

## **Study Guidelines**

by Ari LAAKKONEN, Reporter General Ralph NACK and Guillaume HENRY, Deputy Reporters General Rafael ATAB, Johanna FLYTHSTRÖM, Linda LECOMTE and Lena SHEN Assistants to the Reporter General

## 2024 - Study Question

## Harmonisation of disclosure requirements and consequences of non-compliance

### Introduction

- 1) The laws of some jurisdictions require patent applicants to disclose prior art to the patent office, such as prior art which might be viewed as affecting the novelty and/or inventive step of a patent's claim(s).
- On one hand, such obligation increases the work involved in and therefore also the costs of filing patent applications. On the other hand, such an obligation can serve the public interest because it provides for a more effective patent application examination if the patent office has the opportunity to consider and evaluate more information and material relevant or potentially relevant to patentability.

# Why AIPPI considers this an important area of study

- 3) Harmonisation of disclosure requirements by jurisdictions globally, especially in light of the changing landscape regarding WIPO's proposed disclosure requirements in the draft treaty on "Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources" (see below, paragraph 14) can be helpful to patent applicants, especially those intending to file in multiple jurisdictions.
- 4) It would be especially useful to consider whether a single harmonised standard could apply in relation to what is required from the applicant for any disclosures. For example, should the applicant simply be required to list prior art already known to be potentially relevant even if it is of peripheral relevance, and should the applicant be required to carry out a search to locate prior art of potential relevance? Should the applicant be required to locate/find and review the prior art already in its possession to assess its relevance and if not, how else would the applicant form a view as to what prior art should be submitted? Is prior art accessible to and known to the



- applicant (e.g. specific publications in a library, such as those published by the inventor previously) to be regarded as subject to a disclosure requirement?
- 5) It would also be useful to have a single harmonised standard for relevance. Should the applicant be required to disclose only prior art which is known with a high degree of certainty to be of relevance, or perhaps just prior art which is in the same technical field (or technical classification category)? Should applicants be required to disclose only patent prior art, or *any* documentary prior art, or information in its possession regarding known prior uses?
- 6) Further, it would be beneficial to harmonise the consequences of non-compliance with disclosure requirements to assist with legal certainty, especially if the consequences of non-compliance are 'hard edged' in some jurisdictions.

#### **Previous work of AIPPI**

7) AIPPI has not specifically studied requirements for the disclosure of prior art for patent applications. Further, AIPPI has not studied if and what sanctions should apply in respect of non-compliance.

# **Scope of this Study Question**

- 8) The objective of this Study Question is to determine if and to what extent disclosure of prior art for patent applications should be mandated. This Study Question is not concerned with purely voluntary disclosures of prior art.
- 9) The effect of such duty of disclosure needs to be considered for each of the various stages of the life of a patent application and patent, including:
  - a) at the time of filing and during prosecution;
  - b) during a patent post-grant review in an IP Office, where an examination of the merits of a patented claim occurs;
  - c) during infringement and invalidity proceedings.
- One key issue is to determine, in case such disclosure requirements are desirable, what sanctions should apply for non-compliance with such obligations and what should be the consequences of non-compliance, *e.g.* revocation, non-enforceability with respect to specific infringers, etc.
- 11) This Study Question relates only to patents and utility models. Disclosure requirements for designs and other IP rights are outside the scope of this Study Question.

## **Discussion**

12) National and regional legislation in the area of disclosure requirements is particularly heterogeneous, and harmonisation currently exists only at a low level.



### TRIPs and WIPO treaties

- 13) Article 29 of TRIPs, "Conditions on Patent Applicants", states that: "(...) 2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."
- The World Intellectual Property Organization (WIPO), in its recent draft International Legal Instrument Relating to "Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources", introduces a disclosure obligation for entities seeking to apply for patents for inventions that are "materially/directly based on" genetic resources (GRs) and associated traditional knowledge (TK).

Indeed, Article 3 of the draft of the Treaty provides that:

- "3.1 Where the claimed invention in a patent application is [materially/directly] based on GRs, each Contracting Party shall require applicants to disclose:
- (a) the country of origin of the GRs, or,
- (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.
- 3.2 Where the claimed invention in a patent application is [materially/directly] based on Associated TK, each Contracting Party shall require applicants to disclose:
- (a) the indigenous peoples or local community that provided the Associated TK, or, (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the Associated TK.
- 3.3 In cases where none of the information in paragraphs 3.1 and/or 3.2 is known to the applicant, each Contracting Party shall require the applicant to make a declaration to that effect.
- 3.4 Offices shall provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for patent applicants to rectify a failure to include the minimum information referred to in paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect.
- 3.5 Contracting Parties shall not place an obligation on Offices to verify the authenticity of the disclosure.
- 3.6 Each Contracting Party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information."



