yet to be issued, the minutes of the oral proceedings suggest the EBA may be asked to consider the following: (1) whether Rule 23d(c) extends to patent applications whose claimed subject matter comprises products derived from human embryos; (2) if so, whether the application of Rule 23d(c) to such products is to be judged by whether the product can be traced back to use of a human embryo (or if not what criteria apply); and (3) if Rule 23d(c) does not extend to such applications whether they may nevertheless be refused under Article 53(a) (and if so what criteria apply).

Note: The EPO President has indicated that T 1374/04 is the first case where this issue has arisen before the TBA (EPO Press Release of 27 October 2005 entitled "The EPO follows the EU's Directive on biotechnology patents"). Other proceedings concerning human embryonic stem cells currently before the appeal boards include T 1079/03 (Isolation, Selection and Propagation of Animal Transgenic Stem Cells / University of Edinburgh) and T 552/04 (Mammalian Multipotent Neural Stem Cells / California Institute of Technology).

Inventive Step (Article 56 EPC)

T 330/99: Hair treatment composition / Kao Corporation
TBA Decision of 27 September 2005
Chairman: P Gryczka
Members: B Struif and T Bokor

This decision of the TBA recently-published on the EPO website considered (along with novelty) inventive step in relation to European Patent no. 0 529 437 concerning hair treatments. The opponent had appealed the Opposition Division’s decision to maintain the patent in amended form, and argued that a second piece of prior art (D2) provided a perfectly suitable starting point in addition to the document (D4) which the Opposition Division had selected as closest prior art.

The differences in approach to inventive step between the EPO and the English Courts were drawn into sharp focus recently by the English Patent Court’s decision in Ranbaxy and Arrow Generics v Warner-Lambert [2005] EWHC 2142. There, Pumfrey J found that an EP (UK) patent relating to the hemi-calcium salt of atorvastatin, the compound that comprises LIPITOR, the world’s best selling drug, was invalid for obviousness. This contrasted markedly with an earlier decision of the EPO's Technical Board (T 229/97) where the same patent was found to involve an inventive step over an equivalent piece of prior art. Having analysed the differences between the approaches taken, Pumfrey J considered there were two potential difficulties with the EPO’s problem and solution approach: (1) concentrating on the closest prior art risked offending against the principle that the skilled person is permitted to do that which is obvious over each piece of prior art; and, (2) reformulation of the technical problem could obscure that which is objectively obvious.

Notably in T 229/97, Warner-Lambert had filed experimental evidence of
favourable handling properties of the hemi-calcium salt just a month before the appeal hearing. Those results had provided a basis for Warner-Lambert’s argument that the problem the patent was seeking to solve was the provision of a cholesterol-lowering drug with superior handling properties, a reformulation that the TBA accepted despite it being radically different to the problem suggested by the original patent application (which was concerned with use of a single atorvastatin enantiomer rather than a racemic mixture). Pumfrey J saw this as profoundly dangerous, suggesting that if reformulation is permitted on the basis of after-discovered advantages there was a “substantial risk” that this would lead to a finding of non-obviousness. That said, he considered the differences in approach between the English Courts and the EPO were ones of appreciation rather than principle that would not give rise to different findings in the vast majority of cases.

The present case, T 330/99, provides an interesting subject for comparison. Not only were there issues over the document identified as the closest prior art, but the patentee also submitted experimental results in the appeal, the latest, coincidently, having been filed just a month before the oral proceedings. The TBA noted that according to established jurisprudence, the closest prior art is generally that which corresponds to a purpose or technical effect similar to that of the invention and requires the minimum of structural and functional modifications. Since the modifications needed were similar in both cases, the TBA found D4 was closer since D4, like the patent, was directed at preserving hair elasticity whilst D2 was concerned with inhibiting hair bleaching. It nevertheless considered inventive step from both starting points, and found there was an inventive step in each case. This perhaps suggests that the first difficulty identified by Mr Justice Pumfrey (concentrating on the closest prior art) is not as problematic as it sounds, since by their very nature, documents which are not the closest prior art are less likely to render an invention obvious. Indeed, in T 229/97, the Technical Board had selected equivalent prior art to that which rendered the hemi-calcium (UK) patent invalid before Pumfrey J. Furthermore, it is common practice in revocation proceedings before the English courts for parties to assert only the strongest pieces of prior art, and there has been judicial commentary that a challenge to obviousness can be weakened if multiple prior art citations are relied upon.

