PROTECTION AND ENFORCEMENT OF SECOND MEDICAL USE CLAIMS: A REVIEW OF POLISH JURISPRUDENCE

National courts have a degree of discretion when deciding on claims directed to the second use of a known substance. Various approaches to interpretation of claims may result in significant differences in each country. Marta Koremba provides an update on the situation in Poland.

Polish Intellectual Property Law (IPL) implements standard international rules regarding patent protection. Accordingly, patents shall not be granted in respect of methods of treatment. Nevertheless, inventions concerning the use of a substance for application in a specific disease can be patented in the form of the so-called 'second medical use' claims.

Second medical use inventions are assessed according to general patentability requirements, ie, novelty, inventive step and industrial applicability. However, a careful glance at Polish case law reveals certain peculiarities in the process of assessing the patentability of such inventions. In order to meet the condition of sufficiently clear and complete disclosure, the patent description of a second medical application of a known substance shall indicate not only the pharmacokinetic and pharmacodynamic characteristics of the substance, but also the disease treated by the substance, as well as the group of subjects to which the therapy is directed. The novelty and inventiveness of any of the aforementioned elements result in the novelty and inventiveness of the invention as a whole.

It follows that a second medical use is patentable, if it provides a new and inventive input to the state of the art in the form of a new technical effect, in particular a new therapeutic indication, an application of a known substance to a novel and non-obvious group of subjects, or a new dosage regimen. In the case of a new therapeutic indication, the invention must disclose a therapeutic method exploiting the new medical use, followed by detailed administration recommendations. In addition, the indication must be significantly different from the ones known at the application date.

Regarding the application of a known substance to a new group of subjects, the group must be clearly distinguishable with respect to its physiological or pathological status from, and must not overlap with, the group previously treated. Finally, a dosage regimen can be granted protection on condition that it produces therapeutically unexpected effects. An invention directed to a dosage regimen can consist of both a new administration route and a new dose schedule. A second medical use that results in obtaining a particular application form of the known substance (eg, combining an active ingredient with certain additives and obtaining an application form of the known substance that is clearly distinguishable from the forms previously known), constitutes a patentable second medical use claim.

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A patent application for second medical use will normally have to contain pharmacological and/or biological data in support of the efficacy of the preparation in treatment of a given disease and its safety in the patients. These data may be expressed, for example, in the form of results of experimental tests, to prove that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. The application of this additional requisite in the examination proceedings is questionable, as the IPL provides for an exhaustive list of patentability criteria, and efficacy is not mentioned as one of them. Nevertheless, it is often claimed that the efficacy requirement in the case of second medical use inventions derives from the industrial applicability criterion and, as such, has sound legal grounding.

When determining the scope of protection conferred by a second medical use patent, and its enforceability, it is important to stress that Polish courts tend to follow a literal interpretation of patent claims. However, recent case law reveals a more moderate approach. This is evident in the fact that the extent of patent protection is being determined based on a feature mentioned in the description, even if the claims do not disclose this feature at all.

Essentially, a Polish patent may be granted for claims directed to a second medical use. The approach to patentability of such claims follows that of the European Patent Office. However, due to the lack of specialised patent courts, there is a certain element of risk connected with the effective enforcement of such claims. ■

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