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NEWSLETTER

Lee & Ko IP

Recent IP Developments in Korea – 2026. 08

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Recent Changes to Korea's Deferred Examination and Expedited Examination Systems

In 2026, Korean patent examination practice saw the abolition of the two-month deadline that had applied to requests to modify or withdraw a request for deferred examination, as well as an expansion of the technologies eligible for expedited examination to include advanced fields such as physical AI and synthetic biology. In addition, the processing period for subsequent examination in expedited examination cases was reduced. The key aspects of these changes and practical considerations from the perspective of foreign applicants are outlined below.

1. Abolition of the Deadline for Modifying or Withdrawing a Request for Deferred Examination

Under Korea's deferred examination system, an applicant may, within nine months from the date of filing the request for examination, submit a request designating a preferred time for deferral. This allows the applicant to specify a date for the commencement of examination that falls after 24 months from the date of the request for examination and no later than five years from the filing date.

Previously, an applicant wishing to change the preferred time for deferred examination or withdraw the request for deferred examination was required to file a withdrawal or an amendment within two months from the date of filing the request for deferred examination. As a result, even where market conditions or product launch schedules changed after the request was filed, applicants faced practical constraints in adjusting the timing of examination.

The amended Article 40-3(2) of the Enforcement Rule of the Patent Act and Article 10-3(2) of the Enforcement Rule of the Utility Model Act removed the two-month deadline, effective May 14, 2026. Accordingly, before the examiner commences substantive examination, an applicant may advance or postpone the preferred time for deferred examination, or withdraw the request itself, without being subject to the previous two-month restriction.

As a result of this amendment, companies and applicants can more flexibly manage the timing of patent examination and the acquisition of patent rights in response to changes in business strategy, including financing, the pace of research and development (R&D), product launch schedules, and market competition.

2. Expansion of Expedited Examination for Advanced Technologies and Shortening of Processing Periods

■ Expansion of Expedited Examination in the Physical AI and Biotechnology Fields

Expedited examination for advanced technologies is currently available in six fields: semiconductors, displays, secondary batteries, biotechnology, advanced robotics, and artificial intelligence. Following the addition of biotechnology, artificial intelligence, and advanced robotics to the advanced-technology expedited examination program in 2025, the scope of the artificial intelligence field was expanded in 2026 from technologies relating to artificial neural networks to include physical AI. In the biotechnology field, the scope of eligible technologies was also revised to include synthetic biology and related technologies. The eligible technologies and applicable periods were revised and extended pursuant to the notice dated January 30, 2026, designating biotechnology and artificial intelligence technologies eligible for expedited examination.

■ Shortening of Processing Periods for First and Subsequent Examinations

According to the 2025 performance data released by the Ministry of Intellectual Property (MOIP), the average waiting period until the first examination result was 14.7 months for regular examination and 2.1 months for expedited examination. MOIP plans to reduce the overall average examination waiting period to 14 months within 2026. In particular, for expedited examination cases, MOIP intends to shorten the examiner's internal processing deadline from four months to two months after an applicant submits a response to an office action such as a written opinion or an amendment, thereby also reducing the period until the conclusion of examination.

■ Considerations for Foreign Applicants

The advanced-technology expedited examination program is not available merely by claiming that the technology falls within a relevant field. To qualify, an application must meet the following requirements: ① the patent classification (CPC) specified in the designation notice must be assigned as the primary classification for the application, and ② additional requirements such as manufacturing or preparing to manufacture the relevant product in Korea. Therefore, foreign applicants should verify whether each individual application meets the requirements for advanced-technology expedited examination. If the requirements are not met,

they should consider utilizing other expedited examination programs, such as the Patent Prosecution Highway (PPH) system.

3. Strategic Coordination of Deferred Examination and Expedited Examination

By leveraging both the 2026 amendments to the deferred examination system and the expansion of advanced-technology expedited examination along with the shortening of subsequent examination periods, applicants can manage the speed of patent examination and the timing of acquisition of patent rights more flexibly according to their business stages.

For technologies that require a prolonged period for commercialization, applicants may initially file a request for deferred examination to monitor technology development and market trends while reviewing claim strategies. Subsequently, when a business event occurs that requires prompt securing of rights—such as fundraising, product launch, technology transfer, or overseas expansion—applicants may consider a strategy of withdrawing the request for deferred examination before the examiner commences substantive examination and, if the application meets the requirements for expedited examination, filing a separate request for expedited examination.

