

インドネシア質問状原稿(0917)_特許事務所

【1】出願権利化に関する質問

I. 制度について

(1) 1. 特許審査ハイウェイ(PPH)プログラムあるいは ASPEC を利用した出願を扱ったことはありますか？ある場合、貴所のご経験上、各出願ルート(パリルート、PCT ルート、PPH、ASPEC)の違いによって、権利化のスピード、審査の内容等に違いがあればご教示ください。

1. *Does your firm handle a patent application using PPH program or ASPEC program? If the answer is "yes", please let us know the practical difference with respect to speed or contents of the examination between these routes: Paris Conventional application, PCT application, with or without PPH/ASPEC program, based on your experience.*

Answer

The practical different with respect to speed of examination

PPH

Type of Application	Speed With PPH*,**	Speed Without PPH*
Paris Convention	Around 2 years	Around 3-5 years
PCT application	Around 2 years	Around 3-5 years

*from lodging date

From 360 PPH request, 9 cases have been granted as of August 2015. We filed 14 PPH requests and 1 has proceeded to grant.

For ASPEC, of the 10 requests as of June 2015, all of these are still pending, and no final decision has been issued.

II. 出願書類について

(2) 2. 委任状、譲渡証書への公証/認証(領事認証)は必要ですか？

2. *Does Notarization or legalization by Indonesian Consul is required for each document submitted to DGIPR, such as a Power of Attorney or Deed of Assignment?*

Answer

Power of attorney - need to file original (copy not acceptable). Notarization or legalization is not required.

Deed of Assignment - if original simply signed is sufficient. If photocopy, photocopy is required to be notarized.

(3) 3. 包括委任状を使うことは可能ですか？可能な場合、その法的根拠を教えてください。また、包括委任状の登録方法、願書への記載方法を教えてください。

3. *Is "General Power of Attorney", which fully covers any future patent applications, effective in DGIPR? Please let us know how to register General Power of Attorney(s), and how to identify it in each patent application sheet.*

Answer

General Power of Attorney would not acceptable in DGIPR. The DGIPR would need specific and original Power of Attorney document for each patent

application filed.

- (4) 4. 譲渡証や委任状等の書類を、出願(PCT 各国移行)後に追完することは可能ですか？可能な場合、いつまでに追完する必要があるのか、法的根拠とともに教えてください。
4. *Is it acceptable for DGIPR to submit Deed of Assignment or Power of Attorney, separately after the completion of national phase entry of PCT application? If possible, please let us know the deadline for the later submission of these documents and the legal basis for such practice.*

Answer

No legalisation or notarisation is necessary for the original Power of Attorney or Deed of Assignment.

- (5) 5. 発明者から出願人への譲渡証書は必要でしょうか。特許を受ける権利が使用者にある場合はいかがでしょうか。
5. *Does DGIPR request to submit a Deed of Assignment from inventors to an applicant? How about the case that an employer company originally has a patent right based on an invention made by its employee, under their employment agreement or under the patent law (such as in United Kingdom)?*

Answer

Yes, the DGIPR would request a Deed of Assignment from inventors to an Applicant. In the case that an employer company originally has a patent right, a copy of employee contract would be sufficient as a substitute document for the assignment.

Under Indonesian law, the Employer owns the invention if

- the invention is made in an employment relationship or
- the employee has used data and or facilities available at his work even though the employee is not required to exercise any inventive activity

(Art. 12 of Patent Law)

- (6) 6. 優先権証明書の翻訳文は、フロントページのみで良いのか、全文必要であるのか教えてください。また、その根拠(条文、規則、等)を教えてください。
6. *Please let us have an advice whether we have to submit a full English translation of certified priority document or a partial translation thereof (for*

example only the front page), and the legal basis for such practice.

Answer

Where the application is based on Paris Convention priority claim (other than PCT), the priority document's needs to be translated into English (Art 17 of the Government Regulation no. 34/91).

In practice, the Patent office would require the English translation of front page only, as well as the Indonesian translation.

In the case of PCT, in practice, as the PCT publication is bilingual containing English translation, no need to provide the translation. The patent office would not require the Indonesian translation as well.

(7) 7. パリ条約上の基礎出願(優先権証明書)とインドネシア出願の明細書とに違い(クレームの追加、実施例の追加、表現の変更等)がある場合、優先権証明書の翻訳文はフロントページのみ、あるいは全文のどちらが必要ですか？

7. *In the case that there are some differences between the text of an Indonesian specification and the foreign priority application under Paris Convention, for example, in the case that claims or additional texts are included only in the Indonesian application, do we have to submit a full translation of the certified priority document? Alternatively, is it sufficient to submit only a front page thereof?*

Answer

In the case that there are some differences between the text of an Indonesian specification and specification of the foreign priority application, especially in the case that claims or additional text are included only in the Indonesian application, in practice, it is required to submit a full English translation of the certified priority document.

(8) 8. 優先権証明書の翻訳文は、インドネシア語訳ではなく、英訳が求められる理由および法的根拠を教えてください。

8. *Why English translation, not Indonesian translation, of the certified priority document is required by DGIPR? Please let us have the reason and the legal*

basis for the practice.

Answer

Legal basis- Art 17 of the Government Regulation no. 34/91 concerning Procedure of Patent

- (9) 9. 特許付与請求の意思表示である出願人宣誓書は提出が必要な書類でしょうか。また、この宣誓書には出願人代表者のサインが必要でしょうか。署名者は、企業においてはどの程度の地位の人物の署名が必要ですか？会社の代表権を有する必要がありますか。

9. *Is it required for an applicant to submit the declaration document which shows the intention of an applicant to claim a patent right? Who should sign the declaration? Please let us know the required position or power for the signor. Should the signor be the representative director of the company? Alternatively, the representative director can give an authorized power to someone in the company or Indonesian patent attorney?*

Answer

Yes, according to Article 24 of Patent Law, the documents should be signed by Applicant. The Signor should be the one who works with and has authorization to represent the company. In practice, in addition of Director of the company, the general manager, is acceptable, but not the Indonesian Patent attorney.

- (10) 10. 関連出願の情報を求められた場合に、提出しなかった時のデメリットやペナルティ等がありますか？（=No. 26）

10. *Is there any risk, demerit or penalty, if an applicant does not submit information with respect to the related patent applications to the DGIPR?*

Answer

For filing application the information and document required for filing are mentioned in the Articles 24, of the Patent Law. The risk for not complying the information or documents mentioned on the article within the stipulated deadline, the application will be withdrawn (Art.32 of the Patent Law).

Related with the priority application, if the required priority document formality is not fulfilled within the stipulated deadline, the application may not be filed by using a priority right (Art 27 of the Patent Law).

