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Via Email: tiaofasi@cnipa.gov.cn

Re: "Draft Revised Patent Examination Guidelines (Draft for Solicitation of Comments)" (October 31, 2022)

Dear China National Intellectual Property Administration:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the request for comments on the *Draft Revised Patent Examination Guidelines (Draft for Solicitation of Comments)* ("Draft") published on October 31, 2022.

IPO is an international trade association representing a "big tent" of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO's vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO's mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

IPO recognizes the importance of the objective of the Draft to adapt the guidelines to the newly amended Patent Law, thereby to improve the quality of patent applications filed at the China National Intellectual Property Administration (CNIPA). IPO hopes that our comments below will be helpful during the process of finalizing the Draft Guidelines.

General Comments

IPO appreciates that the Draft for solicitation of comments updates the current patent examination guidelines of the China National Intellectual Property Administration (CNIPA) and the previous draft circulated for comment on August 3, 2021. IPO especially welcomes the increased attention being directed to procedures for preliminary examination, patents on pharmaceuticals and biotechnology, and design patents, and hopes that our specific comments below will be helpful during the process of finalizing the Draft.

Part 1, Chapter 1, Section 6.2.3

Sometimes when the applicant files a request for the addition of a priority claim after the priority period expires, the application is still within the time limit for filing a request for the restoration of right of priority (that is, within the time limit specified in Rule 36 of the draft revised Implementing Regulations of the Patent Law of China). In this case, the question is whether the applicant still needs to submit another request for the restoration of the right of priority. How to deal with this situation relates to whether the two systems of the restoration of right of priority and the addition of a priority claim can be applied without causing confusion in the application.

Also, according to the current draft, it appears priority restoration (Rule 36 of the draft revised Implementing Regulations of the Patent Law of China) and priority addition or correction (Rule 37 of the draft revised Implementing Regulations of the Patent Law of China) are mutually exclusive.

IPO therefore suggests amending the last three paragraphs of Section 6.2.3 as follows, particularly, by removing one paragraph and adding one paragraph to the end of Section 6.2.3:

6.2.3 Addition or correction of priority claim

.....

Priority claims should also be examined in accordance with the other provisions of Sections 6.2.1 and 6.2.2 of this Chapter.

~~*For the situations specified in Article 36 of the Implementing Rules, the provisions of Article 37 of the Implementing Rules shall not apply.*~~

Paragraph 2 of Article 6 of the Implementing Regulations of the Patent Law does not apply to the applicant's delay in Article 37 of the Implementing Regulations of the Patent Law.

If the filing date of the prior application for which the applicant requests addition or correction as the basis of priority is more than 12 months but not more than 14 months from the filing date of this application, the applicant shall file a request for restoration of priority within the time limit specified in Rule 36 of the Implementing Regulations of the Patent Law, and the examiner shall conduct examination in accordance with the provisions in Section 6.2.6.2 of this Chapter.

Part 1, Chapter 1, new section 6.2.6.2

The term “the deadline” in the following paragraph may be unclear. IPO believes it refers to the 12-month priority period, and therefore IPO suggests making that clear by revising new section 6.2.6.2 as shown below:

According to Rule 36 of the Implementation Rules of the Chinese Patent Law, the subsequent application is filed after the expiration of the 12-months priority deadline from the filing date of the earlier application. Before the patent administration department under the State Council is ready for publication, the applicant may request restoration of priority within 2 months from the date of expiry of the 12-months priority deadline.

Similar to our comments on Part 1, Chapter 1, Section 6.2.3, IPO also suggests amending the last two paragraphs of Section 6.2.6.2 as follows, particularly by removing one paragraph and adding the following paragraph to the end of Section 6.2.6.2:

~~*For the situations specified in Article 36 of the Implementing Rules, the provisions of Article 37 of the Implementing Rules shall not apply.*~~

Paragraph 1 and 2 of Article 6 of the Implementing Regulations of the Patent Law do not apply to the applicant's delay in Article 36 of the Implementing Regulations of the Patent Law.

