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Amgen v. Sanofi: The Supreme Court tackles patent enablement

Craig Metcalf of Kirton McConkie reviews the findings in the case that has solidified the enablement requirement for pharmaceuticals in the US patent system.

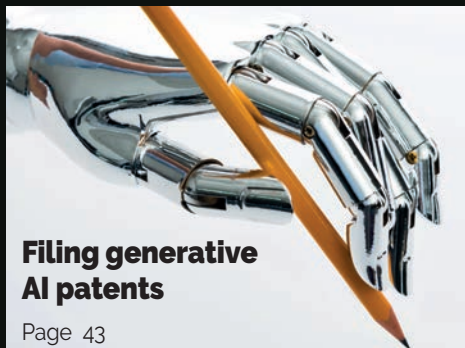
An interview
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AIPPI 2023
WORLD CONGRESS
SPECIAL
EDITION

Suspension of examination for divisional applications in Japan while parent is under appeal

Debra Cheng of Sonoda & Kobayashi Intellectual Property Law details the process, eligibility, advantages, and disadvantages of the introduction of this new practice.

The concept of a divisional application within the Japanese patent system is partially akin to that found in other legal jurisdictions, e.g., trademark and design. Article 44 of the Patent Act outlines the procedure for dividing patent applications, allowing applicants to create new patent applications from portions of an original application containing multiple inventions. When a division occurs, the new application is retroactively considered to have been filed at the same time as the original application. This divisional application mechanism is designed to offer maximum legal protection for inventions within patent applications that lack unity, in line with the overarching purpose of the patent system – to grant exclusive rights for a set duration in exchange for public disclosure.

Notably, the strategic utilization of divisional applications in Japan offers several advantages.



Debra Cheng

In cases where an original application is rejected, including instances of a "Decision of Rejection" or Final Office Action, the disputed inventions can remain in the original application and be contested via written opinions or amendments.

Résumé

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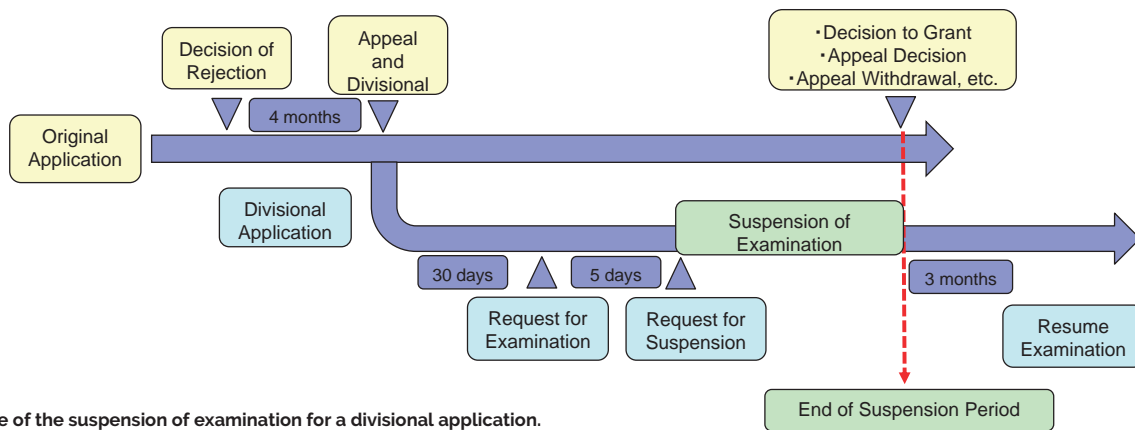
Simultaneously, inventions unaffected by the rejection grounds can be separately filed in a divisional application.

Another advantage to divisional application, also found in other jurisdictions, is the ability to secure a retroactive effect, where the divisional application is treated as though it were filed concurrently with the original application. Failure to attain retroactive effect due to an improper division¹ results in the application being treated as filed on the division's actual filing date, depriving it of the benefits associated with the original filing date.

New practice: suspension of examination for divisional applications

However, as both the divisional and parent applications are processed concurrently by the JPO, there is a possibility that a first Office Action is issued for the divisional application before the outcome of the appeal for the parent application is revealed. This forces applicants to address the divisional application's Office Action without the benefit of knowing the result of the parent application's appeal. This predicament is less than optimal, as most applicants prefer to handle the two cases sequentially, where they wait on results from the parent application first and modify or withdraw the divisional application based on those results.

Under the new practice introduced by the JPO, applicants can request the suspension of substantial examination for a divisional patent



Timeline of the suspension of examination for a divisional application.

