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March 7, 2023

Mr. Daniel Lee
Assistant U.S. Trade Representative for Innovation & Intellectual Property
Office of the U.S. Trade Representative
600 17th St., NW
Washington, DC 20508

Re: Response to Questions, USTR 2023 Special 301 Review (Docket No. USTR–2022-0016)

Dear Mr. Lee:

Intellectual Property Owners Association (IPO) appreciates the U.S. Trade Representative’s careful review of IPO’s comment letter dated January 30, 2023 for the 2023 Special 301 Review, and the opportunity to provide responses to the questions posed by the U.S. Trade Representative. This letter takes up each question in turn:

Question 1: On China, your submission states that “there is some risk and uncertainty that certain aggressive and bad-faith patenting practices may be deemed patent misuse.” Please elaborate on what “bad faith patenting practices” means in this context.

Response: To clarify, in this context, “bad faith patenting practices” refers to those practices that CNIPA has defined as “abnormal patent application behaviors” in its “Methods regarding governing of patent application behavior.”¹ The lack of clarity that this definition creates regarding which practices will be considered patent misuse creates uncertainty in the IP system.

Question 2: Regarding Mexico, your submission states that Mexico’s mechanism for adjusting patent terms to recover up to five years of term lost due to unreasonable delay by Instituto Mexicano de la Propiedad Industrial (IMPI) is unduly burdensome because it “does not provide an automatic patent term adjustment, but rather requires that the applicant file a request, fees, and a supporting brief,” and because “IMPI has in its possession all information necessary to compute the unreasonable delay.” What specifically makes the mechanism unduly burdensome (e.g., the request, the fees, the supporting brief, or a combination of these requirements)? How does this compare to the requirements in other similar jurisdictions?

Response: IPO generally welcomes the patent term adjustment in Mexico as a positive development because there is now a mechanism available to compensate patent owners in cases in which IMPI incurred an unreasonable delay during the prosecution of a patent.

¹See https://www.cnipa.gov.cn/art/2021/3/12/art_527_157670.html.

This change was included in the IP law which entered into force on November 5, 2020. Thus, it applies only to patents filed in Mexico beginning on this date and no patent has yet been subject to it. IPO expects the first petitions to be filed around the end of the year 2026. It is currently expected that the burden for the applicant will primarily be because the adjustment will have to be requested through a brief submitted independently when replying to the notice of allowance. Since calculating the patent term adjustment is a purely mathematical exercise based on information available within IMPI, IMPI should be able to calculate the patent term adjustment without expense to the applicant in preparing and submitting a brief.

As far as IPO is currently aware, other Latin American countries do not make this patent term adjustment available.

Question 3: To what extent do the new public notifications from the Indian Patent Office issued on January 16, 2023, that relate to new limits on pre-grant oppositions address the concerns laid out in your submission regarding deficiencies in the pre-grant opposition system (outlined in the August 2022 Report on “Why India Needs to Urgently Invest in its Patent Ecosystem”)?

Response: It appears that the relevant January 16th Notification from the Indian Patent Office, which essentially pertains to the time-periods granted to Patentees for hearings/adjournments, may not have a significant bearing on the primary concerns identified in the Report regarding deficiencies in the pre-grant opposition system.

The January 16, 2023 Notification supersedes an earlier Notification dated December 26, 2022. Both these notifications relate only to the time-period granted under a hearing notice (time from the date of notice to the date of scheduled hearing) and time-period for adjournments (time between an adjourned hearing and next scheduled hearing). In the December 26th notification, in an attempt to expedite disposal of the pending backlog in applications and oppositions (both pre-grant and post-grant), the Patent Office shrunk both the time-periods to (strictly) 10 days, even though statutorily an adjournment should be available for a minimum of 30 days. Representations were made by certain stakeholders that this change would be prejudicial to applicants/inventors in matters involving substantive issues where more time is required for examining prior art and preparing arguments.

The January 16th Notification superseded the December 26th notification, while issuing a general advisory to the Controllers that shorter time-periods should be adopted where minor procedural issues are involved and longer time-periods may be offered in case of substantive matters. In effect, the January 16th Notification broadly restored the position existing prior to December 26th as far as the time-periods under hearing notice and adjournments are concerned. As indicated in the Notification, stricter implementation of the statutory provision that “no party shall be given more than two adjournments” may, however, have a positive impact on reducing the backlogs.