If the filing date of the prior application on which the applicant requests addition or correction as the basis of priority is more than 12 months but not more than 14 months from the filing date of this application, the applicant shall file a request for restoration of priority within the time limit specified in Rule 37 of the Implementing Regulations of the Patent Law, and the examiner shall conduct examination in accordance with the provisions in this Section.

Part 1, Chapter 1, Section 6.7.2.3

The draft amendments to this section set a one-month time limit for changing inventors. However, the applicant should have more flexibility to make inventor changes, as long as the inventors, as changed, are all those who have made creative contributions to the substantial features of the invention in accordance with the provisions of Rule 14 of the Implementation Rules of the Patent Law. From time to time, the claims may be amended in response to rejections, and thus the inventorship may change accordingly. In such scenarios, the applicant may also want to have the opportunity to file inventor changes.

IPO therefore suggests amending the last three paragraphs of Section 6.7.2.3 as follows:

6.7.2.3 Inventor change

.....

(3) If the request for change is filed due to omission or error in inventors, it shall be filed ~~within one month after receiving the notification of acceptance,~~ together with submitting the supporting documents signed or sealed by all applicants (or patentees) and all inventors before and after the change, which should indicate the reason for the change, and declare that it has been confirmed in accordance with Article 14 of the Implementing Regulations of the Patent Law The

inventors after the change are all persons who have made creative contributions to the substantive features of the present invention.

Part 1, Chapter 1, new Section 6.7.5

IPO applauds CNIPA's efforts to reduce bad faith patent application filings. The draft amendments to this section codify this by treating bad faith filings as if they have never been filed. However, some of the filings initially determined not to be in good faith may have actually been in good faith, and therefore should not be treated as if they have not been filed without giving the applicant a chance to explain. Therefore, IPO suggests amending this section as follows:

For the relevant procedures that violate the principle of good faith, ~~the examiner shall issue a notice that it is deemed not to have been submitted.~~the patent administration department of the State Council shall notify the applicant of its opinions and require him or it to state his or its observations or to rectify his or its application within a specified time limit; if the applicant fails to make any response within the specified time limit, the application shall be deemed to have been withdrawn. Where, after the applicant has made his or its observations or the corrections, and the patent administration department of the State Council still finds that the application is not in conformity with Article 20 of the Patent Law (or corresponding good faith rule in the regulation), the application shall be rejected.

Part 1, Chapter 3, Section 7.4

The draft amendments to this section exclude particular subject matter categories from design patent protection. IPO applauds and thanks CNIPA for changing “relatively separable independent area” to “relatively independent area” in clause 10, consistent with IPO's comments on the previous draft.

However, the exclusions in clauses 3 and 11 continue to concern IPO because they conflict with the allowance of partial designs provided elsewhere in these guidelines. They prevent applicants from obtaining coverage for the full scope of their designs, and they conflict with design patent practice in other countries — for example, the European Community's Council Regulation (EC) No 6/2002 Article 4, and the United States Patent and Trademark Office's (USPTO's) Manual of Patent Examination and Procedure (MPEP) section 1504.01. IPO believes these exclusions also conflict with Article 26.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights:

*Members may provide limited exceptions to the protection of industrial designs, **provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.***

See Article 26.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (emphasis added).

More specifically, the exclusion in clause 3 has been expanded from “components of chess and cards and jigsaw toys” to cover all products “composed of multiple components with different specific shapes or patterns, if the component itself cannot be sold alone and cannot be used alone.” IPO believes applicants should be able to patent the full scope of their designs, which includes not only the overall design of a product, but also designs of its components.

Clause 11 limits the scope of allowable designs by excluding partial designs that are only a pattern or combination of color and pattern that are on the surface of a product. No reason for this change is apparent, and it contradicts the recent expansion of scope to include partial designs.

Thus, IPO believes the categories recited in clauses (3) and (11) should be eligible for design patent protection, and therefore suggests deleting them from the draft:

7.4 Circumstances in which the design patent right is not granted

...

