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**Sheleen Dumas,**

*Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.*

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## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

**[Docket No. PTO–P–2021–0019]**

### Fast-Track Pilot Program for Appeals Related to COVID–19

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice.

**SUMMARY:** The United States Patent and Trademark Office (USPTO) is initiating the Fast-Track Pilot Program for Appeals Related to COVID–19 to provide for the advancement of applications out of turn in ex parte appeals related to COVID–19 before the Patent Trial and Appeal Board (PTAB). An appellant who has filed an ex parte appeal of an application with claim(s) that cover a product or process related to COVID–19 (such product or process must be subject to an applicable U.S. Food and Drug Administration (FDA) approval for COVID–19 use) and received a notice that the appeal has been docketed may file a petition at no cost to expedite the review of his or her appeal without paying a petition fee. The Fast-Track Pilot Program for Appeals Related to COVID–19 sets a target of reaching a decision on an ex parte appeal within six months from the date the appeal is entered into the pilot program.

**DATES:** *Applicability Date:* Petitions for the pilot program can be filed starting on April 15, 2021. *Duration:* The Fast-Track Pilot Program for Appeals Related to COVID–19 is offered on a temporary basis, and petitions to request inclusion of an ex parte appeal in the pilot program will be accepted until 500 appeals have been accorded fast-track status under the program. The USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may terminate it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program. If the pilot program is extended or terminated, the USPTO will notify the public.

**FOR FURTHER INFORMATION CONTACT:** Steven Bartlett, PTAB, by telephone at 571–272–9797, or by email at *COVIDfasttrackappeals@uspto.gov.*

**SUPPLEMENTARY INFORMATION:**

#### Background

Appeals to the PTAB are normally taken up for decision in the order in which they are docketed. *See* USPTO Standard Operating Procedure 1 (Sept. 20, 2018), available at *www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/resources.* Currently, the average appeal pendency is about 13 months. *See* PTAB Statistics, available at *www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics.* However, a small number of appeals are advanced out of turn due to a special status. For example, reexamination proceedings, which are handled by the USPTO with ''special dispatch,'' and reissue applications are treated as special throughout their pendency, including during appeal. *See* Manual of Patent Examining Procedure (MPEP) 708.01. Applications that have been ''made special'' during examination through a petition based on the age or health of an applicant, or for other reasons listed in 37 CFR 1.102 (a)–(d), also maintain their special status through any appeal. *See* MPEP 1203(II). Furthermore, for the same reasons, an appellant may petition the PTAB to have an application on appeal made special. *See id.* Currently, about 1.1% of appeals are given a special status through one of the above methods.

Recently, the PTAB instituted the Fast-Track Appeals Pilot Program, in which the PTAB accepts petitions for advancing out of turn and according fast-track status to ex parte appeals that have already been docketed. 85 FR 39888 (July 2, 2020). This pilot program began on July 2, 2020 and will continue for one year or until 500 appeals have been accorded fast-track status under the program. An appellant can seek fast-track status by submitting a petition to the Chief Administrative Patent Judge under 37 CFR 41.3 and paying the fee required under 37 CFR 41.20(a), currently $420. The Fast-Track Appeals Pilot Program sets a target of reaching a decision on the ex parte appeal within six months from the date an appeal is entered into the pilot program. More information on the Fast-Track Appeals Pilot Program can be found at *www.uspto.gov/patents/ptab/fast-track-appeals-pilot-program.*

In an extraordinary situation, 37 CFR 1.183 permits the USPTO to suspend or waive sua sponte any requirement of its regulations that is not a requirement of the patent statutes. The USPTO considers the effects of the COVID–19 pandemic that began in approximately January 2020 to be an ''extraordinary situation'' within the meaning of 37 CFR 1.183 for affected patent applicants and innovators. Consistent with the USPTO's determination under 37 CFR 1.183, the provisions of 35 U.S.C. 2(b)(2)(G), and the COVID–19 Prioritized Examination Pilot Program, the USPTO has decided to implement the Fast-Track Pilot Program for Appeals Related to COVID–19, under which an appellant may have any ex parte appeal to the PTAB accorded fast-track status by filing a petition under 37 CFR 41.3, without payment of the petition fee under 37 CFR 41.20(a), for certain applications that claim products or processes that are subject to an applicable FDA approval for COVID–19 use. Such approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA). Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at *www.fda.gov.*

The Fast-Track Pilot Program for Appeals Related to COVID–19 will accept petitions for advancing out of turn and according fast-track status to ex parte appeals until 500 appeals have been accorded fast-track status under the program. There is no time limit for receipt of these 500 COVID–19 related appeals. Additionally, the 500-appeal threshold for COVID–19 related appeals is distinct from the 500-appeal threshold used for the regular fast-track appeals pilot. The threshold of 500 granted petitions corresponds to approximately 8% of the total number of new appeals received in the average fiscal year and was chosen in accordance with maintaining the PTAB's overall decision pendency goals. Once the threshold of 500 granted petitions is met, the USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may discontinue it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

**Requirements for Entry Into the Pilot Program**

The PTAB will accord fast-track status to a pending ex parte appeal under the following conditions:

(1) The application must be an original utility, design, or plant nonprovisional application. The Fast-Track Pilot Program for Appeals Related to COVID–19 is not available for applications or proceedings that are already treated as special during appeal, such as reissue applications, reexamination proceedings, appeals made special due to the age or health of an applicant, or appeals subject to any other pilot program that advances an appeal out of turn, including the Fast-Track Appeals Pilot Program. *See* MPEP 708.01 for a complete list of cases that are treated as special.

