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Dosage Regime Claims Allowed

The Enlarged Board of Appeal of the European Patent Office has said that dosage regime claims are allowable at the EPO. In its long-awaited Decision G 2/08, the Enlarged Board found that purpose-limited product claims may be granted in relation to a new and inventive method of treating an indication with a substance or composition which was already known to treat the indication.

The Enlarged Board also stated that Swiss type claims will not be allowed in future applications.

History of Therapy-Related Claims

As will be very familiar to most readers, therapeutic methods of treatment were excluded from patentability under the original version of the EPC (EPC 1973), but claims to substances for use in therapeutic methods were allowed in the case of the first therapeutic method known for the substance concerned. The case law permitted broadly worded claims which were not limited to a specific indication but which were generically directed to, for example, the compound “for use as an active therapeutic substance” (Decision T128/82).

EPC 1973 contained no provision relating to second medical uses but, in Decision G 5/83 (Eisai), the Enlarged Board of Appeal filled this lacuna by allowing so-called “Swiss-type” claims, directed to the use of a substance for the manufacture of a medicament for a specified new and inventive therapeutic application. Following Decision G 5/83, the Technical Boards of Appeal extended Swiss-type claims to methods of treatment characterised by a new patient class (T19/86 “Pigs II”) and in a number of instances also to new modes of administration (although dosing regime claims were not universally allowed by the Technical Boards of Appeal).

The English courts followed G 5/83 and allowed Swiss-type claims for reasons of European harmony, and the English Court of Appeal upheld a dosage regime patent in *Actavis v Merck* ([2008] R.P.C. 26). The same has not been true in other countries, for example the Appeal Division of the Netherlands Patent Office cast doubt on the validity of Swiss type claims in general (“Second medical use/NL”, OJ EPO 1988, 405), whilst the German Federal Supreme Court in *Carvedilol II* found a Swiss-type dosage regime claim to contravene Article 52(4) EPC and Section 5(2) German Patent Act, but did find a modified form of wording in compliance with these legal provisions. In France, the courts have not had to come to a decision as to the validity of Swiss-type claims and, although such claims have consistently been allowed by the French Patent Office, their enforceability remains uncertain.

EPC 2000 replaced the legal regime for protecting therapeutic treatments under EPC 1973 with Article 54(4) and 54(5) EPC 2000, which allow claims to a substance or composition for use, respectively, in a first or further method of treatment.

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The New Decision

The Enlarged Board of Appeal was asked in case G 2/08 to pronounce on whether it is permissible to claim a medicament for a new therapeutic use where the novelty lies in the dosage regime. It was also asked whether Swiss-type claims may no longer be used to protect new therapeutic uses.

In its Decision, the Enlarged Board of Appeal first looked at Art 54(4) EPC 2000 relating to first medical indications, corresponding to former Art 54(5) EPC 1973. The Board found that “no fundamental change was intended” and approved the existing practice of allowing broad generic claims unlimited to specific indications.

The Enlarged Board then considered Art 54(5) EPC 2000, which stipulates that “any” specific use which is novel may be eligible for protection under Art 54(5). The Board found that “any specific use” should be interpreted in accordance with its ordinary meaning and not be arbitrarily limited to require treatment of a new disease. Accordingly, new dosage regimes may be protected using purpose-limited claims under Art 54(5) EPC.

As to Swiss type claims, the Enlarged Board considered that, since the cause of Swiss-type claims has now ceased, Swiss-type claims must also cease. Accordingly, where novelty resides in a new therapeutic use, claims may no longer have Swiss-type format. The Enlarged Board stated that its decision “*shall ... have no retroactive effect*”, and will apply only to future applications whose filing date or, if priority is claimed, priority date is at least three months after publication of G 2/08 in the Official Journal of the EPO (publication has not yet taken place).

Implications for the Future

The Decision is good news for applicants of pending European applications relating to dosage regimes, or to any other specific therapeutic use not characterised by a new indication, since they now have the legislative provision of Art 54(5) EPC and the authority of the Enlarged Board of Appeal to support patentability of purpose-limited product claims directed to their inventions.

Existing applications and those future applications whose priority/filing date is before three months from publication of G 2/08 may continue to use Swiss type claims but, other than for exceptional cases where the invention may lie in the manner of preparation, there would seem to be no benefit in Swiss-type claims. HGF’s advice is to use Art 54(5) claims in Europe because of their greater legal authority. Various countries outside Europe accept Swiss-type claims, e.g. Australia, New Zealand, Canada and Israel, and applicants are therefore recommended to include basis for Swiss-type claims in their applications.

Decision G 2/08 has no good news for proprietors of granted European patents with Swiss-type claims and perhaps has bad news for them. In paragraph 7.1.3 of the Decision, the Enlarged Board acknowledges that “Swiss-type claims could be (and have been) considered objectionable as to whether they fulfill the patentability requirements....”. Accordingly, Decision G 2/08 may increase the probability of Swiss-type claims being found invalid in those EPC member states where the courts have not yet found them valid.

Patentees may therefore be caused to consider whether Swiss-type claims could be converted to Art 54(5) claims in granted patents which are subject to EPC 2000. Apart from the intrinsic procedural problems in changing claim category, even during opposition proceedings, the Enlarged Board in G 2/08 states that the scope of protection of Art 54(5) claims is “likely” greater than that of Swiss-type claims in potentially placing new restrictions on the freedom of medical practitioners. If the Enlarged Board is correct, conversion of Swiss-type claims to Art 54(5) claims after grant would be a breach of the prohibition extending the scope of protection after grant in Art. 123(3) EPC.

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