~~(3) For a product composed of multiple components with different specific shapes or patterns, if the component itself cannot be sold alone and cannot be used alone, the component does not belong to the object of patent protection for design. For example, a group of jigsaw puzzles composed of plug-in blocks of different shapes is the object of protection of the design patent, only when all the plug-in blocks are jointly included in one single design application.~~

...

~~(11) The partial design claimed for patent protection is only the pattern on the surface of the product or the combination of pattern and color. For example, the pattern on the surface of a motorcycle.~~

Part 1, Chapter 3, Section 9.1

The amendments to this section prohibit an overall design of a product and the partial design of its components from being filed as one application. IPO is not aware of any reason for this prohibition, and it would make the process much less efficient for applicants, who would be required to file multiple applications, perhaps tens or more applications, in order to obtain the same design protection.

Moreover, this section may conflict with Article 9 of the Patent Law of China, which prescribes that “For any identical invention-creation, only one patent right shall be granted,” since the application for the overall design and the application for a component of that design may be considered as substantially identical due to their overlap in design.

IPO therefore suggests deleting the part of section 9.1 shown as struck-through as follows:

9.1 Two or More Similar Designs of the Same Product

According to Article 31, Clause 2 of the Patent Law of China, two or more similar designs of the same product may be filed as one application.

~~*The overall design and any design of a component which can also be filed as an application for overall design of the same product cannot be filed as one application.*~~

There shall not be more than 10 similar designs in one application for design patent. If more than 10, the examiner shall issue a notice of office action, and if the applicant fails to overcome the defect after modification, the application for design patent shall be rejected.

Part 2, Chapter 1, Section 3.2

IPO is concerned by extending the definition of “genetic resources” to include not only materials that contain functional units of heredity, but also information generated by utilizing such materials. The rule points to Article 29 of the Implementing Regulations. The current Implementing Regulations do not include such information in the definition of “genetic resources.” See Article 26. That creates a conflict between the Implementing Regulations and these Examination Guidelines that are based on those regulations. IPO suggests deleting reference to information generated in paragraph 6:

According to the provisions of paragraph 1 of Article ~~29~~ 26 of the Implementing Regulations of the Patent Law, the term “genetic resources” as mentioned in the Patent Law refers to materials obtained from human bodies, animals, plants or microorganisms that contain functional units of heredity and have actual or potential value ~~and the information generated by utilizing such materials~~; the inventions-creations accomplished relying on genetic resources as mentioned in the Patent Law refer to inventions-creations accomplished by utilizing the genetic function of genetic resources.

...

Inventions and creations that utilize the genetic function of genetic resources refer to the separation, analysis, and processing of genetic functional units ~~or the analysis and utilization of genetic information generated by genetic functional units~~, etc., in order to complete the invention-creation and realize the value of its genetic resources.

The expanded definition is also unclear. “Genetic resources” appears to encompass information that does not relate to genetics or to any differentiated trait or product of an organism. If one develops an improved beer recipe, for example, it is not clear whether data from testing that recipe is information generated by utilizing such “genetic resources” because brewing uses yeast.

Therefore, if CNIPA does not accept IPO’s suggestion and the “genetic resources” definition is expanded, IPO suggests clarifying that the information is genetic information as follows: “... *actual or potential value and the **genetic** information generated by utilizing such materials; ...*”. Also, if CNIPA does expand the rule to include information, IPO suggests that the new rule only apply to applications with a priority date after it issues these guidelines. Materially expanding the rule like this can unfairly prejudice applicants who drafted and filed patent applications under the existing guidelines.

Perhaps there are proposed changes to the Implementing Regulations that have not yet been published for comment. If so, IPO suggests waiting until those Regulations are

published and finalized then aligning this section with the final rule in the Implementing Regulations.

Part 4, Chapter 1, Section 5

The last sentence of this section replaces specific provisions for avoiding a conflict of interest by the patent review committee with a reference to “relevant regulations on the prohibition of practice.” IPO is concerned that replacing specific rules with a reference to “relevant regulations” weakens protections against conflicts of interest, for at least the reason that no relevant regulations are listed. IPO therefore suggests reciting all known relevant regulations.