(11) 11. 出願人が、明細書中の誤訳を自発的に訂正したい場合、どのタイミング（自発補正・OA 応答時・権利化後）で行うことができますか？また、その根拠となる明細書は英文明細書ですか。日本出願（優先権証明書）に依拠することは不可能でしょうか。日本語 PCT 出願の場合はいかがでしょうか。（=NO.27）

11. When is it possible for an applicant to voluntarily correct a mistranslation? Can the specification of PCT application in Japanese be the basis for the correction? In the case of Indonesian application claiming the priority from original Japanese application based on Paris Convention, is the basis for correction an English specification submitted to DGIPR? Alternatively can we correct a mistranslation based on the original Japanese specification, that is, priority document in Japanese?

Answer

There is no clear guideline on how to voluntarily correct mistranslation of a specification. Mistranslation can basically be voluntarily corrected at anytime during before the grant of a patent. In practice, it is advisable to do it before the issue of the first office action.

The basis for correction must be the English specification submitted to the DGIPR. If the English specification is also mistranslated from the Japanese specification, the mistranslation in the Indonesian application can be corrected using the original Japanese specification as long as a corrected English specification is also provided to the DGIPR. This applies to both to the PCT application and the application claiming for priority under Paris Convention.

However, please note that any corrections or amendments to the specification must not expand the scope of invention as originally filed.

(12) 12. 実務上、どのくらいの頻度で審査官から英文明細書を要求されますか？

12. How often does an examiner in DGIPR practically request an applicant to submit an English specification?

Answer

Under the prevailing regulations, the applicant is always required to submit an English specification for every application filed.

Even when the original specification is written in a language other than English, an English translation is also required in addition to the Indonesian translation (Article 17 of Government Regulation No. 34 of 1991).

III. 審査について

(13) 13. DGIPR の審査官が独自に調査・審査して発行するオフィスアクションは、他国の審査結果を参照したオフィスアクションに比べてどのくらいありますか？

13. *How often does an examiner in DGIPR issue an office action wherein the examiner himself/herself performs the search for a prior art and substantially examine the claimed inventions instead of refer to the examination result of a corresponding foreign application? Please let us know the ratio, if possible.*

Answer

It is very low likelihood that the examiner in DGIPR issues an office action wherein they perform the search and independently examined the claimed inventions.

Particularly, it is only in some cases where the application filed as a national application without any corresponding application, the examiner has to perform independent prior art search and substantially examine the claimed invention.

Basically, Indonesian examiner tends to use prosecution result of a corresponding foreign application to conduct substantive examination of a patent application.

(14) 14. 進歩性の判断基準となる「最初の出願がなされた時、既に存在した専門知識」には、特許法第2条(3)の先願明細書の内容は含まれますか？

14. *Does "the state of the art at the time the Application is filed or which has existed at the time the first Application was filed"(in Article 2(3) of the Law of the Republic of Indonesia Number 14 in 2001 regarding Patents (Patent Law)) include the contents of prior Indonesian or other countries' patent application which has not been published at the time of the application was filed*

Answer

No. The unpublished prior patent art is not part of the "state of the art" on the question of inventive step.

You have used the term "state of the art" in your question. The Indonesian word in Article 2(3) is "keahlian". The meaning of this word is closer to "expertise".

Different terminology is used for inventive step - "expertise" instead of "technology" (on novelty question)

In the case of "technology" (relevant to novelty question), "Technology" "includes" "a number of Patent literatures" (Elucidation to Article 3(1); under Article 3(3). "Technology" include unpublished patent prior art.

We set out the translation for Article 2(2) and 2(3) as follows:

"2(2) an invention contains inventive step if that invention to a person with specific expertise in the technical field is something that cannot be expected previously"

"2(3) The evaluation that an invention is something that cannot be expected previously must be conducted by taking into account the expertise that existed at the time of filing the application or at the time of filing the first application in the event that the application was filed with priority right"

(15) 15. オフィスアクションは、登録までに何回発行されますか？

15. *How many times does an examiner issue office actions for one application?*

Answer

In practice, the examiner normally issue 1-2 office actions for one application. For more complex subject matter, it is possible that more than 2 office actions are issued.

(16) 16. オフィスアクションに対する応答期限の延長はどのくらいの期間、何回まで可能ですか？また、その法的根拠を教えてください。

16. *How long and how many times can an applicant extend a deadline for responding office action? Please let us know the legal basis for your answer.*

Answer

There is no provision under Indonesian Patent Law no. 14/2001 or the Government regulation concerning Patent, stipulating the extension of time for responding the Official Action. According to Art 53 cited therein, the response

shall be filed within the stipulated deadline; otherwise the application will be considered being withdrawn. In practice, normally the examiner allows two requests for extension of time. However, this may not be applicable to the application where the 36 months examination period has passed since the time for examination is 36 months as provided in Article 49.

(17) 17. 第 3 条方式審査の場合はいかがでしょうか。応答期間延長が認められる理由はどのようなものでしょうか。

17. *How long and how many times can an applicant extend a deadline for completing the formality requirement according to Article 3? If a proper reason is necessary for such extension, please let us know.*

Answer

Completing of formality requirement is provided in Art.30 of the Patent Law. Two requests for extension of time may be made. The first two months extension is free of charge, and the second 1 month extension is chargeable.

(18) 18. 出願人が自発的に分割出願を行うことは可能ですか？可能である場合、分割出願が可能な時期を教えてください。

18. *Can an applicant voluntarily file a divisional application? If possible, please let us know any deadline or restriction for filing it.*

Answer

The applicant can voluntarily file a divisional application provided that the application does not expand the scope of invention as filed earlier. The deadline to file the divisional application is before the issuance of Notice of Allowance (Art 36 of Patent Law).

(19) 19. 登録査定通知は、即登録の通知という理解であっておりますでしょうか。特許証の交付を申請しない場合でも特許は有効に登録されているのでしょうか。

19. *Please let us clarify that DGIPR automatically register a Patent if the patent application complies with the provisions of Patent Law without confirming the applicant's intention to register the patent, request for issuance by the*

applicant or issue fee payment, and issue a "Patent Certificate" to the applicant, according to Article 58 of Government Regulation of the Republic of Indonesia NO:34 of 1991.=.

Answer

There is no provision in the Patent Law requiring the DGIPR to confirm the applicant's intention to pursue the patent to grant once the application fulfills all the requirements.

In practice, it is possible for the DGIPR to automatically grant the patent without even issuing any official action. If the DGIPR issues an office action, once the response of the official action filed by applicant is accepted by the examiner, the DGIPR may issue the Notice of Allowance without prior notice.

In practice, normally the Notice of Allowance would be issued around 3-5 year from the lodging date. (With or without office action)

After the Notice of Allowance is issued, in practice the DGIPR will issue the invitation to collect the certificate.