Through this approach, companies can control in the initial stages when examination response costs are incurred while, when business needs require, obtaining at an early stage both the first examination result and the subsequent examination results following the applicant's response. However, it should be noted that expedited examination is merely a system that accelerates the examination procedure and does not guarantee a decision to grant a patent or registration.

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2026 Updates to Trademark Examination Practice in Korea

The Ministry of Intellectual Property (MOIP) has been introducing a series of amendments to its regulations and examination practices aimed at making trademark examination faster and fairer.

The key changes include: ① clarification of when examination suspensions due to prior-filed applications are lifted; ② simplification of the advance-notice procedure before a decision to reject; ③ assignment of new examiners in remanded cases; and ④ revisions to goods classification and the criteria for determining similarity between goods. These changes are outlined below.

1. Clarification of When Examination Suspensions Based on Prior-filed Applications Are Lifted

Under current trademark examination practice, where a prior-filed application covers a mark identical or similar to the mark in a later-filed application, examination of the later-filed application may be suspended until the status of the prior-filed application is finally determined. Previously, however, it was unclear when examination of the later-filed application could resume, which sometimes resulted in prolonged delays.

Under the amended "Regulations on Trademark Examination Administration," effective July 1, 2026, if a decision to reject the prior-filed application becomes final and conclusive with respect to the relevant designated goods, thereby eliminating the conflict with the designated goods in the later-filed application, the examination suspension is deemed lifted as of the date on which the decision becomes final and conclusive.

Accordingly, where examination of a later-filed application has been suspended due to a prior-filed application, it is expected to resume more promptly.

2. Simplification of the Advance-Notice Procedure Before a Decision to Reject

Previously, even where an applicant did not submit a written response or amendment following a notice of grounds for rejection under Article 38(1) of the Trademark Act—such as grounds concerning the classification or description of designated goods—an advance notice reiterating the same grounds would still be issued before a decision to reject the application.

Under the revised practice effective July 1, 2026, this additional advance-notice step will be omitted where the applicant does not respond to the initial notice of grounds for rejection.

Accordingly, if an applicant does not respond to the initial notice, a decision to reject the application may be issued without further notice. Applicants should therefore not wait for an additional notice before responding and should submit any necessary written response or amendment within the period specified in the initial notice.

3. Assignment of New Examiners in Remanded Cases

Previously, when the Korean Intellectual Property Trial and Appeal Board (IPTAB) cancelled a decision to reject a trademark application and remanded the case to the MOIP, the examiner who had participated in the original decision could re-examine the application.

Under the amended regulations effective July 1, 2026, the principle that a person involved in the original decision should not participate in subsequent proceedings has been extended to the examination stage. Accordingly, an examiner who participated in the original decision to reject the application will not take part in the re-examination following remand. Instead, a new examiner will be assigned to the case.

This change is expected to further enhance the objectivity and procedural fairness of examinations in remanded cases.

4. Revisions to Goods Classification and the Criteria for Determining Similarity Between Goods

Since January 2026, the criteria for determining similarity between pharmaceuticals for human use and veterinary pharmaceuticals, as well as between medical devices for human use and veterinary medical devices, have been revised to better reflect actual market conditions.

In addition, the 13th edition of the Nice Classification took effect on January 1, 2026. Key changes include the transfer of spectacles/eyeglasses, spectacle/eyeglass lenses, and sunglasses from Class 9 to Class 10, as well as the classification of essential oils according to their intended purpose—for example, essential oils for use in manufacture in Class 1 and essential oils for flavoring food and beverages in Class 30.

Accordingly, in fields affected by these changes, applicants should select the appropriate classes and designated goods in light of their current business activities and intended future use.

5. Practical Implications

Taken together, these revisions are intended to reduce unnecessary procedural steps and examination delays while enhancing the fairness of examinations in remanded cases.

In particular, if an applicant does not respond to the initial notice of grounds for rejection, a decision to reject the application may be issued without further notice. Applicants should therefore carefully manage the applicable deadlines and submit any necessary written response or amendment within the prescribed period. In addition, before filing an application, applicants should review the revised goods classification and the criteria for determining similarity between goods to avoid omissions or misclassification in their list of designated goods.

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Online Oral Proceedings at Korean IPTAB Accessible from Overseas

The Korean Intellectual Property Trial and Appeal Board (IPTAB) has been fully implementing Internet Video Oral Proceedings starting in July 2026, utilizing the Korean government's 'On-Nara Personal Computer (PC) Video Conference System.'