Part 4, Chapter 1, Section 6.3

IPO applauds the changes to this section on disclosure of patent re-examination and invalidation decisions to remove the prohibition on publication of the decision until after judgment has been rendered in any appeal that was taken.

However, the changes do not otherwise specify any requirement for timeliness, despite the statement in the Explanation of Revised Patent Examination Guidelines that “the examination decisions on reexamination and invalidation requests shall be published on the website of the State Intellectual Property Office in a *timely* manner after they are issued.”

IPO therefore proposes setting a time limit for publication, and further proposes that the time limit be three months, by adding to the end of the section: “The decision shall be published within three months of the date of the decision.”

Part 4, Chapter 3, Section 4.1

IPO remains concerned that the panel could *ex officio* examine the subject of the patent for apparent violations of the China Patent Law and its Implementation Rules. It is not clear when those would be apparent, and the patentee would disadvantageously face such unexpected *ex officio* issues during the invalidation proceedings. IPO again suggests removing this new provision such that the panel could focus only on the invalidation reasons filed by the invalidation petitioner.

Part 4, Chapter 3, Section 3.6

The changes to this section add a paragraph specifying what documents are required for submission to prove the employment relationship between the employer and the employee representing it in oral hearing proceedings. IPO noticed the addition seems to make a distinction on such documents between non-governmental entities and governmental institutions. IPO is concerned that such documents for submission, including labor contracts, social security payment records, and wage payment records, would contain sensitive personal information and business secrets, and thus should not be required for all cases, unless there is a strong reason to challenge the existence of the employment relationship. Issuance of a formal written document would be sufficient for the purpose and thus should be a default rule for all cases, regardless of whether involving non-governmental entities or governmental institutions. This proposal would further relieve unnecessary

administrative burdens on the party concerned. Therefore, IPO suggests revising this section as shown in the markup below:

If the agent is a staff member of the party concerned, a written document stating the position and duration of the staff member issued by the ~~institution~~ party concerned shall be submitted; in the event that either party challenges the authenticity of such written documents, labor contracts, social security payment records, wage payment records, or other documents which are sufficient to prove that there is a lawful human relationship with the party concerned shall be further submitted. ~~; if the party concerned is a governmental or public institution,~~

Further, according to the modification in paragraph (6), where the term “citizen” is replaced with “a concerned party’s close relatives or staff,” it is not clear whether lawyers who are not patent agents can represent a party in invalidation cases (current practice is that lawyers participate in invalidation proceedings as citizen representatives), so IPO suggests clarifying this scenario.

Part 4, Chapter 3, Section 3.7

IPO applauds CNIPA for trying to solve the problem that occurs when an invalidation procedure goes forward on a patent whose ownership is disputed without involving all the parties to that dispute. The true owner may otherwise have no say in the invalidation proceedings.

However, IPO believes a better solution would be to stay every invalidity proceeding over a patent whose ownership is the subject of a lawsuit. This would be better because, otherwise, a non-owner could participate in the invalidation procedure and could sabotage the invalidity case through the arguments and positions it takes. It would also be more efficient, as the true owner of the patent may wish to settle the invalidation proceedings, avoiding the time and resources that the parties -- and the panel in the invalidation proceeding -- would otherwise have to spend.

IPO therefore suggests revising this section as shown in the markup below:

3.7 The parties to the ownership dispute participate in the formal examination of the invalidation procedure

If a party requests to suspend the procedure, but the The patent invalidation procedure ~~has not been~~ shall be suspended when requested by a, ~~the party to the an ownership dispute over the involved patent may request to participate in the invalidation procedure.~~

If a party to a patent ownership dispute requests ~~to participate in~~ suspension of the invalidation procedure, it shall submit a written request for ~~participation in~~ suspension of the invalidation procedure, as well as the documents certifying that the ownership dispute has been accepted by ~~the people's court or the local intellectual property management department~~ a court of competent jurisdiction. After the formal examination, the Department of Reexamination and Invalidation Trial shall issue a notice on whether to approve ~~the participation in~~ suspension of the invalidation procedure to the parties to the dispute over the ownership.