(20) 20. 特許登録後に分割出願をすることは可能ですか？また拒絶査定の場合、分割出願が可能なのは拒絶査定までか、拒絶確定(審判請求期間の満了日)までのどちらでしょうか。

20. *Is it possible to filing a divisional application after "issuance of Patent Certificate"? In the case of a patent application is refused by DGIPR, when is the deadline for filing a divisional application? Can we file a divisional application before the date of refusal of the application or before the deadline for appeal?*

Answer

The divisional application only can be filed before the DGIPR issues the final decision (acceptance/refusal decision). It is not possible to file a divisional application after the issuance of certificate.

(21) 21. 分割出願の審査請求期限はいつまでですか？

21. *When is the deadline of request for examination in the case of divisional application?*

Answer

There is no provision stipulating deadline to file the request of substantive examination of the divisional application. In practice, the Patent Office requires the request for substantive examination to be filed at the same time of filing the divisional application.

(22) 22. 特許出願の審査の種類について、Normal Substantive Examination と Full Substantive Examination とがありますか？これらの違いは何ですか？

22. *With respect to the substantive examination for a patent application, what is the difference between Normal Substantive Examination and Full Substantive Examination?*

Answer

In the patent law or government regulation concerning patent, there is no provision relating to the type of substantive examination.

In practice, full examination usually refers to examination where the examiner examines the application independently without referring to the examination result in other countries.

In practice, the normal substantive examination in DGIPR is a modified examination by referring to favorable examination result from certain countries. The examiner may suggest countries with corresponding grant or the applicant may propose the country with favorable results.

(23) 23. オフィスアクションに対応する際に、特許審査官と面談あるいは非公式な電話インタビュー等を行うことはありますか？

23. *Can an applicant have an opportunity face-to-face interview or informal telephone conversation with a patent examiner after receiving an office action and respond to it?*

Answer

There is no provision in Patent Law regarding face-to-face interview or hearings related to official actions. However, in practice, it is acceptable to request such an interview.

In practice, the IP consultant, in charge of handling the application and/or the Applicant can have an opportunity for a face-to-face interview or an informal conversation with the patent examiner.

(24) 24. 審査官との面談をする場合は、長官への申請が必要とのことですが、どのような場合に面談の申請は受理されますか？また、面談の記録は包袋に残りますか？

24. *We understand that an applicant shall submit a formal request to have a face-to-face interview with a patent examiner. Is there any requirement or specific reason for requesting interview? Is the minutes or contents of such interview recorded in a file wrapper?*

Answer

In practice, for the foreign application, we should submit a formal request to have a face-to face interview with a patent examiner by stating just general reasons - for example that we would like to discuss the official action. The minutes or a content of such interview is not recorded in the file wrapper.

(25) 25. 第49条の実体審査が36カ月以内に始まらない可能性はありますか。その場合は、どのように扱われますか。

25. *Is there any case wherein a substantive examination defined in Article 49 of the Patent Law is not started within 36 months? If there is the case, how is such an application treated? Is any action required for an applicant?*

Answer

Once the substantive examination request is filed at the DGIPR, the substantive examination typically starts within 36 months. The substantive examination may not commence until the six month publication period has expired.

We are aware of cases wherein the official action was issued more than 36 months.

【NO171-176】

(26) 171. 出願人が自発的に、他国(例えばアメリカ)で権利化されたクレームに合わせてその旨を知的財産総局に伝える手続きを行うと、早期な権利化に繋がるかどうか、ご経験からご教示下さい。

171. Please let us have your advice to register a patent earlier than normal schedule based on your experience. If an applicant voluntarily submit corresponding foreign patent (for example, US patent or Japanese patent) to DGIPR and inform his intention to amend the claims to comply with such granted foreign patent, the examiner progresses the case and issue patent certificate quickly?

Answer

To have a patent granted earlier than average time frame, it is advisable to file the application simultaneously with a request for substantive examination, and followed by filing PPH request. The PPH request should be accompanied with submission of examination result and corresponding foreign patent, and amendment of the claims to conform to the claims of the corresponding patent. In our experience, voluntary submission of corresponding patent followed by amending the claims to conform to the granted claims will definitely expedite the examination process.

To further expedite the prosecution, it is also advisable to file a request for accelerated publication of the application sometime during the formality stage.

(27) 172. ベストモード記載要件は拒絶理由となりますか？また、記載要件は無効要件となりますか？

172. There is a provision for written description requirement of "Best Mode" in Indonesian Patent Law. Can it constitute a reason for rejection of the application or the reason for invalid the granted patent?

Answer

The Indonesian regulation do not require "best mode" to be written into the specification. As such, this is not a requirement.

Under the Patent Law, the specification must include description of the invention, which contains complete explanation on how to practice the invention. Further, under the Government Regulation No. 34 of 1991, the description must explain at least one way to practice the invention.

In practice, the Indonesian specification is divided into sections:

- (a) Title of invention
- (b) Technical field of invention
- (c) Background of invention
- (d) Summary of invention
- (e) Brief description of drawings (if any)
- (f) Detailed description of invention
- (g) Claims
- (h) Abstract

The so-called "Best Mode" in Indonesia is usually covered in the section "Summary of Invention".

Given the above, sometimes, in practice the examiner may issue an objection on the lack of clarity in the invention.

(28) 173. 特許請求の範囲の記載形式について、ジェプソンクレーム、マーカッシュクレーム、ミーンズ+ファンクションクレームは記載可能か？また、権利解釈上の決まり事はありますか？

173. Please let us confirm the form of patent claims which are acceptable to DGIPR. Are "Jepson-type claims", "Markush claims" and "Means plus Function claims" acceptable for DGIPR? Are there any specific rules or case law for claim construction in the patent infringement litigation?

Answer

There is no provision in Patent Law specifically stipulating concerning the form of patent claims which are acceptable to DGIPR.

The Government Regulation no 34/91, Art 25 refers to one part and two part

claim formats. The two part claim is similar to the Jepson-type claims. Both types of claim formats are acceptable.

For Markush claims, in practice, this type of claims sometimes receives objections from the patent examiner. The examiner sometimes requires the applicant to narrow down the scope of invention to the extent of the embodiments of invention disclosed in the description. This claim should be supported by the description (in the experimental data, examples disclosed in the description)

For means plus function claims, in practice, we are not aware of any objections issued for this type of claim.

(29) 174. クレームの従属形式についてルールをご教示下さい。また、~~小特許においてはクレーム数の制限はありますか？~~

174. *Please let us know about a rule for dependency of the claims. For example,*

Answer

In practice, multiple dependencies are acceptable in DGIPR

(30) 175. 小特許におけるクレーム制限はありますか？

175. *Is there any limitation for the number of claims of "simple patents (petit patent)"?*

Answer

According to Art 105 of Patent law, a simple patent shall only be granted for one invention. According to the Elucidation, one invention means the application should contain 1 product or 1 device (tangible product). However, it may comprise a number of claims. There is no limitation for number of claims of a simple patent. Normally it would comprise one independent claim.