Parties and their counsel in patent trials will now be able to participate in oral proceedings via the internet from their desired locations, such as offices or homes, without having to appear in person at the IPTAB (located in the city of Daejeon) or the Seoul Office of the Ministry of Intellectual Property (MOIP). In particular, it is expected that participation in the proceedings by overseas clients will be significantly expanded, as parties residing overseas will be able to attend oral proceedings and present their opinions without having to travel to South Korea.

Previously, attending oral proceedings required either appearing in person at the IPTAB (Daejeon) or participating, from the Seoul Office of the MOIP, in remote video proceedings connecting Daejeon and Seoul.

The newly introduced Internet Video Oral Proceedings allow parties to access and participate in the video conference system from anywhere via the internet, without having to visit the IPTAB or Seoul Office. By simply entering the participant's name and the access code shared by the IPTAB on the On-Nara PC Video Conference System website[1)] operated by the Korean government, multiple parties can simultaneously access the video conference system. In addition, a hybrid method is also possible, where legal counsel attends oral proceedings in person at the IPTAB while clients participate via Video Oral Proceedings from overseas or domestic locations. Accordingly, overseas clients can efficiently participate in proceedings while reducing overseas travel time and business trip expenses.

Therefore, the Internet Video Oral Proceedings are expected to be widely utilized by overseas clients, as Korean counsel and overseas parties can jointly participate in oral proceedings without location

restrictions and present their arguments directly to the trial panel.

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1) On-Nara PC Video Conference (https://vc.on-nara.go.kr:8089/guest/)

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Recent Court Decision on the Criteria for Determining "Clinical Significance" of Cell and Gene Therapy Products

The Seoul Administrative Court recently rendered a decision (Case No. 2025Guhap55403, decided on July 9, 2026) setting aside the Ministry of Food and Drug Safety's (MFDS) rejection of a marketing approval application for a stem cell therapy. In doing so, the Court clarified the meaning of, and the criteria for determining, "clinical significance," a key criterion in the safety and efficacy review of advanced biopharmaceuticals.

RNL Regeneration Medicine Research Institute Co., Ltd. (hereinafter referred to as the "Plaintiff"), represented by Lee & Ko, applied twice for marketing approval of JointStem®, an autologous adipose-derived mesenchymal stem cell therapy (classified as a cell therapy product under the 「Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products」) indicated for severe knee osteoarthritis. However, the MFDS rejected the applications on the grounds that "there was insufficient evidence to establish clinical significance," based on the findings of the Central Pharmaceutical Affairs Council that, "although statistical significance had been demonstrated in the Phase III clinical trial, superiority in therapeutic efficacy over osteoarthritis treatments already on the market had not been established."

In this regard, Article 19(4) of the MFDS Notice, "Regulation on Marketing Approval and Review of Advanced Biopharmaceuticals," provides the following standard for the review of clinical trial data in evaluating the safety and efficacy of advanced biopharmaceuticals:

> 4. Evaluation: Clinical significance shall be recognized where the review of the submitted clinical trial data demonstrates such with respect to the relevant indication(s). For confirmatory therapeutic clinical trials, significance must be established in accordance with the pre-specified statistical analysis plan, unless exceptional circumstances are recognized.

In its decision, the Seoul Administrative Court held that (i) once statistical significance has been established in accordance with a pre-approved clinical trial plan, clinical significance should be recognized, and (ii) the statutory requirements for marketing approval under the Pharmaceutical Affairs Act are limited to "safety and efficacy," and it is unlawful to require proof of "superiority" over existing therapies.

This decision is particularly significant in that it establishes a clear standard for determining "clinical significance," which had previously been subject to the discretion of regulatory review practice, holding that where statistical significance is demonstrated in a Phase III clinical trial in accordance with the pre-specified statistical analysis plan, clinical significance, along with safety and efficacy, should, in principle, be recognized.

In particular, in the field of advanced biopharmaceuticals, including cell therapy products and gene therapy products, direct comparison with existing therapies is often difficult, and products are frequently developed through small-scale clinical trials. As a result, whether "superiority over existing therapies" is required has served as an obstacle to obtaining marketing approval. By making clear that such a superiority requirement is an unlawful criterion without any basis under the Pharmaceutical Affairs Act, this decision has served as a catalyst for enhancing the legal predictability of the marketing approval review process.

For more detailed information regarding this decision, please refer to the Lee & Ko Healthcare Group Newsletter.