LEGAL UPDATE

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Supreme Court Ruling on Requirements for Retroactive Application of Critical Date for Patent Requirements of Invention with Patent Application Involving Priority Claim as Priority Date

On February 25, 2021, the Supreme Court of Korea ruled in its Judgment 2019Hu10265 on the requirements to retroactively apply the critical date for patent requirements for the invention with patent application involving a priority claim under the Paris Convention (Article 54 of the former Patent Act) as the priority date. In the judgment, the court determined that "the matters described in the initial specification of the underlying prior application of the priority claim should be the matters that are expressly described in the initial specification of the underlying prior application of the priority claim or, even without such express description, that can be understood by a person with ordinary knowledge in the technical field of the invention as the same as the description of the patented invention involving a patent claim in the initial specification of the prior application, in light of the then-current technical common knowledge as of the priority date."

In the case subject to the above ruling, the issue was whether the new dosage regimen, the uniform administration of an equal dose of "500-1500 mg/m^2 of anti-CD20 antibody" described in Claim 3 of the patented invention in the case ("**Patented Invention**"), can be understood as express description in the initial specification of the prior application or as the same as such description. The initial specification of the prior application had a claim involving administering a dose of 0.1-30 mg/kg of anti-CD20 antibody or injecting a weekly dose of 375 mg/m^2 for four weeks. The embodiment simply described the treatment with the first dose of 375 mg/ m^2 followed by 500-1500 mg/ m^2 and omitted description of administration of an equal dose of 500-1500 mg/m^2 in the claim. In this case, the Supreme Court agreed with

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the lower court's decision that: (i) although the initial specification of the prior application shows that the study of the dose of anti-CD20 antibody for CLL treatment is still underway, it cannot be understood as the same description of the dose of 500-1500 mg/m^2 of the anti-CD20 antibody in the initial specification of the prior application because the fact that the single dose of anti-CD20 antibody for CLL treatment as of the priority date is 500-1500 mg/m^2 does not constitute technical common knowledge to a person of ordinary skill in this art; (ii) the date of determining the patent requirements including the requirements of Claim 3 of the Patented Invention is the filing date, not the priority date,; and (iii) the inventive step of Claim 3 of the Patented Invention is negated by the prior art disclosed prior to the filing date of the Patented Invention.

The issues decided above were initially covered by the Supreme Court Judgment 2012Hu2999 dated January 15, 2015. In the case, the court clarified that the scope of inventions for which the critical date of applying patent requirements of the patented inventions involving a priority claim can be retroactively applied to the priority date should be determined from the perspective of prohibited addition of new matters. The Supreme Court Judgment 2019Hu10265 is the first Supreme Court decision that ruled with respect to the requirements to retroactively apply the critical date of applying patent requirements of the inventions with patent applications involving a priority claim as the priority date in the area of pharmaceuticals.

The issue in the above judgment is that: (i) the administration of an equal dose of anti-CD20 antibody in the initial specification of the prior application is described differently from Claim 3 of the Patented Invention (i.e., administration of a dose of 0.1-30 mg/kg or an weekly injection of 375 mg/m^2 for four weeks); and (ii) although the embodiment of the initial specification of the prior application describes the dose of 500-1500 mg/m^2 of anti-CD20 antibody in Claim 3 of the Patented Invention, the dose is not equal but a subsequent dose following the first administration (375 mg/m^2). In this regard, it seems relatively clear that the new dosage regimen involves the administration of an equal dose of "500-1500 mg/m2 of anti-CD20 antibody" in Claim 3 of the Patented Invention, and such administration is neither expressly described in the initial specification of the prior application, nor can be understood as the same as such description.

The above judgment demonstrates the need to carefully review whether any patent application involving a priority claim in the area of pharmaceuticals, which have more patent applications involving a priority claim than other technical areas, is within the scope of matters described in the initial specification of the prior application. Such need is particularly noted where the prior art can invalidate the patented invention within the priority date and the filing date as in Claim 3 of the Patented Invention. In light of the Supreme Court judgment, such careful review is also required in other technical areas if a priority claim is involved.