Japanese Patent Topics (July 2000)

In June 2000, Examination Standard Department of the Japanese Patent Office prepared and published a typical example dealing with enablement requirement concerning "compounds identified by a specific screening method as well as pharmaceutical use claim of such compounds", patent applications of which have increased in number as development method of new pharmaceutical products evolves, and future application of which has been watched closely from inside as well as outside of Japan. What the Japanese Patent Office imposes here is very demanding and careful determination as to what should be disclosed is called for in the future patent application strategies.

Example

This example shows a case regarding the invention of R-receptor activation-compounds obtained by a specific screening method where the invention is determined not to be operative since no R-receptor activation-compounds other than those cited in the example disclosed in the application can be obtained.

[Claim 1]

R-receptor activation-compounds obtained by the screening method which includes the following processes:
(1) Process to bring test compound into contact with R-receptor expression cell
(2) Process to determine whether test compound activates R-receptor.

[Claim 2]

Obesity inhibitor containing as active principle R-receptor activation-compounds obtained by the screening method described in Claim 1

[Summary of Detailed Explanation of the Invention]

The applicant is the first person who discovered R-receptor. It was also the applicant who first identified the screening method for R-receptor activation-compounds and discovered that R-receptor activation-compounds have obesity inhibitory effect. The detailed explanation of the invention describes in a concrete form a series of procedures including the screening processes given in the claim which is conducted to identify R-receptor activation effect, and determination method to identify such effect (method to determine to what extent R-receptor is activated to be an R-receptor activation-compound). Also

as example, new R-receptor activation-compounds, X, Y, and Z are cited. It is also confirmed that these new compounds have R-receptor activation effect. Further, pharmacological mechanism of obesity being inhibited by activating R-receptor is theoretically described in the patent specifications. In addition, regarding compound X, it is described along with the results of concrete pharmacological test that such compound is proved to have such pharmacological effect.

(However, neither chemical structure nor production method is given on any other new compounds than X, Y, Z.)

Summary of Rejection

Generally it is difficult to grasp the compound itself which has certain desired property by specifying such property alone. Therefore, patent specifications describing no clue, such as chemical structure, to obtain certain active principle, are forcing any person having ordinary skill in the art to do trial and error, in the process of obtaining active ingredient required for the practice of the invention, producing numerous compounds, screening them and determining whether any of these has desired property, which is much more than expected to such person. Thus it should be concluded that such patent specifications are not clear or sufficient enough for any person having ordinary skill in the art to practice the invention.
Applying the above to the patent specifications at issue, though the screening method to identify desired compounds and example of such compounds obtained by such method, X, Y, and Z are described, there is no clue, such as chemical structure, to obtain active principle other than those described above, or at the same time, it was not deemed possible that such other active principles were assumed at the time of application by any person having ordinary skill in the art. Therefore, such person cannot understand active principles contained in the claims other than those specifically described in the specifications, and such person is required to do trial and error, producing and screening numerous compounds and determining if any of these compounds has desired property, which is much more than expected to such person. Thus detailed explanation of the invention is not clear or sufficient enough for any person having ordinary skill in the art to practice the invention involved in these claims.

Countermeasure to Rejection

(Claim 1)

Since based on the patent specifications at issue which do not supply any clue to obtain desired compounds, such as chemical structure, any person having ordinary skill in the art cannot understand or obtain new compounds having R-receptor activation effect other than those disclosed in the example, the rejection will not be resolved unless amendment is made.
In case amendment should be made to limit to new compounds having R-receptor activation effect which any person having ordinary skill in the art can obtain based on the patent specifications as given at the time of application and common knowledge in technology at the time of the application, rejection will be resolved.
However, amendment should be made within the scope of the patent specifications as written at the time of application.

(Claim 2)

Even though R-receptor was first discovered by the applicant and active principles having R-receptor activation effect are not deemed to be in common knowledge in technology at the time of the application, detailed explanation of the invention in the patent specifications as written at the time of application cannot be accepted as being described fully enough for any person having ordinary skill in the art to understand exactly what is considered as the active principle at issue. Therefore, it should be concluded that the patent specifications at issue require any person having ordinary skill in the art to do trial and error, screening and determining various compounds to obtain desired active principles, which is considered to be much more than expected to such person. Usually rejection is not resolved unless amendment is made.
In case amendment is made which limits to obesity inhibitor having as active principle R-receptor activation-compound which can be obtained by any person having ordinary skill in the art based on the detailed explanation in the patent specifications as written at the application and common knowledge in technology at the time of application, rejection is resolved.
However, amendment should be within the scope of the patent specifications as written at the time of application.

(2) Agonist and Antagonist

Even if the invention involved in Claim 1 has in its title "R-receptor agonist" or "R-receptor antagonist", for example, keeping the meaning of these terms in

mind, such invention will be dealt with as the invention of "R-receptor activation compound" and "R-receptor inhibitory compound", respectively.

(3) Invention of "R-receptor activation agent containing as active principle R-receptor agonist (activation compound)"

Although not being dealt with in this additional examples, regarding invention of "R-receptor activation agent containing as active principle R-receptor agonist (activation compound)", indication of use such as "R-receptor activation agent" in the end of the title, merely repeats the property of the compound of active principle, namely "R-receptor activation effect" in other words. Therefore, the enablement requirement of the claims in a form such as this will be handled exactly as the claims of "R-receptor activation compound (agonist)" described above.