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Patentability of Use Inventions in Vietnam

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For a long time, the patentability in Vietnam of use inventions, especially new indications of a known substance in the pharmaceutical area, was a subject of controversy. An amended version of Circular No. 01/2007/TT-BKHCN (Circular 1) that took effect on January 15, 2018, seemed to settle this debate.

The patent examination department of the Intellectual Property Office of Vietnam (IP Office) has often applied amended Point 25.5.d(i) of Circular 1 to reject use inventions. Recently, the IP Office's appeal department has also issued a number of decisions applying this amended point to refuse use inventions, confirming the position of the examination department.

An example of a recent decision of the appeal department is discussed below.

Case Background

International Application PCT/JP2006/318675 for the invention "Pharmaceutical compositions comprising probucol and tetrazolylalkoxy-dihydrocarbostyril derivatives useful in suppressing superoxide" entered the national phase in Vietnam under Application No. 1-2008-00901. On March 26, 2014, the IP Office issued a decision on refusal of the application, ruling that the claims did not satisfy the novelty and inventive step requirements, citing five references, D1-D5. The applicant, a Japanese pharmaceutical company, filed an appeal against the decision on June 23, 2014. The IP Office then issued Decision No. 5698/QD-SHTT dated November 21, 2019, dismissing the appeal.

Decision on Appeal Settlement

The appeal and the IP Office's decision covered three main points, as summarized and discussed below:

Issue 1: Patentability

Summary of Appeal and IP Office Ruling:

The appellant argued that its invention, related to new indications of a composition of probucol and carbostyril derivative and its use as a superoxide suppressant, was patentable. Specifically, although the IP Office's Reference D1 (SEKIYA M. et al. American Journal of Cardiology 1998, Vol. 82, No. 2, 144-147) discloses the composition of probucol and carbostyril derivative, the combination under D1 is used for treating restenosis, which is different from the treatment of cerebral infarction, arteriosclerosis, renal diseases and diabetes recited in the claims of the appellant. Further, D1 does not imply or mention the composition's use as a superoxide suppressant.

The appellant also argued that References D2-D5 were not applicable as they do not mention the composition of probucol and carbostyril derivative of the application, and further argued that the composition has a synergistic effect which would be difficult for a person skilled in the art to discover when consulting D1-D5.

The IP office ruled that the claims are directed to an agent (composition) comprising probucol and carbostyril derivative useful for treating cerebral infarction, arteriosclerosis, renal diseases and diabetes based on the effect of superoxide suppression of the composition, while D1 discloses the composition of probucol and carbostyril derivative for treating restenosis.

Thus, the IP Office and the appellant shared the same position that the agent of the claims and the composition of D1 have the same components (both contain probucol and carbostyril derivative) but differ in utility; namely, the agent of the invention is to treat cerebral infarction, arteriosclerosis, renal diseases and diabetes, while the composition of D1 is to treat restenosis.

However, the IP Office contended that under Point 25.5.d(i) of Circular 1, the feature of utility of "the treatment of cerebral infarction, arteriosclerosis, renal diseases and diabetes" is not an essential feature of the agent of the invention. Thus, this feature does not have the effect of limiting the scope of protection of the agent and giving novelty as well as an inventive step to the agent itself. In addition, although D1 does not mention or suggest the function of superoxide suppression of its composition, this function is brought about by the composition itself. The finding of a new function as well as the finding of new medical indications of an agent with known components do not render that agent itself novel and inventive.

Comments:

The IP Office did not discuss References D2-D5, implying that D1 is sufficient to conclude that the claims do not satisfy the requirements of novelty and inventive step.

The appeal department's main argument was that, under Point 25.5.d(i) of Circular 1, a feature of utility of an agent is not a limiting feature (essential feature), and therefore cannot make the agent novel or inventive.

As mentioned above, Circular 1 was amended and effective as from January 15, 2018. Before the amendment, Point 25.5.d(i) of the circular included the phrase "The essential feature of the technical solution can be a feature of function, utility, ..." Previously, when the IP Office refused use inventions, the applicants usually argued, based on Point 25.5.d(i), that features such as new indications can be essential features, and therefore constitute a proper invention; thus, the refusal was not reasonable.

