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February 2013

DEPOSIT OF BIOLOGICAL MATERIAL – IMPACT ON VALIDITY OF PRIORITY CLAIM

In decision T107/09, the competent EPO Technical Board of Appeal 3.3.04 provided important guidance with respect to the timely deposit of biological material in order to fulfill the "same invention" requirement when assessing the validity of a priority claim.

The case concerned European patent 0 555 880 B1 relating to ligands for the CD40CR receptor. Claim 1 as granted reads:

> *A soluble ligand which comprises at least a binding portion of an immunoglobulin molecule, in which the immunoglobulin molecule is capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by a hybridoma cell line deposited with the ATCC and assigned accession number HB 11048, to CD40CR molecule […].*

The original patent application claimed the priority of U.S. patent application 07/835,799. However, the hybridoma cell line had only deposited with the ATCC after the filing date of the priority application and is not further described in the application documents.

During opposition proceedings it was concluded that the priority claim were not valid, since the priority document did not disclose an essential element of the invention (i.e. the hybridoma cell line), and thus not the "same invention" as the subsequent filing.

On appeal, the Board initially referred to decisions G2/93 and G2/98 of the Enlarged Board of Appeal in which it was held that the expression the "same invention" means the "same subject-matter." That is, the subject matter of a subsequent filing must be derivable for the skilled person "directly and unambiguously, using common general knowledge, from the earlier application as a whole."

Furthermore, following the principle that a document must contain an "enabling" disclosure for it to be considered to be detrimental to the novelty of claimed subject matter, it was also established that "same invention" requirement implies that the earlier application must disclose the invention in such a way that a skilled person can carry it out.

The Board continued that in order to reproduce the invention characterized in claim 1 as granted, the antibody MR1 is indispensable for the skilled person to be able to select from all immunoglobulins produced those being "capable of competitively inhibiting the binding of monoclonal antibody MR1 as produced by hybridoma cell line deposited with the ATCC and assigned accession number HB 11048." However, the "written" disclosure in the U.S. priority application, even if supplemented by common general knowledge, would not enable the skilled person to carry out the invention characterized in the later filing.[1]

For inventions which use biological material not being available to the public and where a mere written description is not sufficient to enable a person skilled in the art to carry out the invention, the EPC foresees in Rule 31 that this deficiency can be rectified by a valid deposit of the biological material at a recognized depositary institution.

In this context, the Board pointed out that Rule 31(1) EPC is concerned with the requirement of sufficiency of disclosure in relation to a European patent application and stipulates that the deposit has to be made not later than the filing date of the patent application, the application documents shall give relevant information on the characteristics of the biological material and state the depositary institution and the accession number of the deposited biological material. However, the latter information may be submitted within sixteen months after the date of filing of the application or, if priority has been claimed, after the priority date (Rule 31(2) EPC).

Thus, the Board concluded that there are no explicit provisions in the EPC as to when a deposit of biological material has to be made in relation to an earlier application in order to ensure that a later European patent application can enjoy the right to priority from that earlier application.

However, it is established case law of the Enlarged Board of Appeal that the requirement of sufficiency of disclosure must be complied with at the date of filing of the European application or – in relation to an earlier application from which priority is claimed – at the date

[1] Cf. T107/09, point 14 of the reasoning.

of filing of that earlier application. The requirement of sufficiency of disclosure would ensure that a patent is only granted if there is a corresponding contribution to the state of the art. Such a contribution would not be present as long as the person skilled in the art is not able to carry out the invention. Deficiencies in this respect could not be remedied during the proceedings before the EPO [2]

Hence, the Board ruled that if the deposit of biological material is necessary for the requirement of sufficiency of disclosure to be fulfilled for a "priority application", the deposit of this material must have been made no later than the date of filing of that earlier application.[3]

The above position is also reflected in the "Notice of the European Patent Office dated 7 July 2010 concerning inventions which involve the use of or concern biological material", stating in point 1.4 (emphasis added):

> *Where a European patent application claims the priority of a previous application in accordance with Articles 87 to 89 EPC, the invention is only considered disclosed in the previous application for the purposes of Article 87(1) EPC, if the deposit of the biological material was made no later than the date of filing of the previous application whose priority is claimed. The depositary institution and the legal statute under which the micro-organism is deposited must comply with the requirements of the country in which the previous application was filed. The previous application must also refer to this deposit in a manner enabling it to be identified.*

However, in the present case, it is undisputed that the hybridoma cell line producing the antibody MR1 has been deposited with the ATCC only after the filing date of U.S. patent application 07/835,799.

