Taiwan International Patent & Law Office

TAIPEI MAIN OFFICE
7th Floor We Sheng Building,
No.125, Nanking East Rd. Sec.2,
P.O.BOX 39-243, Taipei 10409, Taiwan
Tel: 886-2-2507-2811 ‧ Fax: 886-2-2508-3711
E-mail: tiplo@tiplo.com.tw
Website:www.tiplo.com.tw

TOKYO LIAISON OFFICE
No.506 Lions Mansion ,
13-11, Shinjuku 2-Chome,
Shinjuku-ku, Tokyo 160-0022, Japan
Tel: 81-3-3354-3033 ‧ Fax: 81-3-3354-3010

Updates regarding Taiwan Patent Examination Guidelines

CHANGES MADE IN 2018

I. Adopted as of 1 April 2018:

Changes made to Chapter 11 *(Patent Term Extension)*, Part II Invention Patents Substantive Examination:

1. The exclusive licensee of a patent may seek patent term extension (hereinafter "PTE") without regard to whether or not the exclusive licensing is recorded with the Taiwan IPO.

2. Eligibility requirements of the holder of the first regulatory approval relaxed.

3. Where the first regulatory approval is held by a licensee of the patent, the PTE applicant must upon application present documents proving the consummation of that licensing arrangement, which licensing may or may not be one recorded with the Taiwan IPO.

4. The determination of the active ingredient of the first regulatory approval must be based on the active ingredient *per se* of the pharmaceutical as opposed to the active moiety having pharmacological effects (free form).

5. A regulatory approval issued on a bulk drug or a technical grade agrichemical is not a first regulatory approval for the purpose of the PTE.

6. In regard to determining the correlation between the patent claims and the first regulatory approval, the previously required correspondence correlation is amended to an inclusivity correlation. Relevant explanations are revised and additional examples are given.

7. The start date and the completion date of the clinical trial conducted abroad must respectively correspond with the study initiation date and the study completion date as defined in the clinical trial report produced in compliance with the ICH standards, namely the standards laid down by the *International conference on harmonization of technical requirements for registration of pharmaceuticals for human use*.

8. *Removed :* A PTE application based on trials or tests conducted abroad must be filed with documents proving the grant of PTE by the relevant foreign Patent Authority. *[This removal is made in line with the removal of paragraph 2, Article 5 and paragraph 2, Article 7 of the Regulations Governing the Determination of Patent Term Extension)]*

9. The completion date of the examination of the request for registration of an agrichemical is re-defined to be the issue date of the regulatory approval of that agrichemical.

10. *Aborted :* The rule that the field test taking the longest period of time to complete among all conducted home and abroad shall prevail no longer applies. (This change is made in line with the removal of paragraph 3, Article 6 of the Regulations Governing the Determination of Patent Term Extension.)

11. *New :* Duration of interruption or delay (if any) in obtaining the regulatory approval due to non-conformity of any information produced for obtaining the regulatory approval shall be accounted the duration of inaction imputable to the applicant.

12. *New :* The time period from the publication date of the method and scope of use of an agrichemical to the date when all documents needed for registration of that agrichemical will be accounted the duration of inaction imputable to the applicant.

13. Where a clinical trial conducted for academic study purposes is shifted to a clinical trial for the purpose of obtaining regulatory approval, the study initiation date of that clinical trial may be admitted as the start date of a local clinical trial.

14. Explicitly laid down the principle of handling a PTE application which does not comply with the stipulation set forth in Art. 53 of the Patent Act that only one extension of the patent term may be requested for one patent and that the first regulatory approval may be used only once for seeking PTE.

15. Defined the particulars that must be indicated in the notice of allowance of PTE.

II. Adopted as of 1 November 2018:

Changes made to Part I Procedural Examination and Patent Right Administration, including changes made to Chapter 2 *(Patent application form)*, Chapter 7 *(Priority right and grace period)*, Chapter 8 (*Deposit of biological materials)*, Chapter 10 *(Amendment)*, Chapter 13 *(Division and conversion)*, Chapter 14 *(Application Fees)*, Chapter 15 *(Service)*, Chapter 17 *(Obtaining and maintaining patent rights)*, and Chapter 18 *(Patent Term Extension)*.

With a view to providing applicants with clear, specific guidelines to follow, the above-said Chapters were revised in line with 1) the implementation of the Operational Directions Governing the Mutual Cooperation between Taiwan Intellectual Property Office and United Kingdom Intellectual Property Office in the Field of Deposit of Biological Material for the Purposes of Patent Procedure, 2) revision of Chapter 11 *(Patent Term Extension)*, Part II Invention Patents Substantive Examination, 3) change of the required amount of copies of application documents to produce and in consideration of practical operation concerning, for example, declaration of two applications for same creation, priority document.

III. Adopted as of 1 January 2019:

Changes made to Chapter 14 *(Biological inventions)*, Part II Invention Patents Substantive Examination :

1. Revised the specific variants of inventive step and the explanatory descriptions on the inventive step patentability requirement with 13 additional case examples presented for elucidation.

2. Certain sections contextually restructured with relevant provisions revised for clarity and text coherently amended where

a) Repetitions are removed or consolidated;
b) Rare illustrations are removed and replaced with common practical examples;

c) Text of no relevance with substantive examination is removed;
d) Further explanation is given in response to frequently asked questions;
e) Case examples are revised where necessary and appropriate;
f) Certain text and paragraphs are removed in consideration of coherence of the Examination Guidelines as a whole; and
g) The text of the entire Examination Guidelines is reviewed, modified to enhance clarity and in consideration of practice.