When the circular was amended, a new phrase was added to this point to clearly indicate "The function or utility of a subject-matter seeking protection is not an essential feature, but may be the purpose or the obtained result of the subject-matter." As a result of this amendment, when a substance/composition is known, the IP Office does not consider features of its use, such as new indications, when assessing novelty and inventive step. Therefore, the claims of the application would not be novel.

It should be noted that the scope of "function, utility" is currently interpreted broadly; for example, for a compound for use in a method, the feature "for use in a method" is generally considered to be one of function or utility. However, if the applicant converts such substance claim into a method claim, the converted claim will be objected to because methods of medical treatment are excluded from patent protection. In addition, use claims (claims commencing with "Use of") are not accepted in Vietnam, and therefore, an applicant cannot convert substance claims into use claims like Swiss-type claims.

In sum, use inventions are being refused in Vietnam.

Issue 2: TRIPS Agreement

Summary of Appeal and IP Office Ruling:

The appellant also argued that Vietnam must protect second medical use inventions, like the invention in question, under the TRIPS Agreement's Article 27 ("Patentable Subject Matter"). Specifically, under this article, members must protect any inventions except those which are contrary to public policy or morality, or methods of medical treatment.

The IP Office countered that the invention is being refused because it is not novel and not inventive, two of the three fundamental requirements for patentability stated in Article 27.1 of TRIPS. The other parts of Article 27 cited by the appellant are irrelevant because the subject-matter of the claims is not prevented from commercial exploitation and is not an excluded subject matter.

Comments:

As a further reference on this issue, as noted by the International Association for the Protection of Industrial Property (AIPPI) in its September 17, 2014, Resolution on Question Q238 regarding second medical use and other second indication claims (Toronto Resolution):

> "As a matter of principle clearly reflected in the TRIPS Agreement, patents should be granted without discrimination for any inventions in all fields of technology, including inventions relating to second medical uses."

Accordingly, AIPPI also assumes that use inventions (even second medical use inventions) are patentable under TRIPS.

Vietnam is a member of the WTO; accordingly, it needs to follow TRIPS. Nevertheless, it seems that the provisions of the TRIPS Agreement are not specific enough to deal with this issue, as the IP Office's refusal on the grounds of novelty and inventive step is not clearly in contravention of TRIPS.

Issue 3: Reference to Foreign Patents

Summary of Appeal and IP Office Ruling:

The appellant noted that many patent offices such as the USPTO and the EPO have granted patents for the corresponding patent applications. This proves that the invention is patentable.

The IP Office found this argument irrelevant because Vietnam patent law differs from the laws of the other countries, especially for use inventions.

Comments:

The main international patent agreements allow their members to specify their own substantive conditions (patentability requirements). Therefore, it is not unusual for an invention to be granted a patent in one country, but be refused in another country.

Outlook for Use Inventions

While it is clear that, at present, patents for use inventions are being refused in Vietnam, it is uncertain how long this practice will continue. Could Vietnam change its policy on use inventions? Some broad overall trends are discussed below.

International Agreements

Vietnam participates in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Under Article 18.37.2 of the agreement:

> "[E]ach Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such."

Under this provision, it is likely that use inventions would be patentable. However, the parties to the CPTPP have agreed to suspend some articles of the agreement, including Article 18.37.2. It is uncertain whether and when Article 18.37.2 of the agreement will be reactivated.

Domestic Law

In 2016, the Ministry of Science and Technology launched a project to evaluate the implementation of the Law on Intellectual Property over its first 10 years (the law took effect on July 1, 2006). A draft report on the results of the project was published, which indicated that there were many different opinions on the "use invention" issue, and suggested its reconsideration.

It is worth noting, however, that in a recent draft proposal to amend the IP Law, the protection of use inventions was nowhere to be found.

Industry Development

It is commonly believed that the main reason Vietnam does not protect use inventions is to keep drug prices down. However, as the domestic pharmaceutical industry has developed to a certain extent, many observers have suggested that this is an outdated policy, and Vietnam should at least proceed with a broad project to investigate all different aspects of the protection of use inventions, including how the protection will affect domestic pharmaceutical companies, how similar countries are dealing with this issue, and so on. The result of the project would be an objective basis to decide whether to protect use inventions.

For now, the outlook is uncertain, but the trends suggest that protection of use inventions could be in Vietnam's future.