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Swiss IP News We provide you with updates on new decisions, the relevant legislative process and other trends in the fields of intellectual property and unfair competition law from a Swiss perspective.

Swiss Federal Supreme Court follows the practice of EPO's Board of Appeal on singling out



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In a recent decision (4A_613/2019, 11 May 2020), the Swiss Federal Supreme Court (Supreme Court) followed the practice of the Board of Appeal of the European Patent Office (EPO) as it held that the *singling out* of single features from two separate lists of features and therefore the combination of these two specific features constitutes an extension of the subject-matter of the patent application leading to its nullity.

Background

MundiPharma Medical Company (MundiPharma) holds several European patents for an opioid analgesic containing oxycodone and naloxone, including the patent in dispute EP 2 425 821. Develco Pharma Schweiz AG (Develco) filed a nullity suit with the Swiss Federal Patent Court (FPC) requesting the revocation of the Swiss part of said patent on the grounds of extension of the subject-matter. The patent in dispute is based on a European divisional patent application divided from a European patent application (parent application, EP 1 492 505 B1), corresponding to an international patent application (WO 2003/084520). Compared to claim 1 of the parent application, MundiPharma amended claim 1 of the European divisional application by explicitly mentioning the features *weight ratio oxycodone to naloxone of 2:1* and *reducing opioid induced obstipation*. This amendment required a double selection of features from two independent lists (so-called *singling out*), namely: a first selection out of a list of several equally preferred weight ratios oxycodone to naloxone; and a second selection out of a list of at least three potential undesirable side effects of opioids (obstipation, breath-

depression, and development of addiction) to be equally suppressed (or abolished), or at least significantly reduced. The question was whether this *singling out* led to an extension of the subject-matter of the European divisional patent compared to its parent application which would result in its nullity pursuant to Article 26(1)(c) Swiss Patent Act (wording almost identical to Article 138(1)(c) European Patent Convention (EPC)).

The FPC answered this question in the affirmative and revoked the Swiss part of MundiPharma's European divisional patent EP 2 425 821 B1 (O2017_009, 7 November 2019). MundiPharma appealed the decision before the Supreme Court.

Decision

In its decision, the Supreme Court concluded that the *singling out* of the features *weight ratio oxycodone to naloxone of 2:1* and *reducing opioid induced obstipation* in the application proceedings of the European divisional patent constituted an extension of subject-matter compared to the parent application, and consequently the Supreme Court upheld the FPC's decision to revoke the patent in dispute.

The Supreme Court based its decision on the so-called "*gold standard*", a test established by the EPO in connection with Article 123 EPC (amendments) and also applied to Article 76 (divisional applications). Pursuant to Article 76(1) EPC, second sentence, a European divisional application "*may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed*". The EPO applies the same principles for determining compliance of a divisional application with the require-

ments of Article 76(1) EPC in relation to the earlier application as filed, as it does for examining compliance of amendments with Article 123(2) EPC with respect to an application as filed. According to the established case law of the EPO, the criterion for assessing whether amendments comply with Article 123 EPC is the so-called “gold standard”. The “gold standard” is met if the subject-matter as amended is directly and unambiguously derivable by the skilled person from the original disclosure, as determined by the whole technical content of the application as filed (claims, description, drawings), when read in context. In order for a divisional application to comply with these requirements, it is necessary, but also sufficient, that anything disclosed in the divisional application is directly and unambiguously derivable from what is disclosed in (each of) the preceding application(s) as filed.

Following the established case law of EPO’s Board of Appeal, the Supreme Court applied the “gold standard” in the present case by examining whether the claimed subject-matter of the patent in dispute, or in other words the claimed feature combination *weight ratio oxycodone to naloxone of 2:1 and reducing opioid induced obstipation* singled out from two separate lists, could be directly and unambiguously derived by a skilled person from what was disclosed in the parent application as filed. The Supreme Court held that the limitation to a single feature from a single list of features or the restriction to (complete) lists of examples for substituents, such that the restriction maintains the remaining subject-matter as a generic group of compounds differing from the original group only by its smaller size, would be allowed. It however concluded that there is an extension of subject-matter if the application is amended by limiting the claim to single features from several lists of features. Such a limitation would be considered an artificial combination of features which provides technical contri-

bution to the originally disclosed subject-matter and has no basis in the original application, or in other words, generates another invention.

As a result, the Supreme Court held that the singling out of the features *weight ratio oxycodone to naloxone of 2:1 and reducing opioid induced obstipation* out of two different lists of features and therefore the combination of those two features is not directly and unambiguously derivable by a skilled person from what was disclosed in the parent application. It upheld the decision of the FPC to revoke the Swiss parts of the patent in dispute and dismissed MundiPharma’s appeal in so far as it was admissible.

The Supreme Court’s decision, which is intended for publication, is legally-binding and cannot be appealed before any other court. On a European level, co-proceedings are still pending at the EPO. The Opposition Division of the EPO revoked the entire European divisional patent EP 2 425 821 applying the mentioned “gold standard” test. The decision was appealed before the Board of Appeal (Case No. T3035/19-3.3.07). Public oral proceedings will be held on 23/24 September 2021.

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