(31) 176. 審査基準またはそれに準ずるものはありますか？

176. *Is there an "Examination Manual" for a patent examiner or something like that?*

Answer

Yes, there is internal examination guidance at the Patent Office, but it is not officially published.

IV. 年金について

(32) 28. 権利放置・放棄に伴い年金を納付しなかった案件について、年金不払いの督促がきます。この年金不払いであるとする法的根拠を教えてください。

28. *As you know, we are receiving a reminder for annual fee payment from Indonesian Government for a patent we did not intend to maintain. Please let us know the legal basis for Indonesian Government (which ministry?) to request a patent owner to pay three years annual fees bore eflgal lapse of the patent.*

Answer

The Indonesian Patent law provides that unpaid annuity remains payable notwithstanding that the patent has lapsed.

Rationale and basis for such demand - Article 18 of the Patent Law provides some rationale for this payment - it is for the administration of the patents; and in Article 115's elucidation clarifies the patent would be deemed cancelled from the end of the third unpaid anniversary - which means that the Patentee has already enjoyed three years of protection despite non-payment.

Article 18 of Patent Law

For the administration of Patents and recording of licenses, the Patent Holder or Patent licensee shall pay an annual fee.

Elucidation: Annual fee is the fee payable by the Patent Holder regularly on annual basis. In some countries, such fee is called maintenance fee.

Article 115 of Patent Law

(1) If in three consecutive years the patent holder fails to pay the annual fee as described in Article 18 and Article 114, the Patent shall be declared

cancelled from the last date of the third year the payment should have been made.

Elucidation: The period of three (3) years is meant to give the Patent Holder enough time to develop the sustainability of his or her Patent. A cancellation of a Patent due to failure to pay the annual fee shall be informed in writing by the Directorate General to the Patent Holder. The notice will indicate the date the Patent expires as provided by this Law. The annual fee to be paid in the **three (3)-year period shall remain payable by the Particular Patent Holder.** (Emphasis added)

(33) 29. 貴所においては、このような督促が来た場合、権利者に対してどのようなアドバイスをしておこなっていますか？また、そのようにアドバイスする理由を教えてください。

29. *How do you advise your client with respect to such a request? Please let us know your view with its reason.*

Answer

For patents where you have already received a demand letter, we recommend to pay.

For the patents which you have not received a demand letter but you no longer wish to maintain, we recommend filing a request to cancel the patent. This is to minimize the payment obligation because you could be liable for up to three year's unpaid annuity before the patent is deemed cancelled. We understand it may not be an easy decision whether to file request cancelling a patent. Such decision would probably have to take into account:

- The patent holder's current and future business activity in Indonesia,
- The competitors' business operation and patent filing activity.

We are aware that certain patent holders from various countries settled the debt because they were concerned that this might affect their relationship with the Patent Office and in turn affect the treatment of their pending applications. These companies usually have significant filings at the patent office. Other motivations for paying - these companies have significant investment in Indonesia and they do not wish to be exposed to possible adverse publicity nor take the risk of having their assets seized by the KPKNL or exposing their staff to harassment.

The responsibility to recover the outstanding annuity is now handed over to the KPKNL or Kantor Pelayanan Kekayaan Negara dan Lelang is State Assets and Auction Services Office.). They are the debt recovery unit of the government. The KPKNL is interviewing local agents of the defaulting patent holders to see how the debt recovery can proceed further. In reality, the KPKNL may not be able to do very much against a foreign patent holder at least for now, but note the risk of continuance to ignore demand discussed under next section. We understand that the KPKNL intends to target foreign patent holders with local business interests and with big investments in Indonesia.

It is a legal obligation to pay. Before paying, it is advisable to verify the payment with the record section of Patent Office because the demand letters are based on data from the finance section of the Patent office and there may be discrepancies.

(34) 30. 特許法第 115 条第 1 項に関して、登録時に費用納付を行わなかった場合に、登録は取り消されますか？あるいは、登録費用の納付期限から 3 年目までは、特許は存続していることになるのですか？

30. *If an applicant does not pay some official fee (if any) and the annual fees based on Article 115(1) of Patent Law at the timing of issuance of patent certificate, is the registration of the patent canceled? Or is the patent effective for three years from the deadline of the payment for issuance fee (or the date of issuance of Patent Certificate), without payment?*

Answer

In 2014, the DGIPR made amendments to the official fee based on the new Government Regulation No. 45/2014 concerning the types and the tariffs of non-tax state revenue, applicable within the Ministry of Justice and Human Rights. For applications filed after the enactment of the above regulation (July 3, 2014) there is no official fee payable to collect the certificate once granted.

If the applicant does not pay the official fee and annuity fee, the patent is not cancelled up to the deadline of payment of the third annuity fee (*Article 115(1)*).

The patent is therefore effective within three years up to the deadline of payment of the third annuity fee (*Article 115(1)*).

【2】先使用に関する質問

I. 関連法、規則及び実施行為について

(35) 31. 先使用証明手続きのための政令がございましたら、その内容(例えば、外国での行為、輸出入が先使用に該当するかどうか等)や英訳文をご教示ください。また、第 15 条にいう「先使用者証明書」取得のための手続きを教えてください。

31. Please let us know the summary of the specific law or regulation for the procedure to secure prior use of the patent inventions under Article 13 in the Patent Law, if any. In addition, please explain the process to request for "recognition as a prior user" under Article 15 in the Patent Law.

Answer

Up to present, there is no implementing regulation for the procedure to secure prior use of a patent invention under Article 13 of the Patent Law.

Based on Article 15 of the Patent Law, any party who implement an invention which has been applied for a patent by other party can file a request for "recognition as a prior user" at the Directorate General. The request must be accompanied by evidence that the implementation is not performed by using any information or material from the invention which is being applied for patent.

We do not believe there is a request for the prior user as there are no Implementing Regulations to date.

(36) 32. もし制定がまだでしたら、制定される見込みや時期がおわかりでしょうか。また、政令が決まるまで、どのような手続きを経て制定されるのかご教示ください。さらに、先使用申請手続きのための政令案等ご存知でしたら、概要、骨子のみでも教えていただけないでしょうか。

32. If there is no specific law or regulation for request for "recognition as a prior user" at present, do you know information about any plan or timing for such law or regulation. If you have a draft of the law or regulation, is it possible to explain a backbone or a summary thereof?

Answer

There is no information about any plan to issue a draft implementing regulation on recognition as a prior user.

In the proposed patent law, there is no amendment in the provisions related to recognition as a prior user. The provisions related to recognition as a prior user in the proposed law still require the issue of implementing regulation to cover requirements and procedures for obtaining recognition as a prior user.