The 193 WIPO member jurisdictions are expected to discuss and potentially adopt this new treaty on disclosure requirements in 2024. It is currently unknown if the disclosure requirement in the proposed treaty will be modified before the treaty is adopted.

## Regional/national legislation

- In the United States, there exists a duty to disclose information material to patentability. Specifically, 37 CFR 1.56(a) ("Rule 56"), states that there is a duty to disclose information material to patentability for each *pending* claim, until cancelled or withdrawn from consideration. Each of the persons substantively involved in the preparation or prosecution of the patent application owes this duty, e.g., each inventor, each attorney/agent preparing/prosecuting, an applicant, an assignee, etc. The consequences of not disclosing information material to patentability of a pending claims may amount to fraud, and the resulting patent can be revoked.
- 16) For the duty of disclosure in the United States, information material to patentability may include prior art cited in search reports of a foreign patent office in a counterpart patent application and background information. Rule 56 identifies information material to patentability as the following:
  - "(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
    - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
    - (2) It refutes, or is inconsistent with, a position the applicant takes in:
      - i. (i) Opposing an argument of unpatentability relied on by the Office, or
      - ii. (ii) Asserting an argument of patentability.
    - (3) A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability."



- Many other jurisdictions, whilst not requiring disclosure of all known information material to patentability, do require disclosure of counterpart or related patent applications in foreign jurisdictions. For example, the India Patent Act, 1970, Section 8, requires information concerning such applications which is known to be disclosed to the Patent Office. Further, the Patent Office can request that the applicant provide information relating to objections, if any, regarding novelty and patentability of the invention, including search or examination reports from other jurisdictions on related or "substantively the same invention" patent applications, etc.
- 18) In Israel, applicants are required to submit known prior art information, upon a formal request from the Patent Office.
- 19) In South Africa, applicants are not specifically required to disclose prior art to the Patent Office, however, the applicant is under a duty to ensure that the patent application is maintained in allowable form. The grounds for revocation of a South African patent includes the situation in which the applicant made a false statement that is material to patentability during prosecution, or if the applicant knew or should have known that their statement was false.
- 20) In the European Patent Office, during prosecution, an applicant can be required to provide details of prior art cited by other patent offices on corresponding patent applications. Article 124 of the European Patent Convention (EPC) provides that:
  - "(1) The European Patent Office may, in accordance with the Implementing Regulations, invite the applicant to provide information on prior art taken into consideration in national or regional patent proceedings and concerning an invention to which the European patent application relates.
  - (2) If the applicant fails to reply in due time to an invitation under paragraph 1, the European patent application shall be deemed to be withdrawn."

### Rule 141 of the EPC Implementing Regulations provides that:

- "(1) An applicant claiming priority within the meaning of Article 87 shall file a copy of the results of any search carried out by the authority with which the previous application was filed together with the European patent application, in the case of a Euro-PCT application on entry into the European phase, or without delay after such results have been made available to him.
- (2) The copy referred to in paragraph 1 shall be deemed to be duly filed if it is available to the European Patent Office and to be included in the file of the European patent application under the conditions determined by the President of the European Patent Office.



- (3) Without prejudice to paragraphs 1 and 2, the European Patent Office may invite the applicant to provide, within a period of two months, information on prior art within the meaning of Article 124, paragraph 1."
- A policy consideration that clearly emerges from the above examples is that requiring disclosure of potentially relevant prior art may assist in improving the quality of granted patents, because the scope of claims can be better tailored to not cover known prior art.
- The improvement of patent quality is a current focus of leading Patent Offices. Patent quality flows through into the value of a patent as an asset (higher quality patents are more predictably enforced and therefore worth more), as well as improved legal certainty for third parties (it is easier to ensure that practising the prior art is clearly does not infringe if such prior art is required to be disclosed).
- These objectives apply to some degree in relation to GRTK disclosures too, although the benefits are debatable in the case of e.g. ancient treatment methods that are no longer in active use, and in respect of which a public prior user defence to infringement is unlikely to be raised.
- Another policy objective that is reasonably clear is to prevent fraudulent patent applications, made knowingly, to patent that which is old. This again assists with patent quality.
- A further issue arises in connection with allegations of infringement by equivalents. It is sometimes argued that an equivalent should be ruled out (and not form part of the scope of protection of the granted claim) because it is disclosed in the specification of the patent as a prior disclosure and yet not expressly claimed in the patent. Accordingly it is argued that the inclusion of a prior disclosure is prejudicial to an argument of infringement by equivalents. A mandatory requirement to include and/or list known prior art in patent applications could therefore have the effect of later reducing the scope of protection of the patent. Whether such a reduction in scope of protection is desirable depends in turn on whether, from a policy perspective, the claims in patents should be interpreted more (or less) literally.

