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November 2011

EPO RULING ON THE PATENTABILITY OF MEDICAL TREATMENTS BY THERAPY

In a recent decision, the EPO Technical Board of Appeal (TBA) 3.3.02 ruled on the admissibility of claimed subject matter relating to the use of a pharmaceutical composition for oral contraception. The decision provides detailed insight into the requirements for exclusion from patentability pursuant to Article 53(c) EPC, possible claim formats to circumvent such exclusion, and the scope of protection conferred by different types of claims concerning second medical indications (that is, the use of a known compound for the treatment of a new medical indication).

The case relates to European patent EP 0 735 883 B1 whose subject matter is directed to the use of an oral monophasic dosage form comprising the estrogen ethinylestradiol and a gestagen, the gestagen being selected from a group of six species, for contraception for a woman of fertile age who has not yet reached the premenopause, by administering the dosage form for 23 or 24 days, starting on day one of the menstrual cycle, followed by 5 or 4 days without administration, for a total of 28 days in the treatment regime.

Four oppositions were filed against the grant a European patent. The competent Opposition Division maintained the patent in amended from with a considerably restricted scope of protection. This decision was appealed by the patentee and three of the opponents. The complexity of the proceedings is illustrated by as many as 24 different claim requests on file and 136 cited prior art references.

Initially, the Board noted that when considering the question of whether the use as claimed is an activity being excluded from patentability pursuant to Article 53(c) EPC, first of all, it has to be taken into account that, according to established

EPO case law, pregnancy is not an illness, and thus contraception is not to be considered as a therapeutic treatment, not even within the meaning of prevention.[1]

Furthermore, the Board noted that the purpose of use as specified in the claimed subject matter is not the sole criterion based on which it is to be decided whether or not an exclusion from patentability is given. Rather, it has to be examined whether the claimed subject matter, when taken in its entirety, comprises one or more therapeutic steps because an exclusion from patentability pursuant to Article 53(c) EPC is already to be acknowledged if only part of the claimed subject matter is concerned.

Notably, all active ingredients specified in the claims (i.e. the estrogen and the gestagens) are provided in comparably low doses. In the specification of the patent, it is stated that the reduction of the daily hormone dose aims at a reduction of adverse secondary effects, such as cardiovascular disorders or thrombolytic complications. In this context it has to be emphasized that the low doses of active ingredients do not result in an improvement of contraceptive efficiency of the composition but only in a reduction of secondary effects.

Hence, even though the claimed subject matter as such is directed to a non-therapeutic use (i.e. contraception) but, at the same time, the formulation of the composition (i.e. the concentrations of active ingredients) also caused therapeutic effects by preventing of secondary effects commonly observed during the non-therapeutic use. The TBA pointed out that in view of the pathologic nature of the secondary effects this prevention is unequivocally to be classified as therapeutic and cannot be separated from the contraceptive effect, which as such is non-therapeutic.[2]

Hence, the use of a composition for oral contraception, where the claimed concentrations of the hormones contained in the composition are chosen sufficiently low to avoid or reduce the pathological secondary effects that are to be expected in

[1] Cf., for example, TBA decisions T820/92 (points 5.2 and 5.3 of the reasoning) and T74/93 (point 2.2.3 of the reasoning).
[2] Cf. T1635/09, point 3.1 of the reasoning.

oral contraception, constitutes a method of treatment by therapy that is excluded from patentability pursuant to Article 53(c) EPC.[3]

As an auxiliary request (i.e. "Auxiliary Request 1"), the patentee restricted the claimed subject matter to the "non-therapeutic use" of the composition. The Board came to the conclusion that such disclaimer is only appropriate to exclude a therapeutic use that can be factually and objectively separated from a non-therapeutic use. However, such disclaimer cannot define a use which necessarily and as essential feature(s) comprise(s) one or more therapeutic steps as being non-therapeutic. The question of whether a use is regarded therapeutic or non-therapeutic is to be decided exclusively on the basis of the actions carried out during this use and/or the effects obtained.[4]