II. 実施行為について

(37) 33. 先使用権が認められるためには、インドネシアで出願をしていない善意の使用者による実施行為が該当するとの認識ですが、実施行為に、外国での実施は含まれますか。それともインドネシア国内のみでの行為のみでしょうか。

33. *We understand that "recognition as a prior user" is applied for a good faith third party who exploits an Indonesian granted patent. Is it also applied for a party who exploits a patented invention in a foreign country, or the exploitation should be limited only in Indonesia?_*

Answer

There is no provision under the prevailing law that gives limitation on whether the exploitation of the invention applies only to Indonesia or to foreign countries too.

(38) 34. 外国での実施行為に対してインドネシアの先使用権が認められる場合、当該先使用権を主張するために必要な書類、および当該書類を用いた手続きをそれぞれ具体的に御教授ねがいます。

34. *If the exploitation in a foreign country is acceptable for requesting "recognition as a prior user", please let us know the required documents, evidences and a procedure.*

Answer

See above.

(39) 35. 特許法第16条、19条には輸入が特許権者の権利とされています。先使用において、輸入行為は実施として認められますか。また、輸出行為についてはいかがでしょうか。

35. *According to Article 16 and 19 in the Patent Law, a patent owner has a power to import a patented product. Does "Importation" correspond to a prior use in view of "recognition as a prior user"?*

Answer

There is no provision under the prevailing Patent Law that specifically regulates this issue.

Ⅲ. 先使用証拠確保の手法について

(40) 36. 日本では公証役場で確定日付という手続きがあります。その手続き時点にて、その書面が存在した証明となり、先使用証拠として有効と考えられています。インドネシアにおいても同様に書面存在の日付を確定するための手続きはありますか。確定するための手続きがありましたら、具体的にご教授ねがいます。

36. *We have a system that notary authorizes the date when a specific document, for example production record, exists, in Japan, and a company can secure the evidence for its prior use. In Indonesia, do you have any system to secure the evidence for prior use? If any, please let us know the procedure.*

Answer

Article 15 only stipulates that request for recognition as a prior user must be accompanied by evidence. Due to lack of implementing regulation, it is not clear on how to secure evidence for prior use.

(41) 37. 先使用に関し、民法規定等に関連する条項はありますか。あれば、具体的に条項番号などをご教授ねがいます。

37. *Do you have any sections in a civil law or regulations with respect to "recognition as a prior user"? If any, please identify the law or regulations and its article numbers.*

Answer

The prior user defense requires registration of prior use with the DGIPR. However, there are still no implementing regulations to enable such recordation.

(42) 38. 上記の書面存在の日付を確定するための手続きがインドネシアに存在する場合、当該手続きは、日本と同じように先使用証明のための有力な証拠となると考えられないでしょうか。

38. *If you have a procedure to secure the date or term of the prior use, can it be an evidence to prove the "recognition as a prior user".*

Answer

We can seek the notary public help to preserve the evidence. As to whether it is effective defense, we still cannot be certain. To improve the prior user position, it is also advisable to use prior user evidence to challenge the patent novelty assuming that prior use is disclosed.

- (43) 39. 日本では電子書面に日時を記載するタイムスタンプ押印が民間により行われてい
ます。インドネシアでもタイムスタンプをした書面が、その時点で存在した書面として有効と
考えられますか。

39. *In Japan there is a private service provider to submit a time stamp, record of the modified date of electric documents saved in the computer system. Do you think electric file documents are acceptable as an evidence for prior use?*

Answer

Unfortunately, we do not recognize timestamps system in our judicial system. Therefore, we believe that electric file documents are still unacceptable as evidence in our judicial system.

- (44) 40. 事業実施の証拠保全方法について、インドネシアにおいて、公証人に証拠保全を依
頼する場合、公証人を介して証拠保全を行う方法として推奨する方法があればご教授
ねがいます。

40. *As for preservation of an evidence of exploitation of the business, please let us have your advice for a procedure to request a notary the preservation of evidences.*

Answer

Unfortunately, we do not have any procedure on how to request a preservation of evidences by a Public. A legalization of a document by a Public Notary is only made for the signature, and not about the accuracy of the contents of the document.

How to legalize a foreign document to be used as evidence in Indonesia? – it should be legalized at the Republic of Indonesia Representative in the document origin state. This means that any legalized document from the Embassy or the Consulate General will be acceptable.

The Legal grounds of this are as follows:

- Law No. 1 of 1982 on Ratification Vienna Convention on Diplomatic Relations and Optional Protocol to the Vienna Convention in Diplomatic Relations Concerning Acquisition of Nationality, 1961 and Ratification Vienna Convention on Consular Relations and Optional Protocol to the

Vienna Convention on Consular Relations Concerning Acquisition of Nationality, 1963.

- Law No. 37 of 1999 on Foreign Relations.
- President Decision No. 108 of 2003 on Representative Organization of Republic of Indonesia in Foreign Country.
- Minister of Foreign Affairs Regulation No. 09/A/KP/XII/2006/01 on General Guidelines on Procedures for Foreign Relations and Cooperation by Local Governments.

(45) 41. タイムスタンプを含め、公証人以外の方法で、先使用权確保を目的に証拠保全を行うための有効なアプローチがあればご教授ねがいます。

41. *Please let us know the effective approach for preservation of an evidence to secure our prior use other than authorization by notary.*

Answer

Unfortunately, there is no other effective approach for preservation of evidence beside to the procedure as mentioned in the above No.40. As long the document was notarized and legalized according to the above mentioned procedure, there will be no issue about the credibility and admissibility of the evidence. The court will simply rely on the legalization of the document by the Embassy or the Consulate General of Republic of Indonesia.

IV. その他

(46) 42. 先使用权について争いとなった事例があったらご教示ください。特に外国企業が当事者となった事例があればご教示ください。

42. *Do you know any case wherein the "prior use" is an issue, especially the case related to a foreign company?*

Answer

We are not aware of parties relying on prior use as defense. It is necessary to register and be accepted by the DGIPR as a prior user. However there is still no implementing regulation to enable such a recordation.

(47) 43. 営業秘密の保護について：先使用は製造ノウハウ等、営業秘密に該当すると考えます。インドネシアでは、営業秘密法がありますが、どのように保護されるのでしょうか。営業秘密法に基づき、営業秘密を守ることができる場合、営業秘密に該当する条件をご

教授ねがいます。

43. *About trade secret under Law No. 30 of December 20, 2000: The prior use issue is related to trade secret including know-how of the process in the factory and there is a Law of trade secret in Indonesia. Please let us know how trade secret is protected? Please show us the conditions for protecting a company's information as a "trade secret".*

Answer

In accordance to trade secret definition as stated in Law No. 30 year 2000 concerning Trade Secret, to be protected as a trade secret, the following requirements must be satisfied:

- The trade secret is a secret in that it is only "known by a particular party or is not known by the general public";
- The trade secret has economic value in that it will create for its holder advantages over those who do not hold or use it; and
- The owner of the trade secret maintains its secrecy through proper efforts with appropriate company procedures to protect such trade secrets.

