JAPAN

IP High Court affirms validity of crestor patent

ABE & Partners
Osaka

Takanori Abe

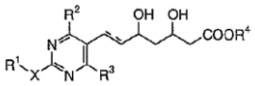
Summary of the case

Shionogi is the owner of a patent entitled Pyrimidine Derivatives (JP2648897). X filed a request for a trial for invalidation of the patent. Nippon Chemiphar intervened in the trial as a plaintiff, and AstraZeneca UK intervened in the trial in order to support the defendant.

The scope of the claim 1 of the patent after the correction (invention 1) is described as follows:

Claim 1 (invention 1)

A compound represented by the formula (I):



R1 is lower alkyl; R2 is phenyl substituted by halogen; R3 is lower alkyl; R4 is calcium ion forming hydrogen or hemi-calcium salt; X is imino group substituted by alkylsulfonyl group; and the dotted line represents the presence or absence of a double bond, or the corresponding ring-closed lactone.

The Japan Patent Office (JPO) dismissed Nippon Chemiphar's request. Nippon Chemiphar appealed to the IP High Court seeking rescission of the JPO's decision.

Since the patent right lapsed during the litigation, Shionogi argued that Nippon Chemiphar lacked any interest in filing an action. It asserted that the case should be dismissed because Nippon Chemiphar did not practise the patent right during the patent term, and Shionogi did not have the right to claim compensation for damages.

Judgment of April 13 2018, the Grand Panel of IP High Court

The Grand Panel of the IP High Court (Presiding Judge Shimizu) dismissed Nippon Chemiphar's claim holding as follows.

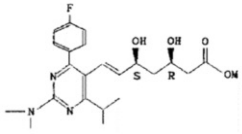
1) Interest in filing an action

An interest in filing an action to seek rescission of the JPO decision dismissing the request for trial for patent invalidation still exists even after the lapse of the patent right. This is the case unless there is a special circumstance; there must be no possibility that anyone is subject to a claim for compensation of damages, a claim for return of unjust enrichment, or a criminal penalty regarding conduct during the patent term. Here, no special circumstance was found.

2) Inventive step

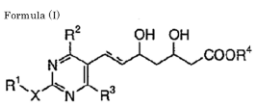
When a cited invention is a prior art disclosed in the publications and the compounds of the invention are described by a general formula which has an enormous number of choices, unless circumstances exist to positively or preferably ascertain the technical idea regarding a certain choice, the concrete technical idea regarding the certain choice cannot be extracted and it cannot be a cited invention.

The cited invention 1 is specified as a compound whose substituent M represents sodium.



The common features and differences between invention 1 and the cited invention 1 are detailed below.

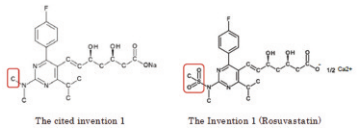
The common features



R1 is lower alkyl; R2 is phenyl substituted by halogen; R3 is lower alkyl; and the dotted line represents the presence or absence of a double bond, or the corresponding ring-closed lactone.

The differences

(1i) X in invention 1 represents the imino group substituted by alkylsulfonyl group, whereas X of the cited invention 1 represents the imino group substituted by methyl group.

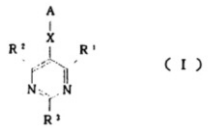


(1ii) R4 of invention 1 represents the calcium ion forming hydrogen or hemi-calcium salt, whereas R4 of the cited invention 1 represents the sodium ion forming sodium salt.

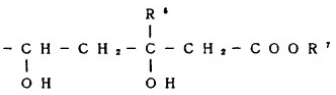
Regarding the difference (1i), the plaintiffs argued that skilled persons can easily arrive at the constitutions in invention 1 by combining the cited invention 1 with the cited invention 2, specifically by substituting one of the two methyl groups (-CH3) included in dimethylamino group (-N(CH3)2) located in the second position of pyrimidine group of a compound of the cited invention 1 with alkylsulfonyl group (-SO2R' (R' represents alkyl group)) of cited invention 2.

The cited reference 2 (JPA1989-261377) discloses the following compound:

A substituted pyrimidine represented by formula (1):



R1 is alkyl; R2 is aryl; R3 is alkyl wherein the said substituent is -NR4R5 wherein R4 and R5 are identical or differential and are alkyl or alkylsulfonyl; X is -CH=CH-; and A is group represented by the formula below.



R6 is hydrogen and R7 is a cation.

The cited reference 2 discloses -NR4R5 as a choice for the substituent R3 as "a particularly preferred compound" among the general formula (I), and also discloses methyl group and alkylsulfonyl group as the choice for R4 and R5.

However, the choices for R3 as "particularly preferred compounds" described in the cited reference 2 are extremely large in number. There are at least more than twenty million choices. Thus, selecting methyl group and alkylsulfonyl group as R4 and R5 of -NR4R5 as R3 is one of more than twenty million choices.

In addition, the cited reference 2 discloses not only "particularly preferred compounds" but also "particularly extremely preferred compounds". However, the latter does not disclose -NR4R5 as a choice for R3.

Furthermore, -NR4R5 is not disclosed as the choice for R3 in the examples of compounds which X and A of the general formula (I) of the cited invention 2 represent as the same constitutions as in the cited invention 1.

It is impossible to ascertain from the cited reference 2 how skilled persons should positively or preferentially select -NR4R5 as R3 of the general formula (I) of the cited invention 2. Thus, it is difficult to assert that skilled persons would select methyl group and alkylsulfonyl group as R4 and R5 after selecting -NR4R5.

Practical tips

Under the Japanese patent linkage system for product patents that the Ministry of Health Labour and Welfare (MHLW) will not approve unless the product patent is invalidated by the JPO, factors seem to exist which lean towards denying the interest in filing an action under the facts of this case. However, the court held the interest in filing an action will not be lost even after the lapse of the patent right unless there is a special circumstance. Legally, the door remains open to file a litigation rescinding the trial decision even after the lapse of the patent right. However, as the generic drug manufacturer can receive approval after the lapse of the patent right even without filing such a lawsuit, this lawsuit makes no sense from a business perspective. As a result, similar lawsuits will not increase in the future.

There will be a dispute in the future about what "enormous number" means. As the court pointed out "at least more than twenty million" in this case, this number will be a good indicator. Whether a certain choice is described as examples is a key factor when deciding whether circumstances exist to positively or preferably establish a technical idea regarding a certain choice, if the cited invention is a patent.

This judgment became final and binding without being appealed.