Beginning April 1, 2023, the Japan Patent Office (JPO) introduced a new practice pertaining to divisional patent applications, allowing applicants to suspend the examination of a divisional patent application while the parent (original) application remains under appeal. This suspension remains in effect until three months following the conclusion of a pre-appeal reexamination or an appeal examination pertaining to the parent application. Importantly, this new practice applies solely to divisional applications for which a Request for Examination is submitted on or after April 1, 2023.

In the realm of Japanese patent practice, since there is no guarantee under the Patent Act that an opportunity for filing a divisional application is obtained during an appeal, in many cases, the final opportunity to file a divisional application is the same period in which an appeal can be filed against the rejection decision for a parent application by the Examiner². As such, it is common for applicants considering an appeal to simultaneously consider the filing of a divisional application as a precautionary measure to mitigate risk.

application. This option becomes available when the divisional application is filed after the issuance of a Decision of Rejection concerning the parent application. This suspension of examination falls under the provisions of Patent Law Article 54, Paragraph 1. The suspension remains in effect until three months after the conclusion of a pre-appeal reexamination or appeal examination relating to the parent application.

Criteria for eligibility and procedural steps

Several criteria govern the eligibility of patent applications for the new practice of suspension:

1. The subject applications must be divisional applications filed after the issuance of a Decision of Rejection by the Examiner in relation to the parent application.
2. An Appeal must have been filed against the rejection imposed on the parent application.

¹ An improper division is, for example, when the division is made at an inappropriate time, or when the divisional application introduces new matter that is not present in the original application.

² On the other hand, if an Office Action is issued during a pre-appeal reexamination or an appeal examination, a divisional application can be filed in the response period.

3. The parent application must be pending preliminary examination or undergoing appeal examination by the Board of Appeal.
4. Waiting for the outcome of preliminary examination or examination by the Board of Appeal should be deemed suitable.

To request suspension, the following procedural steps are required:

1. Submission of a petition outlining the circumstances necessitating the suspension of examination in line with Article 54, Paragraph 1 of the Japanese Patent Law.
2. Provision of a statement in a specified format, explaining the circumstances leading to the request for suspension of examination as per Article 54, Paragraph 1 of the Japanese Patent Law.

Both procedures 1 and 2 described above must be done within five working days from the filing of the request for examination for the divisional application. Note that the request for suspension incurs no JPO official fees.

Following the request for suspension

Once the request for suspension of examination is made and accepted, the examination of the divisional application will be suspended until three months after the below-mentioned scenarios of 1 or 2 as long as the appeal is not dismissed or withdrawn:

1. A Decision to Grant is issued for the parent application based on the preliminary examination;
2. The first Appeal Decision is issued concerning the appeal; or

It is crucial to note that retracting a Request for Suspension of Examination is not permitted.

Strategic implications and considerations

The new practice of suspending examination for divisional applications introduces several advantages and disadvantages, influencing the strategies adopted by applicants:

Advantages:

1. Informed decision-making: applicants gain the ability to tailor their divisional application based on the outcome of the parent application's rejection appeal, thus devising a more efficient and effective overall strategy.



The introduction of the option of suspending examination for divisional applications in Japan marks a significant improvement in the patent filing system.



2. Enhanced examination efficiency: the divisional application's examination can be conducted with greater efficiency, as the examiner can take the results of the parent application's reexamination or appeal into account. As such, this potentially reduces the burden of examination on the applicant's side.

Moreover, applying for the suspension of a divisional patent application can be useful in maximizing time for amending divisional applications for certain filing strategies, including:

- When industrial standards are under discussion but yet to be finalized, keeping a divisional application pending until the finalization of standards allows for subsequent adjustments to claims.
- For pharmaceutical inventions where the authority acknowledges the effectiveness of the same compound/molecule for different indications one by one, keeping a patent with the first indication pending until the subsequent indications are authorized allows amendments to be made to target the authorized indications through divisional applications.

Disadvantages:

Delayed rights acquisition: the suspension approach precludes the early acquisition of rights for the divisional application.

Waiting period: despite substantially determining the divisional application's claims, the applicant must wait for the parent application's outcome.

Cost: the official fee for the examination of a divisional application must be paid before the appeal result is issued. As the fee is calculated based on the number of claims, it is recommended to reduce the number of claims to one, which can be later increased after the result of the appeal is revealed, so long as the amendment is submitted before the first Office Action is issued.

The introduction of the option of suspending examination for divisional applications in Japan marks a significant improvement in the patent filing system. By offering the option to defer examination until the resolution of a parent application's appeal, this practice allows for greater examination efficiency as well as enabling applicants to make more informed decisions and devise more efficient filing strategies.

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