IV. Adopted as of 1 January 2019:

Changes made to Chapter 4 *(Unity of invention)*, Part II Invention Patents Substantive Examination :

1. Steps of assessing unity: To begin with, is it obvious that unity does not exist among the inventions of the independent claims? If the answer is *yes,* the patent application shall be determined lack of unity. If the answer is in the negative, a prior art search shall be conducted beginning with, in principle, the invention of claim 1 to determine whether or not the invention claimed has any special technical feature. The assessment shall move on to determine whether or not the other independent claims each have the same special technical feature or any corresponding technical feature. If they do not, the patent application shall be determined lack of unity. If they do, the patent application shall be determined as meeting the unity requirement.

b) As a general rule, to determine whether or not the patent application meets the unity requirement, at least an independent claim and its dependent claims must be examined as a group of claims.

c) Certain sections contextually restructured with relevant provisions revised for clarity, illustrations rewritten and re-formatted as case examples with relevant text coherently amended.

[Source: Taiwan Intellectual Property Office
https://www.tipo.gov.tw/np.asp?ctNode=6703&mp=1]

Taiwan Patent Examination Guidelines Changes Adopted in 2017

Most recent amendments to Patent Examination Guidelines pertain to invalidation actions, grace period claims and the inventive step patentability test :

1. Effective as of 1 January 2017:

a) Amendment to Chapter 9 (*Amendments & Corrections*), Part II Invention Patents Substantive Examination;

b) Amendment to Chapter 1 *(Invalidation)*, Part I Invalidation Examination.

Important changes pertaining to invalidation :

1) Added: exceptions where the amended will not be deemed withdrawn as a matter of course;

2) Added: items of matters which applicant of a dual application may exercise the right to clarify;

3) Added: taking of evidence retrieved online and taking of foreign-language evidence;

4) Removed: some of the examples given to explain what items may be subject to *ex officio* examination.

2. Effective as of 1 May 2017:

a) Amendment to Part I Formality Examination & Patents Administration, including Chapter 2 (*Application Form*), Chapter 4 (*Attorney*), Chapter 7 (*Priority Claim & Grace Period*) and Chapter 13 (*Divisional Applications*);

b) Amendment to Part II Invention Patents Substantive Examination: Section 4 Exceptions to Being Determined Obvious or Non-inventive, Chapter 3 (*Patentability Requirements*);

c) Amendment to Part III Design Patents Substantive Examination: Section 4 Exceptions to Being Determined Obvious or Non-inventive, Chapter 3 (*Patentability Requirements*).

Important changes pertaining to grace period (Section 4 Exceptions to Being Determined Obvious or Non-inventive, Chapter 3, Part II):

1) Grace period granted to inventions and utility models extended to 12 months (previously 6 months);

2) Laying-open related eligibility conditions for claiming grace period relaxed: Applicant may seek grant of grace period where the patent claimed has been laid open as a result of applicant's own intention to do so or in case of involuntary laying-open;

3) Manners and forms of publications (other than in Patent Gazette) no longer restricted.

4) Requirement that grace period claim (if any) must be made upon filing removed.

5) Added: laying-open made in Patent Gazette (Section 4.4); examination of claimed exceptions to being determined obvious or non-inventive (Section 4.7); points for attention regarding examination (Section 4.8). The Design Patents Examination Guidelines pertaining to grace period shall change in line with the amendment to those applicable to invention patents except that the grace period granted to design patents shall remain 6 months.

3. Effective as of 1 July 2017:

Amendment to Section 3 (*Inventive Step*), Chapter 3 Patentability Requirements, Part II Invention Patents Substantive Examination

Important changes regarding examination of the inventive step patentability requirement:

1) Added: A person skilled in the art in the relevant field of the invention claimed may be a group of persons;

2) Added: Elucidation of each step of the inventive step patentability test with step no. 5 illustrated in flowchart.

3) Sections 3.4 and 3.5 combined and consolidated to perfect step no. 5 of the test.

4) Added: scenario where a person skilled in the art is motivated to and capable of manifestly combining references (Section 3.4.1); scenario where a person skilled in the art is capable of manifestly combining references without considering his/her motive, if any (Section

3.4.2); other factors to consider in testing inventive step (Section 3.4.3); secondary factors to consider in testing inventive step (Section 3.4.4); additional explanatory examples.

[Source: Taiwan IPO https://www.tipo.gov.tw/np.asp?ctNode=6703&mp=1]

Taiwan International Patent & Law Office

TAIPEI MAIN OFFICE
7th Floor We Sheng Building,
No.125, Nanking East Rd. Sec.2,
P.O.BOX 39-243, Taipei 10409, Taiwan
Tel: 886-2-2507-2811 ‧ Fax: 886-2-2508-3711
E-mail: tiplo@tiplo.com.tw
Website:www.tiplo.com.tw

TOKYO LIAISON OFFICE
No.506 Lions Mansion ,
13-11, Shinjuku 2-Chome,
Shinjuku-ku, Tokyo 160-0022, Japan
Tel: 81-3-3354-3033 ‧ Fax: 81-3-3354-3010