In a further line of argument the appellants referred to Article 87(2) EPC stating that "every filing that is equivalent to a regular national filing [...] shall be recognized as giving rise to a right of priority" and, on the other hand, to case law in relation to U.S. patent applications – *In re Lundak*, 773F.2d 1216 (Fed. Cir. 1985) – according to which "the enablement requirement of §112, first paragraph does not require such assured access to a microorganism deposit as

[2] Cf. G2/93, point 10 of the reasoning and G1/03, point 2.5.3 of the reasoning.
[3] Cf. T107/09, point 18 of the reasoning.

of the filing date; what is required is assurance of the access [...] prior to or during pendency of the application, so that, upon issuance of a U.S. patent on the application, the public will, in fact, receive something in return for the patent grant".

The appellants therefore argued that, since a deposit in relation to a U.S. patent application is not necessary at its date of filing, but must only be made at the latest before the grant of the corresponding patent, the U.S. patent application at issue here complies with the requirements of US patent law. It must therefore be considered as a regular national filing and thus, in accordance with Article 87(2) EPC, must give a right to priority.

The Board pointed out that what Article 87(2) EPC merely set out is that the date of filing of an application that may give rise to a right to priority under the EPC is accorded in accordance with national law for the purposes of Article 87(1) EPC. It cannot be inferred from these provisions, so the Board, that the standards of national law are applied in relation to other requirements of a potential priority application, for example, in relation to criteria for determining the disclosure content of such an application. Whether an earlier application and a subsequent European application disclose the "same invention" is assessed in accordance with the EPC and not the law of the state in which this earlier application is filed.[4]

In the light of the above citation from the decision of the U.S. Federal Circuit the Board accepted that, when it comes to the point in time when a deposit of biological material has to be made in order to fulfill the sufficiency requirement according to the EPC and the enablement-requirement according to U.S. patent law, the provisions according to the EPC were stricter than those of the US law.

Nevertheless, it was concluded that it is undeniable that in a situation where a deposit of biological material was necessary for a disclosure in an earlier application to be accepted as being "sufficient", this had the consequence that an applicant who filed a patent application at the U.S. Patent and Trademark Office had, already when drafting the U.S. application, to take account of the requirements to be complied with in countries or regions that were eligible for filing subsequent applications claiming the priority of the first application. That might be inconvenient for applicants for European patents claiming priority from U.S. patent applications, but it is the consequence of the distinct provisions of the two legal regimes.[5]

[4] Cf. T107/09, point 23.1 of the reasoning.
[5] Cf. T107/09, point 24 of the reasoning.

The Board further noted that it was and is not uncommon when drafting potential priority applications that differences in the patent laws of different countries and/or their interpretation have to be taken into account. Another such example appears to be the different interpretation of the disclosure content of "closed ranges" of numerical parameters according to German and European patent law practice (although this may be harmonized if the principles developed by the German Federal Supreme Court in its decision *Olanzapin* (case X ZR 89/07) should be applied to "closed ranges"). While according to the present German jurisprudence the indication of a closed range by a start and an end point is considered as disclosing all intermediate points within this range, this is not necessarily considered to be so according to the case law in relation to the EPC. If this difference is not taken into account when drafting and filing a German application, this may have the consequence that a later European application claiming only an intermediate point or intermediate part of the complete range disclosed in the earlier German application may not be allowed to rely on that earlier application for claiming priority.

In conclusion, the Board held that, due to the failure to deposit the hybridoma cell line producing the antibody MR1 no later than the filing date of the U.S. priority application, this U.S. filing does not provide a disclosure which is sufficient for the skilled person to carry out the invention claimed in the subsequent European filing. Therefore, the requirement of the "same invention" according to Article 87(1) EPC cannot be considered as being fulfilled. Hence, the subject matter of granted claim 1 is not entitled the right of priority from the earlier U.S. filing. This had the consequence that a publication cited during the opposition proceedings became relevant for assessing patentability.

For applicants seeking patent protection in Europe for subject matter involving biological material which is not available to the public and cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art it is thus essential to deposit this material at a recognized depositary institution before filing a priority-establishing patent application – either in Europe or abroad. The institution and the accession number should be given in the application. Failure to comply with this requirement may result in the invalidity of the priority claim, should the deposited biological material represent an essential element of an invention.