Medical use claims in Europe – Does the format of the claim matter?

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A recent decision by the EPO Technical Board of Appeal has cast doubt on the scope of so-called “Swiss-type” or second medical use claims. In the decision (T1780/12), the Board overturned a decision of the Examining Division (ED) refusing European Patent Application No. 99940802.4.

This article briefly summarises the facts of the case and considers its implications in the context of earlier case law and practice relating to the interpretation of the scope of “Swiss-type” medical use claims.

Background

EP99940802.4, a divisional application, was refused by the ED under Article 97(2) EPC in conjunction with Article 125 EPC, on the basis that the claims of the application related to the same subject matter as that of its parent application. Despite no explicit provision in the EPC prohibiting double patenting, the EPO does not allow the grant of applications with claims directed to the same subject matter, since this is prohibited in most EPC contracting states under double patenting provisions in their national laws. In this instance, the parent (EP1) and divisional application (EP2) contained analogous Swiss-type claims of the format “Use of a compound X for the manufacture of a medicament for treating a disease Y”, and EPC 2000 medical use-type claims.

Claim 1 of EP1 read as follows:

“1. Use of a composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, in the manufacture of a medicament for the treatment of cancer by killing tumor vascular endothelial cells of a vascularised tumor.”

Claim 1 of main request before the ED (which is identical to claim 1 of the main request before the Board) read:

“1. A composition comprising a biologically effective amount of an anti-aminophospholipid antibody, or antigen-binding region thereof, for the treatment of cancer by killing tumor vascular endothelial cells of a vascularised tumor, inducing coagulation in tumor vasculature or destroying tumor vasculature”.

The reasons provided in the ED’s refusal decision were that it was established practice of EPO first instance departments not to allow two applications from the same applicant to claim the same subject matter. This is the case, not only where two applications have claims of substantially identical scope, but also where two applications claim the same subject matter but in different words. The ED referred to decisions G1/05 and G1/06 where the Enlarged Board of Appeal accepted the principle of prohibiting double patenting at the EPO on the grounds that an applicant has no legitimate interest in proceedings for obtaining the grant of a second patent for subject matter that he already possesses one for. The ED found that a Swiss-type claim and its analogous EPC 2000 medical use claim (i.e. “Compound X for use in the treatment of disease Y”) are directed to the same subject matter, because both of the claims claim the same invention in a different format. Furthermore, double patenting is concerned with the substantial identity of claimed subject matter and is not related to the (only potential) variance in granted protection.

The Decision

The applicant appealed the decision on the basis of the following arguments.

- A European application could not be refused for double patenting because no section of the EPC expressly dealt with this issue.
- The claims of EP1 and EP2 were directed to different subject matter. The majority of case law stated that scope was important in assessment of same subject matter. The ED had completely ignored the issue of scope in assessing what and wasn't the same subject matter. A Swiss-type claim formatted in view of decision G5/83 is a purpose-limited process claim, whereas an EPC 2000 medical use claim is a purpose-limited product claim. The analogous claims may be directed to the same inventive concept but were different in scope. This point was alleged to have been confirmed in decision G2/08.

The Technical Board of Appeal first discussed the origin of Swiss-type medical use claims. It discussed how the EPC 1973 did not explicitly provide for novelty of further medical uses. This gap in the legal provisions had been filled by using Swiss-type claims as prescribed by decision G5/83. When the EPC 2000 was drafted, Article 54(5) EPC was included to explicitly provide purpose-limited product protection for medicinal products. The reason for this amendment had been to remove doubts as to the validity of Swiss-type claims.

The Board then went on to discuss the passages in the EPO's guidelines for examination used by the ED as basis for their decision. The Board concluded that double patenting was restricted to where two applications claimed "*the same invention*", and more specifically to where they claimed "*the same subject matter*". The Board noted that most recent Board of Appeal decisions (and decisions G1/05 and G1/06) had taken the approach that for the double patenting prohibition to apply, the applications must claim the same subject matter. Thus, the Board decided the first thing to do was to determine whether the applications claimed the same subject matter.

The Board went on to state that it agreed with the ED that the claims of EP1 and EP2 related to the same invention, but that the ED was wrong when finding that relating to the same invention meant the claims had to relate to the same subject matter. The Board stated that this approach was not supported by the Guidelines for Examination before the European Patent Office, or EPO case law. The Board concluded that, contrary to the view of the ED, the potential variance in scope of protection is crucial to the decision to be taken.

The Board went on to state that both the claims of EP1 and EP2 defined the same compound and the same therapeutic use. However, it could not be ignored that the claims of EP1 contained the additional step of the manufacture of a medicament. The Board noted that it was a generally accepted principle under the EPC (and referring to decision G2/88) that a process claim provided less protection than a product claim. Thus, a purpose-limited process claim was narrower in scope than a purpose-limited product claim.

The Board rejected the ED's argument that the EPC legislator considered the two claim formats to be equivalent. The Board agreed that this was the intention of the legislator, but that this did not necessarily mean the scope of the two claim formats were identical. It referred to the passage from EPC 2000 preparatory document MR/18/00 which stated "*This limitation [Art. 54(5) EPC] is intended to match as closely as possible the scope of protection to the scope provided by a Swiss-type claim*". Thus, even the EPC 2000 legislator had acknowledged the claims may not be of identical scope, despite the intention for them to be so. The Board also referenced decision T250/05, where it was considered amending a granted Swiss-type claim to an analogous EPC 2000 format claim contravened Art. 123(3) EPC, indicating an extension of claim scope.

The claims were found to be of different scope and thus to relate to different subject matter. The Board concluded that grant of claim 1 would not lead to double patenting, and that the appeal was thus allowable. The Board also stated that in the circumstances, there was no need for them to address the issue of legal basis in the EPC for a prohibition of double patenting.

Conclusions

This decision is interesting since it is another EPO decision where the scope of an EPC 2000 medical use claim has been found to be of different scope to its analogous Swiss-type claim. Originally, it was thought that Swiss-type claims and EPC 2000 medical use claims

would be of the same scope, since the purpose of introducing Swiss-type claims in decision G5/83 was simply to provide protection for further therapeutic uses of known compounds. Furthermore, decision G5/83 did not state that a Swiss-type claim was to be interpreted as a purpose-limited process claim.

EPO Examining Divisions when examining Swiss-type claims, have generally considered them of equivalent scope to EPC 2000 medical use claims when assessing novelty, and generally do not consider interconversion of the two claim formats to add subject matter. In addition, features relating to the "method of manufacture of a medicament" in the Swiss-type claim format have been held not to confer patentability.

More recently, the generally accepted principle that the two claim formats have equivalent scope has been questioned. This is especially so for the purposes of assessing double patenting and post grant amendment. In addition to the present appeal, it was held in decision T250/05 that the post grant conversion of a Swiss claim to its analogous EPC 2000 medical use claim infringed Article 123(3) EPC. In decision G2/08, the Enlarged Board of Appeal commented that the rights conferred by an EPC 2000 medical use claim were "likely broader" than its analogous Swiss-type claim.

The practical implications of this decision (and other decisions discussed above) for applicants are becoming less relevant over time since Swiss-type claims are no longer allowed under current EPO practice, and the allowance of EPC 2000 medical use claims for further medical uses under Article 54(5) EPC. However, for existing applications, applicants should not assume that the different claim types provide identical scopes of protection.

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