~~*During the invalidation procedure, the parties to the dispute over ownership may put forward opinions for the collegial panel to refer to when hearing invalidation cases.*~~

Alternatively, if CNIPA does not require suspension when a patent is involved in an ownership dispute, then IPO would suggest that this section should be changed to apply to any ownership dispute anywhere in the world, not just in “the people's court or the local intellectual property management department.” That is because a Chinese patent may be the subject of an ownership dispute in other courts; for example, when the Chinese patent is only one of a family of related patents whose ownership is disputed. If the changes IPO proposes above to require staying the proceeding are not accepted, IPO suggests replacing “the people's court or the local intellectual property management department” with “any court of competent jurisdiction.”

Part 4, Chapter 3, Section 4.6.1

The Draft adds language that the amendments made during the invalidation proceedings shall be for overcoming the defects indicated in the grounds of invalidation or the defects pointed out by the collegial panel.

IPO suggests removing this added language. In practice, it may happen that the grounds of invalidation only point out a defect concerning inventiveness, while the claims may further have clarity issues. In this exemplary scenario, claim amendments in accordance with the principle of modification and modification methods and from the standpoint of making the scope of protection of the claims clearer should not be prohibited. Therefore, adoption of this suggestion may avoid unnecessary disputes in practice.

IPO therefore suggests revising this section as shown in the markup below:

~~*4.6.1 The amendment of the patent document for invention or utility model is limited to the claims, and should be amended according to the reasons for invalidation or the defects pointed out by the collegial panel. The principles are as follows:*~~

Part 4, Chapter 3, Section 7

Newly added section 7 refers to methods of serving documents in international design applications. IPO suggests amending section 7 to eliminate announcement as a method of service, as the method of announcement is unclear and it would presumably require the active monitoring of a regularly published bulletin, which could easily lead to an applicant missing the announcement.

Part 4, Chapter 4, Section 5

The changes to this section add a paragraph permitting the panel leader to preside over an oral hearing alone if the collegial panel agrees. IPO is concerned that this departs from the settled expectations of the parties, without notice, and deprives the parties the benefit that different viewpoints of the collegial panel can provide in reaching a decision. IPO suggests that this added paragraph be struck.

Alternatively, if this new paragraph is retained, IPO suggests requiring the parties' consent to conduct the hearing without the collegial panel:

Oral hearings are usually chaired by the panel leader. For simple cases with clear facts and clear focus of disputes, with the unanimous consent of the collegial panel and the parties, the presiding judge may also attend and preside over the oral hearing on behalf of the collegial panel.

If CNIPA does not adopt this suggestion, however, IPO proposes that the parties be notified of the change at least 30 days in advance of the oral hearing.

IPO is also concerned by the lack of clarity regarding what a "simple case" is and what constitutes "clear facts and clear focus of disputes." If CNIPA includes this new paragraph, IPO suggests clarifying these terms, perhaps by including an example or two.

Part 5, Chapter 11, new Section 3.3

The draft amendments add a specific maximum lump sum fee and a specific royalty rate regarding the royalty fee for open license. IPO suggests removing this as it does not comply with the normal licensing practice and may mislead the market towards rigid pricing without considering actual market value of the licensed patents in the related technology areas.

Part 5, Chapter 6, Section 2.3.1

IPO applauds the principle behind this change, which makes calculation of deadlines for responding to notifications issued by the CNIPA easier and clearer. IPO notes, however, that this change would significantly reduce the time to handle re-examination notices issued by the Re-examination and Invalidation Department (1 month to respond), and office actions subsequent to the first office action issued by the Examination Division (2 months to respond). This reduction is particularly significant to foreign applicants, who require additional time for translation. As such, IPO suggests that if this change to remove the 15-day mail period for electronically transmitted notifications is to be implemented, the time to respond to re-examination notices and office actions subsequent to the first office action be increased to 3 months. Alternatively, IPO suggests retaining the 15-day mail period for foreign applicants.