【3】 その他の事項

I. 特許データベースについて

- (48) 44. インドネシア知的財産総局のデータベースへの収録期間、収録率を教えてください。また、明細書全文にアクセス可能ですか。Web 上で公開されているデータベースと、審査官が利用する庁内のデータベースは同じですか。また、今後のデータベース作成(登録公報へのアクセス、英語版等)のご予定をお聞かせください (=No.54)

44. *Please let us know the term and coverage of patent database provided by DGIPR. Is it possible to access to the full specification? Does an examiner in DGIPR use the same database disclosed in the web-site? Please let us know the DGIPR's plan to release or update a patent database, for example, access to the granted patent publication or English version of the database.*

Answer

The online patent database (www.dgip.go.id) provided by DGIPR includes:

- Publication A
- Bibliographical data, and abstract

It does not have information relating to the claims and full specification.

This online database may also not be complete or updated.

The examiners in DGIPR use their internal database i.e. IPAS which has wider scope since it also has information relating to the claims and provides full specification details.

(49) 45. 商標データベースは、審査官以外にも開放されていますか。例えば法律事務所(特許事務所)が利用可能ですか。(=No.55)

45. *The Patent database in DGIPR is available for a person other than examiners? Can Law firms use the database?*

Answer

The internal patent database is not available for a person other than examiners.

(50) 64. インドネシアに出願されている特許について、国内出願、PCT ルートの出願含めて公報は発行されておりますでしょうか。発行されていない場合、どのような形で公開されるのでしょうか。

64. *Are the Indonesian domestic patent applications or PCT route patent applications published by DGIPR? If not, how can the patent applications be available for public?*

Answer

All applications filed will be published by DGIPR to allow possible opposition by third party. There is no separate publication between domestic application and PCT application.

(51) 65. 特許出願(優先日)から公開まで、又は特許登録からその公開までに要している期間はどの程度でしょうか。また、PCT 出願の各国移行はどのように公開されますか。

65. *How long does it take for DGIPR from the priority date until patent publication or from the issue date of the granted patent until its publication? In addition, how are PCT route patent applications published after entering into Indonesia?*

Answer

DGIPR will publish a patent application within 18 months from the priority date of the application concerned. In practice, publication of a PCT national phase application usually takes place within 3-6 months since the application has practically been published during the international process

(52) 66. 登録公報のデータベースを構築される予定はありますか。

66. *Does DGIPR have a plan to release a database for granted patent publications?*

Answer

Up to present, we are not aware of plan by the DGIPR to release a database for purely granted patent publication information.

(53) 67. データベースの英語版を構築される予定はありますか。

67. *Does DGIPR have a plan to release a database in English version?*

Answer

Similarly, up to present, we are also not aware of any plan by the DGIPR to release a database in the English version.

(54) 68. (申請により)包袋を閲覧することは可能ですか。

68. *Is a file wrapper for each patent application available for any person or an interested party?*

Answer

File wrapper of a patent application is treated as confidential information by the DGIPR. Therefore, we are not able to obtain any file wrapper of a patent application unless we are the proxy of the application.

(55) 69. 包袋閲覧(複写)をサービスとして行っている事務所、調査会社はありますか。

69. *Does a law firm or a search/investigation company provide a service to obtain a copy of a file wrapper?*

Answer

As explained above, file wrapper of an Indonesian patent application is not accessible except for the proxy of the application.

(56) 70. 一般公開されている LADI HKI 以外に、審査官が調査時に用いる独自のデータベースはありますか。ある場合、どのような内容が収録されているのでしょうか。また、庁職員以外の第三者が、そのデータベースを使うことは可能ですか。

70. *Does DGIPR have a database for an examiner to search for a prior publication*

or application, other than LADI HKI which is in the public domain? If the answer is yes, please let us know what kind of information included in the database? And can anyone other than DGIPR examiners use the database?

Answer

Yes, DGIPR has their own internal database named IPAS. This database contains all information and documents of all patent applications filed in Indonesia. To our understanding, apart from the IPAS, DGIPR also has cooperation with other countries to share patent publications.

(57) 71. LADI HKI 以外にデータベースが庁内にない場合、審査官自身、又は特許事務所・調査会社等は、どのようにして先行技術調査、無効資料調査を行っていますか。

71. *If DGIPR has no additional database other than LADI HKI, how does an examiner perform his/her patentability search, and how does a law firm or a search/investigation company perform its search for invalidation of the patent?*

Answer

The examiner uses IPAS and other database to perform the search. If a law firm or an investigation company needs to perform a search for invalidation of a patent, a formal search request can be filed at the DGIPR. The official search is payable per subject matter, based on the Government Regulation No. 45/2014 concerning the types and the tariffs of non-tax state revenue.

II. 法制度について

(58) 46. 2002 年以降制定・改正された知的財産関連法案、及び施行規則はありますか。あればそのリスト、及び内容の概略を教えてください。(=No.56)

46. *Is there any amended law or rule with respect to intellectual property after 2002? If there is, please provide the list thereof and let us have a summary of each one.*

Answer:

No.	Patent - Law / Regulation
1.	Government Regulation No. 27 of 2004 on Procedures of Patent Exploitation by Government
2.	Presidential Decree No. 83 of 2004 on Patent Exploitation by

	Government for Anti Retroviral Drugs
3.	Presidential Decree No. 6 of 2007 as Amendment of Presidential Decree No. 83 of 2004
4.	Presidential Regulation No. 76 of 2012 on Patent Exploitation by Government for Antiviral and Anti Retroviral Drugs

No.	Copyright - Law / Regulation
1.	Joint Regulation of Ministry of Law and Human Rights of the Republic of Indonesia (No. 14 of 2015) and Ministry of Communication and Information of the Republic of Indonesia (No. 26 of 2015) on the Course of Actions to Take Down Copyright Infringing Contents
2.	Law No. 28 of 2014 on Copyrights
3.	Ministerial Regulation No. 29 of 2014 on the Application Procedures and Issuance of Operational License and Evaluation of Collective Management Institution
4.	Government Regulation No. 29 of 2004 on High Technology Production Facilities for Optical Disc
5.	Presidential Decree No. 74 of 2004 on Ratification of WIPO Performances and Phonograms Treaty

No.	Industrial Designs - Law / Regulation
1.	Government Regulation No. 1 of 2005 on the Implementation of Law No. 31 of 2000 on Industrial Designs

No.	General
1.	Government Regulation No. 45 of 2014 on Types and Tariffs of Non-Tax State Revenue Applicable to the Ministry of Law and Human Rights
2.	Ministerial Decree No. M.HH-01.HI.07.02 of 2015 on Management Guidelines of Criminal Investigation in the field of Intellectual Property Rights

(59) 72. 著作権登録の具体的な内容と、権利行使の手続を教えてください。【No.61】

72. *Please let us know contents of the copyright registration, and the procedure for enforcement of the copyright.*

Answer

Copyright protection arises when the work is reduced into permanent form. Although copyright protection does not depend on registration, registration helps to establish ownership over a particular work's copyright.

