

# Updates - Taiwan Patent Examination Guidelines

## CHANGES MADE IN 2024

### ■ Adopted as of 1 July 2024:

#### **Changes made to Chapter 1, Chapter 3, Chapter 11 and Chapter 14 of Part II Substantive Examination of Invention Patent Applications and changes made to Chapter 1 of Part V Examination of Invalidation Actions.**

The changes are proposed and made in line with the change of the relevant laws and regulations to reflect practical needs of patent applications examination, consolidate practical opinions and enhance the quality of examination. New principles and examples are introduced with the relevant text amended where necessary and appropriate to strengthen the operability and operation of the guidelines in practice.

Key takeaways of the changes made:

#### **1. Chapter 1 of Part II concerning description, claim(s), abstract or drawing(s)**

Wording of Section 1.3.1 concerning enablement is revised consistent with the text of paragraph seven, Article 17 of the Enforcement Rules of the Patent Act which provides that the sequence listing required to produce on the enablement of the patent claimed may be submitted electronically in the format and form required by the Taiwan IPO.

#### **2. Chapter 3 of Part II concerning patentability tests**

An Example 1 is added to Section 2.6.4 on the novelty test and explained in workable details to demonstrate how a patent claimed could be determined to be failing the test.

#### **3. Chapter 11 of Part II concerning patent term extension**

The designation of *Council of Agriculture* present in the Chapter is globally replaced with *Ministry of Agriculture*, the new designation of the same body after being restructured.

Paragraph (2) of Section 3.1.3.1.1 concerning the duration of the domestic/foreign clinical trial of a pharmaceutical where the foreign clinical trial report must be produced in accordance with the ICH Guidelines is revised: the full English title of the ICH Guidelines required to be shown in the report produced is replaced with ICH's current full English designation.

#### **4. Chapter 14 of Part II concerning biological inventions**

Section 4.1 and Section 4.3 are revised in accord with the provision of paragraph seven, Article 17 of the Enforcement Rules of the Patent Act and the adoption of WIPO Standards ST.26.

Section 4.3.2 on submission of the sequence listing is revised to explain where the patent application is filed electronically, the sequence listing produced must be presented in an XML conforming to WIPO Standards ST.26, and where the patent application is filed in writing, the sequence listing may be presented in paper version conforming to WIPO Standards ST.26 or in an XML conforming to WIPO Standards ST.26.

#### **5. Chapter 1 of Part V concerning the examination of invalidation actions**

Section 2.1.2 elaborates the definition of an interested party in an invalidation action and points out an interested party named shall be examined with comparable investigation conducted and identified in form.

Section 9 regarding the relationship between the invalidation action against a patent and the patent lawsuit alleging infringement of the same patent is revised in line with the amendment of Article 17 of the Intellectual Property Case Adjudication Act by reference to the provision and the legislative reasoning of the amendment, by which amendment, 1) said Article 17 is re-designated as Article 44, 2) the role of the Taiwan IPO intervening the patent infringement action to assist the court is removed and 3) a framework is prescribed for the court adjudicating a dispute over patent to, where necessary, seek the advice of the competent intellectual property authority.

## 6. Others

Other changes made include revision of the text based on the relevant provision of the laws and regulations and correction of typographical errors, etc.

[Source: Taiwan IPO at <https://www.tipo.gov.tw/patents-tw/np-685-101.html>]

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