You are invited to submit a Report addressing the questions below. Please refer to the 'Protocol for the preparation of Reports'.

Questions



# In the context of this Study Question, the below terms have the following meaning:

"Related patent application": means continuation-in-part applications, divisional applications, and/or continuation applications.

"Prior art": Consistently with Resolution Q167 (Lisbon, 2002), means "all information which has been made available to the public anywhere in the world in any form before the filing date or, where applicable, the priority date".

"Post-grant proceedings": means proceedings before the IP office after the grant of the patent, such as opposition, re-examination, reissue, post grant review, inter partes review, etc.

# I) Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

# **Disclosure requirement**

1. Does your Group's current law provide for <u>a requirement to disclose information</u> such as prior art and/or related patent application(s)?

Please answer YES or NO and you may provide an explanation.

If you answer YES to question 1, please explain the <u>context/time of such disclosure</u> <u>requirement</u>:

- a. at the time of <u>patent application filing</u> and/or during prosecution of the patent application;
- b. at the time of post-grant proceedings;
- c. at the time of a proceeding before a court (infringement, nullity action, etc.);
- d. at any other time.
- 2. Must the disclosure to be <u>spontaneous and in all cases</u> or only <u>in certain circumstances</u> (e.g., at the request of the IP Office or a judge, etc.)?

# Scope of the disclosure requirement

3. Please indicate which information is concerned by the disclosure requirement:

For each of the following, please answer YES or NO and you may provide a brief explanation.

- a. all patent publication documents defined as prior art;
- b. all non-patent publication documents defined as prior art;



- c. <u>related patent application</u> filings, *i.e.* continuation-in-part applications, divisional applications, continuation applications;
- d. published or unpublished patent applications (and/or grant procedure documents, such as research reports, etc.) covering the same invention in other jurisdictions (whether claiming or not the associated priority benefit);
- e. any information other than a patent publication (products, photography, invoices, statements, information on internet, traditional knowledge, genetic resources, information concerning prior uses etc.);
- f. any other information.
- 4. Does the disclosure requirement concern all <u>information that may affect the validity</u> of the patent application, e.g., novelty and/or inventive step, insufficiency/plausibility, etc.?
- 5. If the document is published in a language which is not one of the permitted languages in which applications can be filed, does your legislation require that a <u>translation</u> be provided (formal or informal translation)?
- 6. What level of analysis is required to determine relevance of a document/prior art publication? For example, is a full legal opinion on relevance required, before a publication can be dismissed as irrelevant?
- 7. Does your Group's current law provide for <u>exceptions</u> to the disclosure requirement prior to filing a patent application, e.g., during a grace period?
- 8. Does your Group's current law provide for a <u>publication of the information</u> disclosed by the person on whom the disclosure requirement rests (e.g. by inclusion in the patent application as published)?

### **Burden of disclosure**

- 9. Who is required to disclose such information:
  - a. the inventor?
  - b. the applicant?
  - c. assignees of the patent?
  - d. licensees of the patent?
  - e. any other person (e.g., patent agent, employees, another patent office, etc.)?
- 10. Does the disclosure requirement concern only information actually known by the person who has the burden of disclosure or also information that he/she should have known?
- 11. Is the person who has the burden of disclosure required to identify or describe which portions of the prior art are relevant or material?



# **Sanctions**

- 12. Does your Group's current law provide for an option to <u>cure a failure to disclose</u>, when disclosure requirement has <u>not been met in a timely fashion?</u> Please briefly explain.
- 13. Does your Group's current law provide for a way to <u>ensure compliance</u> with the disclosure requirement (e.g., how to ensure that the person who has the burden to disclose has complied with his/her obligation)? Please briefly explain.
- 14. Does your Group's current law provide a <u>consequence or penalty for non-compliance</u> with the disclosure requirement? Please briefly explain.