Enforcement of copyright can be done through criminal procedure by filing a criminal complaint or by filing civil action in the commercial court. Civil infringement action is rare because of the difficulty in getting the court to issue significant damages award and also because the interlocutory injunction procedure is considered unworkable. So far, the only application for interlocutory injunction was denied. In the case of infringing material on the internet, an application can be made for such sites to be blocked.

(60) 73. ライセンス契約登録の手続きの手順、及びどのように利用されているかを教えてください。また、通常実施権の許諾に際しても登録・公告は必要でしょうか。ライセンス契約の登録を怠った場合の不利益はありますか。

73. *Please let us know the procedure for registration of license agreement. How does the authority use the record? Is it necessary to register and publish non-exclusive license agreement? Is there any risk or demerit, if a company fails to register and publish its license agreement?*

Answer

It is provided in article 73 that license agreement shall be recorded by the minister in the general register of license. However the detailed procedure is still not implemented. The advantage of a recording a license is to be able to assert the license against an assignee of the copyright since it is provided in the article 83 of the Copyright Law that

- (1) A licensing agreement must be recorded by the Minister in the general list Copyright License agreement with the charge.
- (2) A licensing agreement which does not comply with the provisions referred to in Article 82 shall be recorded in the public register of the licensing agreement.
- (3) If the license agreement is not recorded in the public list referred to in

paragraph (1), the license agreement has no legal effect against third parties.

(4) Further provisions on the procedure for registration of a licensing agreement as referred to in paragraph (1) is regulated by the Government.

(61) 74. 特許法第 73 条にいう施行規則は制定されていますか。制定されていればその内容の概略を教えてください

74. *Was the Government regulation described in Article 73 in the Patent Law established and in effect? If the answer is yes, please let us know the summary thereof.*

Answer

No

(62) 75. 特許ライセンス・技術移転を規制する法律はありますか。

75. *Are there any laws or regulations with respect to the patent license or technology transfer?*

Answer

Patent license

License of patent is governed by Articles 69 to 73 of the Patent Law.

Restriction - Article 71 provides that the license shall not contain any term "either directly or indirectly, that may adversely affect the economy of Indonesia nor a restriction that may retard the ability of Indonesians to master and develop technology in general in respect of the Patented Invention in particular"

Know-how transfer

Transfer of know-how is governed by article 6 of Trade Secrets Law.

Restriction - Article 9 requires that the license agreement "shall not contain any provisions that may adversely affect the economy of Indonesia, nor contain any provisions that may create unhealthy competition as provided in the prevailing laws and regulations"

Article 8 provides that the license shall be recorded at the patent office; but there is still no implementing regulation to enable recordation.

Out-right transfer is provided under Article 5. Article 5(3) requires the assignment to be recorded but there is still no implementing regulation enabling recordation.

III. 強制実施権について

(63) 47. 強制実施権の制度及び現状を教えてください。実施希望者側から申請する手続があるのでしょうか。あるいは政府主導で設定されるのでしょうか。(=No.57)

47. *Please let us know the rule or current situation about "compulsory license". Is there any system for a licensee (practitioner) to request DGIPR (or Court?) a compulsory license? Or Indonesian Government identifies the patent which should be licensed to a third party and seek for a practitioner?*

Answer

There are two frameworks for compulsory license

- a. Compulsory license issued by the DGIPR on application of a third party under provided in Articles 74 to 87;
- b. Implementation of patent by Government under Chapter VII of Patent Law Article 99

Application still cannot be made for compulsory license by a third party because the implemented regulations have not been passed.

With regard to Exploitation of patent by Government Exploitation of patent by Government, a total of two government decrees have been issued and they are for a total of three HIV drugs.

(64) 48. 強制実施権の場合、特許権者への実施料額はどの程度が設定されるのでしょうか。(=No.58)

48. *In a case of "compulsory license", how is the license fee (royalty) to a patent owner decided?*

Answer

Compulsory license

Royalty is determined by the Director General of intellectual property rights. The only guidance we get from the patent law is in article 78(3): "The sum of the royalty is determined with a view of the procedures commonly applied in a Patent license agreement or other such agreements."

Implementation of patent by Government

In the case of Implementation of patent by Government, it is provided that "exercise of a patent shall be done by giving patent holder a reasonable reward".

(65) 49. 特許権者からの不服申し立て制度はありますか。また、実際に不服の申し立てはありましたか。(=No.59)

49. *Is there any system for a patent owner to file a complaint with respect to the "compulsory license"? Was any such a complaint filed for the previous compulsory license?*

Answer

Compulsory license

It is provided in article 76 (2) that the Director General shall take into account "considerations of the opinions given by the related agencies and parties, and the patent owner". The patent owner therefore has an opportunity to file reasons for its objections. As to the specific procedure, there is still no implementing regulation for this. Note, there is no provision for appealing against the decision of the Director General.

Exploitation of patent by Government It is provided in article 102, that the decision of the government is final. However the patent owner may still file complaint to the commercial court if it does not agree with the amount of reward determined by the government.

(66) 50. 特許権者(又はそのライセンシー)が、該当する製品をインドネシアにおいて製造・輸入・販売している場合であっても強制実施権の対象となるのでしょうか。(=No.60)

50. *In the case that a patent owner or its licensee already produces, imports or sells a patented product in Indonesia, is there any possibility that "compulsory license" is required by a government?*

Answer

Yes. The main consideration is that the government considers that patent "is urgently needed in the interest of the public" article 99.

The following drugs were available in Indonesia when the government issued decision that the respective patents be subject to Exploitation of patent by Government.