The second notable aspect of the present decision (late filing of supportive experimental results) did not, in contrast to T 229/97, lead the TBA to reformulate the technical problem, which remained largely as it had been throughout the patent’s prosecution and the subsequent proceedings: the provision of a hair treatment imparting improved elasticity. This analysis suggests that whilst it is not uncommon for supportive experimental data to be filed during EPO proceedings, this is unlikely to lead to conflicting decisions on obviousness by the EPO and the English Courts, unless the data are used as a basis for significant reformulation of the technical problem in the EPO.

Amendment (Article 123 EPC)

T 175/03: Process for polymerizing monomers in fluid beds / ExxonMobil Chemical Patents Inc
TBA Decision of 3 November 2005
Chairman: R Young

In this appeal from an interlocutory decision of the Opposition Division concerning maintenance of a patent in amended form, the TBA had to consider the permissibility of a disclaimer. The disclaimer had been introduced during the opposition proceedings to remove overlap with the disclosure of a patent application D1 that formed novelty-only state of the art under Articles 54(3) and (4) EPC, having been filed but not published before the priority date.
In its appeal, the Opponent/Appellant argued on the basis of early decisions G 2/98, T 323/97 and T 507/99 that disclaimers generally do not comply with Article 123(2) EPC. It also alleged that the Respondent had known of D1. Subsequent to the appeal being filed however, the EBA had handed down its decisions in G 1/03 and G 2/03, clarifying the position on disclaimers. They were not to be refused for the sole reason that neither the disclaimer nor the excluded subject-matter had basis in the application as filed, and were to be permitted in a number of circumstances including where their use is to restore novelty by excising material disclosed in an Article 54(3)/(4) citation. Following these more recent authorities, the TBA held that D1 could be validly disclaimed. Interestingly, the TBA dismissed the Appellant’s argument that the Respondent had known of the prior art as “not convincing”, even though D1 had in fact been filed by the Respondent itself (formerly Exxon Chemical Patents Inc).

In T 86/04, the TBA had to consider the validity of European patent 643 907 ('907) granted from a divisional application of a parent application which was in turn filed as a divisional of a grandfather application. The Opposition Division had held that an amended version of '907 met the requirements of the EPC. Divisional applications have become a hotly debated topic recently, with the referral of questions to the Enlarged Board (case reference G 1/05) in decision T 39/03 of 26 August 2005. Most significantly, the EBA’s opinion has been sought as to whether a divisional application, which does not meet the requirements of Article 76(1) because at the actual filing date it extended beyond the content of the parent application, can later be amended to make it a valid divisional. This has traditionally been allowed, and if such validating amendments were curtailed, this would radically change divisional filing practices.

The EPO’s Notice of 2 November 2005 (OJ EPO 12/2005, 606) states that proceedings before the EPO’s first-instance departments (Examination and Opposition Divisions) depending entirely on the outcome of G 1/05 have been suspended pending the EBA’s decision, suggesting appeal proceedings may continue even where only this point is in issue. In T 86/04, the validity of the child patent was challenged under Articles 100(c) and 123 EPC, and the appellant’s arguments were based largely on subject-matter having been added that extended beyond the content of the divisional application as filed. The TBA agreed and revoked the patent. Its reasoning suggested the disclosures of the divisional application, the parent and grandparent were largely consistent, at least with regard to the subject-matter in issue. It will however be interesting to see the outcome of any decisions on the validity of divisionals handed down by the appeal Boards ahead of G 1/05 that consider the issues referred.

This decision concerned the “purported appeal” from a decision of the Examination Division refusing European Patent application no. 99 204 298.6. The relevant document had been transmitted electronically by the “epoline®” online filing system set up pursuant to the EPO President’s decision of 29 October 2002 (OJ EPO 11/2002, 543). That decision and the subsequent EPO notice (OJ EPO 12/2003, 609) permitted the filing of European and International patent applications amongst other
documents, but noted that electronic filing was not available in opposition and appeal proceedings.

The formalities officer therefore wrote to applicant pointing this out, and requesting the appeal be re-filed in an appropriate manner. Although no response was received, the matter was referred to the Technical Board which had to rule on whether the appeal had actually been filed, a question of law it considered was “not trivial” given the EPC provides for electronic filing of certain documents. The TBA held that because use of electronic filing must be expressly permitted by the EPO President under Rule 36(5) before it is allowable, the formal conditions for filing had not been fulfilled. The board also concluded it had no discretionary power to deem the filing valid — to do so would be *ultra vires*, that power being reserved to the President – and observed that absurd results could arise if different boards of appeal had to adjudicate on the validity of different means of communication, arriving at potentially different conclusions in relation filings by the likes of epoline®, email and maybe even SMS. Accordingly, the purported appeal was treated as not to having been filed, and the appeal fee, which had been debited from the applicant’s account, was to be refunded.

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