Accordingly, in the case of a therapeutic method comprising a non-therapeutic use (here, contraception) being inseparably linked with a therapeutic use (here, avoiding or reducing pathological secondary effects), the exclusion from patentability pursuant to Article 53(c) EPC cannot be overcome by limiting the claimed subject matter to a non-therapeutic use by introducing a corresponding disclaimer.[5]

In further auxiliary requests (i.e. "Auxiliary Requests 2 and 23"), the claimed subject matter was directed to the use of a composition for the manufacture of an oral monophasic dosage form for contraception. In other words, the claim was re-drafted as a classical Swiss-type claim based on the provisions of the former EPC1973 (now, under the EPC2000, the claim format is a purpose-restricted compound claim according to Article 54(5) EPC):

Hence, it was to be examined whether such a change of the claim category (from a claim being restricted to a particular use of a product to a claim further including the previous manufacture of the product) is in compliance with the

[3] Cf. T1635/09, headnote 1.
[4] Cf. T1635/09, point 5 of the reasoning. Notably, Article 84 EPC (i.e. clarity) would also be an issue to be considered as a "non-therapeutic" use appears to contradict the original intention on which the content of the claimed subject matter is based.
[5] Cf. T1635/09, headnote 2. In this context, also see the recent Enlarged Board of Appeal decision G2/10 on disclaimer practice (Newsletter issue of September 2011).

provisions of Article 123(3) EPC, that is, the amended claimed subject matter does not it extend the scope of protection conferred.

In this context, the TBA referred to Enlarged Board of Appeal (EBA) decision G2/88 (in particular, point 5.1 of the reasoning), in which, as far as the scope of protection of a manufacturing claim in comparison to a use claim is concerned, the EBA ruled referring to Article 64(2) EPC:

> *"Article 64(2) EPC is not directed to a patent whose claimed subject matter is the use of a process to achieve an effect (this being the normal subject of a use claim): it is directed to a patent whose claimed subject matter is a process of manufacture of a product; Article 64(2) EPC provides that, for such a patent, protection is conferred not only upon the claimed process of manufacture, but also upon the product resulting directly from the manufacture. Thus, provided that a use claim in reality defines the use of a particular physical entity to achieve an "effect", and does not define such a use to produce a "product", the use claim is not a process claim within the meaning of Article 64(2) EPC."*

Accordingly, the TBA concluded that the manufacturing method claimed in the auxiliary requests extends beyond the scope of protection of the use claims as granted: pursuant to Article 64(2) EPC, when a claim is directed to a manufacturing method, the protection conferred extends to the (immediate) "products" manufactured by the method. In contrast, a use claim does not include the manufacture of the pharmaceutical product (see EBA decision G1/83, point 11 of the reasoning). Accordingly, the scope of protection conferred by such use claim does not cover the product that is directly obtained by the method. The requirements of Article 123(3) EPC are not fulfilled.[6]

Hence, the Board ruled that the conversion of a claim directed to the use of a compound or composition for a certain purpose into a Swiss-type claim or a purpose-

[6] Cf. T1635/09, point 14.2 of the reasoning.

restricted product claim pursuant to Article 54(5) EPC results to an extension of the scope of protection, and thus contravenes the requirements of Article 123(3) EPC.[7]

Hence, when seeking patent protection in Europe for medical treatments that include therapeutic and non-therapeutic steps or aspects (irrespective of the question whether or not these steps or aspects can factually be separated) applicants should thoroughly draft their patent applications and include multiple alternative fallback positions in order to circumvent the above-mentioned pitfalls.

From the present TBA ruling as well as recent EBA decision G2/10 it is apparent that it is a dangerous exercise to simply rely on disclaimers as it appears that disclaimer practice becomes more restrictive in Europe. Rather, whenever reasonably possible, it should be attempted to define the "non-therapeutic" part of the claimed subject matter in positive term. In cases, where therapeutic and non-therapeutic aspects cannot be readily separated, it will likely become a more than complex task to obtain patent protection for a non-therapeutic treatment regimen in Europe.

[7] Cf. T1635/09, headnote 3.