No.	Active Ingredient	Patent owner	Patent ID No.	Implementation Period
1	Efavirens	Merck & Co,	ID 0005812	Patent expired on

		Inc		August 7, 2013
2	Abacavir	Glaxo Group Limited	ID 0011367	Until patent expires on May 14, 2018
3	Didanosin	Bristol - Myers Squibb Company	ID 0010163	Until patent expires on August 6, 2018
4	Combination of Lopinavir and Ritonavir	Abbot Laboratories	ID P0023461	Until patent expires on August 23, 2018
5	Tenofovir	Gilead Sciences, Inc	ID 0007658	Until patent expires on July 23, 2018
6	Combination of Tenofovir and Emtricitabin Combination of Tenofovir, Emtricitabin and Evafirenz	Gilead Sciences, Inc	ID P0029476	Until patent expires on November 3, 2024

(67) 76. 第 17 条にいう「実施義務」に期限等は設定されておりますでしょうか。実施義務に違反すると、強制実施権の対象となりますか。

76. *Is there any deadline for obligation according to Article 17 in Patent Law? Can it be a candidate for "compulsory license" if a patent owner does not comply with the obligation?_*

Answer

No, there is no deadline to comply with article 17. There is no consequence provided for failure to comply with article 17. We are not aware that any patent has been revoked for failure to comply with article 17. The fact that a patent is not implemented in Indonesia can be a factor for compulsory license; however such a factor is implicitly provided under Article 99 "urgently needed for the interests of the general public, the Government may exercise the Patent by itself." We are not aware that the government cited Article 17 as a rationale for invoking Government use provision under Article 99.

(68) 77. 2012 年にいくつかの医薬品の強制実施権について報道されておりますが、実際に強制実施権に基づく医薬品提供はありますか。2012 年以降、強制実施権の対象となる医薬品は増えていますか。

77. *Some pharmaceuticals are listed as a candidate for "compulsory license" in 2012. Is there any pharmaceutical products launched by such "compulsory license"? Does the number of pharmaceuticals increase after 2012?*

Answer

Yes, there are some generic products registered under the name of Kimia Farma, a local company assigned by the government with regards compulsory liscence:

- Efavirenz (patent has been expired since August, 2013)
There are 2 products registered in the name of Kimia Farmaat NAFDC (BPOM) containing Efavirenz, i.e.: Efavirenz and Eviral
- Tenofovir (patent will be expired on July 23, 2018)

There is 1 product registered in the name of Kimia Farma.

We are not aware of any new degrees relating to pharmaceuticals after 2012.

(69) 78. 現在でも、抗 HIV 薬等の医薬品について、患者が高価なため患者が入手できない、特許権者が上市していないなどの問題がありますか。

78. *Are there any problems with respect to availability of pharmaceuticals for people in Indonesia, for example, "the pharmaceuticals are too expensive", or "A patent owner or innovative company who sells the drug in foreign country does not do a business in Indonesia"?*

Answer

Indonesia has several problems with respect to the availability of pharmaceutical products, such as:

- The price of pharmaceutical products, this also relates with the purchasing power and the limited budget
- The distribution/availability of the pharmaceutical products in particular in rural areas

(70) 79. 今後も強制実施権の行使する予定はありますでしょうか(医薬品に限らず)

79. *Does Indonesian government have a plan or idea to perform "compulsory license" in the future, not limited in the field of pharmaceuticals?*

Answer

Under the prevailing government regulation, other than in the field of pharmaceuticals, "compulsory license" also includes national defense. However, there is no information on any plan to perform "compulsory license" in this field.

IV. 特許期間延長について

(71) 51. 医薬品許認可当局が要求する臨床試験、申請に要した期間について、医薬特許存続期間を延長する制度はありますか。また、今後制定される可能性はありますか。(= No.61)

51. *Is there any rule for "Patent Term Extension" for a patent covering pharmaceutical product (drug) in order to recover the term required for regulatory submission, for example, clinical trials or examination in The National Agency of Drug and Food Control? If the answer is "no", is there any plan or discussion for the rule?*

Answer

There is no rule for "Patent Term Extension" for a patent covering pharmaceutical product (drug). There is no information on any plan or discussion for the rule.

(72) 80. 医薬品承認機関は、特許の有無を確認して審査をおこないますか。

80. *Is the National Agency of Drug and Food Control check existence of a third party's or applicant's own patent, when it examines an approval of a pharmaceutical product?*

Answer

Yes, they do. In practice, during the examination of drug approval, NADFC (BPOM) checks the existence of patent through the documents provided by the registrant. Related with patent checking, in particular for registration of the patent-related drugs (drugs which contains patent-protected active ingredients or new drugs which the registrant is not the innovator), NADFC requires patent-related documents as follow:

- Statement regarding the related patent
- Search Result issued by DGIP
- Self-assessment related with patent

(73) 81. 医薬品承認機関の審査において、ジェネリック医薬品の申請は、フルの臨床試験は不要で、Bioequivalence を示せば許可されますか。

81. *In the approval procedure of the National Agency of Drug and Food Control, is generic drug approved without (full) clinical trial if it shows bioequivalency with a innovator's original product?*

Answer

Yes, it is.

(74) 82. 上記の質問に関して、許可される場合、イノベーター医薬品の申請内容(臨床データ)に対する「データ保護」の制度はありますか。

82. *If your answer is yes in question NO.81, is there any rule to protect the data, such as results of clinical trials, submitted by Innovator Company?*

Answer

There is no specific rule to protect clinical trial data submitted by Innovator Company. However, it is stipulated in Article 23 (5) of the Head of NADFC (BPOM) Regulation No. HK.03.1.23.10.11.08481 of 2011 about Criteria and Guidance of Drugs Registration that registration documents are confidential and are issued only for the purpose of evaluation by the authorities.

V. 職務発明について

(75) 52. 現地企業における、職務発明の承継、発明報奨についての運用の実態を教えてください。(=No.62)

52. *Please let us know a practice or a situation with respect to a procedure for assignment of an invention from an employee to a employer, Indonesian company, and a consideration for such assignment.*

Answer

- Employer owns the invention if
 - the invention is made in an employment relationship or
 - the employee has used data and or facilities available at his work even though the employee is not required to exercise any inventive

activity

- Employee entitled to reward considering economic benefits from invention
 - Paid in lump sum, percentage, a combination of both, gift or bonus, other any other forms agreed between the parties

Related with formality requirement:

Common practice – Assignment from inventor to employee.

If not, provide employment agreement (original or notarized copy) – rare

(76) 83. インドネシア国内で生じた発明を、最初にインドネシアで出願する必要は無いという理解でよろしいでしょうか。

83. *We understand that we do not need to file a patent application in Indonesia, first, for an invention made in Indonesia. Is our understanding correct?*

Answer

Yes, there is no requirement in the prevailing Patent Law to file a patent application in Indonesia first for an invention made in Indonesia.

VI.免責について

(77) 53. 第 16 条第 3 項の免責(試験・研究)の範囲に企業の R&D は含まれますか?(= No.63)

53. *Is "Research and Development activity" by a company included in exemption for "research", "experiment" or "analysis", based on Article 16(3) in Patent Law?*

Answer

Article 16 (3) provides exemption for education, research, experiment or analysis on the basis that such actions do not harm normal interest of the patent holder. There is an ambiguity whether the company can be included in the exemption.