These time-periods, however, were not identified as concerns (outlined in the August 2022 Report) regarding deficiencies in the pre-grant system. The primary concern identified in the Report is the lack of a fixed timeline for filing pre-grant oppositions, thereby resulting in

staggered oppositions causing significant delays in grant of patent applications. Accordingly, the recommendation in the Report was to fix the timeline for filing pre-grant opposition to six months from the date of publication. Another concern identified in the Report is the shortage of Controllers, which translates into delays in scheduling of hearings and issuing of final orders in substantive matters (which essentially includes pre-grant oppositions).

Question 4: Your submission notes concern with Andean Decision 486, which “requires that patent applications include requirements relating to the acquisition or use of genetic resources if the relevant inventions “were obtained or developed from” genetic resources originating in one of the Andean Community countries (Bolivia, Peru, Ecuador or Colombia).” Can you provide more detail on how Andean Decision 486 has inhibited innovation in relevant technologies in the region?

Response: IPO is concerned about laws requiring information about the source of genetic resources used in the invention and any requirements for obtaining advanced access and benefits sharing agreements, for patent disclosures. Access to genetic resources is regulated in the Andean Community (Bolivia, Colombia, Ecuador and Peru) by Decision 391, which, among others, defines what is considered such access. Under current practice, if the resource is considered indigenous or native to any of these countries, and it has been accessed or is going to be accessed, it is expected that a contract will be requested before the corresponding Agency in each country (regardless of the status of the research and possible patent applications). Decision 486 establishes that a copy of the contract should be provided upon filing, but it could be later requested either in formal or substantive examination.

Each patent office in the Andean Region handles this issue differently, and in the recently issued Andean Patent Manual (APM), a chapter was included explaining the general procedure and providing examples of cases in Colombia and Peru where a contract was required during prosecution and the rationale for that requirement. IPO understands that applications have been declared abandoned for not being able to formally comply with the requirements. As a result, innovation can be inhibited, and innovators will be reluctant to invest in related research.

IPO also believes that, in addition to unnecessarily linking the risk of patent validity to the patent disclosure, the “or developed from” language implicates the use of genetic digital sequence information (DSI) which is currently maintained in publicly accessible databases. The concerns are that such legislation is very likely to deter investment in research on these genetic resources because the validity of any patents based thereon could be determined by the accuracy of voluntarily uploaded research information. Moreover, limiting free access to such DNA sequence databases would impede commonly performed large scale sequence comparisons, and likely result in more privatization of DSI databases.

Question 5: On China, on page 23 of your submission, you indicate that seeking relief in trade secret cases can require waiting until damages occur. Have recent amendments to the Criminal Law and Anti-Unfair Competition law had an impact on this requirement? Is clarification needed on terms included in those provisions?

Response: Positive developments regarding this issue have occurred in the civil law, but it is still not likely that a criminal investigation in China will begin until there is proof that significant damage has occurred (at which time the damage may be irreversible). More specifically, under recent amendments to China’s Anti-Unfair Competition Law, a civil plaintiff may make a showing of certain elements that allow for burden shifting to the defendant, which is an improvement in this area. Recent amendments to the criminal law have also been made, but showing damage of 300,000 RMB for criminal cases is currently an element to be proven.² Although proving “use” is not required, the test to meet the damage requirement, in the absence of proof of damages based on use, is, in IPO’s opinion, subjective.³ Absent clarification of the test, in practice, proof of significant damage remains the test in criminal cases.

Question 6: On China, your submission states that “[b]eginning in August 2020, Chinese courts have issued anti-suit injunctions that have arguably tipped the scales in favor of domestic businesses, while raising due process and transparency issues.” Are there any recent developments from Chinese courts or government authorities with respect to anti-suit injunctions?

Response: Due to limited transparency regarding anti-suit injunctions in China, IPO is unable to say whether there have been any recent developments from Chinese courts or government authorities with respect to anti-suit injunctions. IPO does note the development that the EU has decided to move forward with its complaint against China at the World Trade Organization (WTO) on the basis of China’s usage of anti-suit injunctions, and a panel at the WTO has now been formed to hear the complaint.

We again thank the USTR for reviewing IPO’s original comments and posing these questions. IPO would welcome any further dialogue or opportunity to provide additional information to assist your efforts in developing the 2023 Special 301 Report.

Sincerely,



Karen Cochran
President

² See the Interpretation on Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights, released jointly by the Supreme People’s Court and Supreme People’s Procuratorate on September 13, 2020, at Article 4. (IPO notes that a subsequent revised draft of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights was published for comment on January 28, 2023.)

³ See *id.* at Article 5.