## II) Policy considerations and proposals for improvements of your Group's current law

- 15. According to the opinion of your Group, is your current law regarding the disclosure requirement adequate and/or sufficient? Please answer YES or NO and briefly explain, listing areas in which your current law is not sufficient/adequate.
- 16. According to the opinion of your Group, is your current law regarding its disclosure requirement, if any, relating to the GR/TK adequate and/or sufficient? Please answer YES or NO and briefly explain.
- 17. Please explain whether in your Group's view it would be beneficial for having a duty to disclose prior art in patent applications, and why the duty would provide / would not provide a benefit to third parties. In particular, what benefit do third parties gain from having access to a list of disclosed prior art for any given patent application?
- 18. According to the opinion of your Group, are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question?

# **III) Proposals for harmonisation**

Please answer all questions in Part III without taking into consideration your Group's current law.

19. Do you consider harmonisation regarding a requirement/duty to disclose information as desirable in general?

If you answer YES to the question above, please respond to the following questions <u>without</u> regard to your Group's current law or practice.



Even if NO, please address the following questions to the extent your Group considers your Group's current law or practice could be improved.

## **Disclosure requirement**

- 20. What should be the <u>context/time of such disclosure requirement</u>:
  - a. at the time of <u>patent application filing</u> and/or during prosecution of the patent application?
  - b. at the time of <u>post-grant proceedings</u> (e.g., opposition, reexamination, reissue, post grant review, inter partes review)
  - c. at the time of a <u>proceeding before a court</u> (infringement, nullity action, etc.)
  - d. at any other time.
- 21. Should the disclosure be <u>spontaneous and in all cases</u> or only <u>in certain circumstances</u> (for example, at the request of the IP Office or if ordered by a Court, etc.)?

## Scope of the disclosure requirement

- 22. Please indicate which information should be subject to the disclosure requirement.
  - For each of the following, please answer YES or NO and you may provide a brief explanation.
  - a. all <u>documentary</u> patent prior art.
  - b. all <u>documentary</u> non-patent prior art.
  - c. <u>related patent application</u> filings, *i.e.* continuation-in-part application, divisional applications, continuation applications.
  - d. published or unpublished patent applications (and/or grant procedure document, such as research reports, etc.) covering the same invention in other jurisdictions (claiming or not the associated priority benefit)?
  - e. any information other than a patent application (products, photography, invoices, statements, information on internet, traditional knowledge, genetic resources, information about prior uses etc.)
  - f. any other information.
- 23. Should the disclosure requirement concern all <u>information that may affect the validity</u> of the patent application, e.g., novelty and/or inventive step, insufficiency/plausibility etc.?
- 24. What level of analysis should be required to satisfy the duty to disclose, e.g. should a formal legal opinion be required in the case of every potential disclosure?



- 25. If the document is published in a language not permitted for patent applications, should a <u>translation</u> (formal or informal translation) be required?
- 26. Should there be <u>exceptions</u> for disclosure requirement, for instance prior to filing a patent application (e.g., during the grace period)?
- 27. Should the information communicated to the IP office and/or courts as regards the reason why the disclosure requirement applies or does not apply for a certain disclosure be available to the public?
- 28. Should the reason why particular prior is disclosed as potentially relevant constitute a binding admission in all later proceedings as to the relevance of the prior art?

# The person who should have the burden of disclosure

- 29. Who should be required to disclose such information:
  - a. the inventor?
  - b. the applicant?
  - c. assignees?
  - d. licensees?
  - e. any other person (e.g., patent agent, employees, etc.)?
- 30. Should the disclosure requirement concern only <u>information known</u> by the person who has the burden of disclosure or also <u>information that he/she should have known</u>?
- 31. Should the person who has the burden of disclosure required to identify or describe which portions of the prior art are relevant or material?

## Sanctions

- 32. How should the compliance with the disclosure requirement should be enforced (e.g., how to ensure that the person who has the burden to disclose has complied with his/her obligation, and what sanctions should follow if there is non-compliance)?
- 33. What should the <u>consequence or penalty for non-compliance</u> with the duty of disclosure be, and should an option to cure a failure to disclose be available?
- 34. Please comment on any additional issues concerning any aspect that you consider relevant to this Study Question.
- 35. Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.