Further, in our experience, when the notification or decision is served electronically, the notification or decision does not always arrive at the server of the recipient immediately. Instead, there may be delays or system failures that prevent timely delivery. Hence, IPO suggests amending this section as follows:

For notices and decisions served electrically, the date of issuance shall be the date of service. For notices and decisions served electronically, if a party can provide evidence to prove that the actual date of receipt is later than the presumed date of receipt, the actual date of receipt shall be the date of service.

Part 5, Chapter 9, Section 3.1(1)

IPO notes that one of the requirements to obtain drug patent term extensions is that “[t]he grant publication date of the patent requesting extension shall be earlier than the drug marketing approval date.” IPO is not aware of any legal basis for this requirement, and is concerned that this will exclude patent(s) granted later than the drug marketing approval date, which could happen due to typically long prosecution of drug-related patents. IPO suggests removing this requirement.

Part 5, Chapter 9, Section 3.4

IPO is disappointed to see that the restrictions on drug patents that could obtain drug patent term extensions remain in this section. Below, IPO repeats the comments that it made on this issue in response to the previous draft.

According to the National Medical Products Administration (NMPA) classification system effective since 1 July 2020, while innovative drugs could obtain PTE, IPO notes that only improved new drugs belonging to the following drug classifications are allowed to obtain PTE:

- a) Chemical drug
 - 2.1 Chemical drugs that contain esterified known active ingredients, or salt of known active ingredients
 - 2.4 Chemical drugs for new indications that contain known active ingredients.
- b) Preventive biological drugs class 2.2, vaccine with strain improvement.
- c) Therapeutic biological drugs class 2.2, for new indications of improved already marketed products.
- d) Chinese medicine class 2.3, for new indications of Chinese medicine.

It is unclear from the draft whether the above is an exclusive list, and therefore excludes the following classes of drugs from obtaining PTE:

- Chemical drugs
 - 2.1 Drugs that contain an optical isomer of known active ingredients obtained by resolution or synthesis, or change in acid group, basic group, or metallic element of known active ingredients of salt, or formation of other non-covalent bond derivatives (e.g., complex, chelate or clathrate), and have significant clinical advantages.
 - 2.2 Drugs that contain known active ingredients with new dosage form (including new drug delivery system), new formulation process or new route of administration, and have significant clinical advantages.
 - 2.3 New compound preparations that contain known active ingredients and have significant clinical advantages.
 - All biological drugs other than b) and c) above.

IPO seeks clarification on the above that innovative drugs could obtain PTE, that are drugs that have not been marketed in China or overseas, including chemical drugs class 1, innovative vaccines class 1, and innovative biological products class 1.

If the above restrictions exist for improved new drugs, IPO suggests removing the above restrictions so that PTE is available to all drugs patents for improved new drugs. Even for drugs that have been marketed overseas or in China with known dosage and indications, there could be improvements over such known drugs for which patents could be granted. IPO notes that there is no restriction on the type of drugs that could obtain PTE in the Chinese Patent Law (2020), and the US-China trade agreements (2020).

Part 5, Chapter 10, Section 1

According to the Civil Code of China, only a pledge on a proprietary right in intellectual property is created upon registration. Therefore, to avoid possible extra formality requirements in assignment and license recordation, IPO suggests amending this Section as follows:

For utility model or design patent rights ~~for assignment~~, pledge registration, ~~and recordation of patent license contract~~, the State Intellectual Property Office may, if necessary, request the submission of a patent right evaluation report.

IPO thanks the China National Intellectual Property Administration for its attention to IPO's comments submitted herein, and welcomes further dialogue and opportunity to provide additional comments. IPO has enclosed this letter as translated herewith.

Sincerely,



Karen Cochran
President

Attachments