(2) Petition Requirements.

A petition under 37 CFR 41.3 must be filed in the application involved in the ex parte appeal for which fast-track status is sought and must identify that application and appeal by application number and appeal number, respectively. *See* MPEP 502.05. The petition may be submitted via: (1) The USPTO patent electronic filing systems (EFS-Web or Patent Center), (2) the U.S. Postal Service by Priority Mail Express under 37 CFR 1.10 or with a certificate of mailing under 37 CFR 1.8, or (3) hand-delivery to the USPTO Customer Service Window (MPEP 501). Electronic submission of a petition is preferred for faster petition processing. In addition, the appeal for which fast-track status is sought must be an appeal for which a notice of appeal has been filed under 37 CFR 41.31 and an appeal docketing notice has been mailed by the PTAB.

The petition must certify that the application involved in the appeal claims products or processes that are subject to an applicable FDA approval for COVID–19 use. Such approvals may include, but are not limited to, an IND application, an IDE, an NDA, a BLA, a PMA, or an EUA. Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at *www.fda.gov.*

The USPTO has created a form-fillable Portable Document Format (PDF), ''Petition—Fast-Track Pilot Program for Appeals Related to COVID–19'' (Form PTO/SB/454), that is recommended for filing a petition under 37 CFR 41.3 for the Fast-Track Pilot Program for Appeals Related to COVID–19. Form PTO/SB/454 is available on the USPTO's website (*www.uspto.gov/patent/patents-forms*). Form PTO/SB/454 contains all necessary certifications for participation in the program. Form PTO/SB/454 does not collect ''information'' within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). *See* 5 CFR 1320.3(h). Therefore, this notice does not involve information collection requirements that are subject to review by the Office of Management and Budget. It is recommended, but not required, that appellants use Form PTO/SB/454 when petitioning for entry into the Fast-Track Pilot Program for Appeals Related to COVID–19. Any petition filed by any means other than Form PTO/SB/454 must still contain the required information.

(3) Signature Requirements.

The petition under 37 CFR 41.3 must be signed by an applicant who is prosecuting the applicant's own case under 37 CFR 1.31 (except that a juristic entity must be represented by a registered practitioner even if the juristic entity is the applicant), a registered practitioner who has a power of attorney under 37 CFR 1.32, or a registered practitioner who has the authority to act under 37 CFR 1.34, in order for the application involved in the appeal to be accorded fast-track status.

(4) Fee.

The petition fee ordinarily required under 37 CFR 41.20(a) will be waived pursuant to 37 CFR 1.183.

(5) Limit on Number of Ex Parte Appeals Accorded Fast-Track Status.

The number of granted petitions in the Fast-Track Pilot Program for Appeals Related to COVID–19 is limited to a total of 500 granted petitions.

The threshold of 500 granted petitions has been chosen to allow for robust participation in the Fast-Track Pilot Program for Appeals Related to COVID–19 without compromising the PTAB's ability to deliver on other appeal pendency goals. The limit of 500 granted petitions corresponds to approximately 8% of the total number of new appeals received in the average fiscal year. The USPTO may modify or terminate the pilot program depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

**Handling of Petitions in the Fast-Track Pilot Program for Appeals Related to COVID–19**

Petitions for entry into the Fast-Track Pilot Program for Appeals Related to COVID–19 will be decided in the order they are received. Petitions meeting the requirements listed above for entry into the pilot program will be granted, and the petitioner will be notified by a decision granting the petition to accord fast-track status. Petitions not meeting the requirements listed above for entry into the pilot program will be denied, and the petitioner will be notified of a decision denying the petition. A petitioner may reapply if a first petition is denied. Any second petition filed by a petitioner for the same application and same appeal covered by a first, failed petition will not be accorded the filing date of the first petition for purposes of determining whether the second petition fell within the threshold of 500 granted petitions.

The PTAB will communicate the number of granted petitions for fast-track appeal via the PTAB web page, *www.uspto.gov/PTABCOVIDFastTrack,* and appellants should take this information into account when deciding whether to file a petition. The PTAB may also exercise discretion to grant a small number of petitions in excess of the threshold of 500 granted petitions.

**Conduct of Fast-Track Pilot Program for Appeals Related to COVID–19**

*(1) Time to Decision*

The goal for rendering a decision on the petition to accord fast-track status to an ex parte appeal is no later than one month from the filing date of the petition. The goal for rendering a decision on the ex parte appeal is no later than six months from the date an appeal is entered into the program, which occurs when a petition to accord fast-track status to the appeal is granted.

*(2) When a Petition May Be Filed*

A petition may be filed anytime between (1) the date when the PTAB issues a notice that the appeal has been docketed to the PTAB, and (2) the date at which the appellant withdraws the appeal, a final decision is rendered by the PTAB under 37 CFR 41.50, or PTAB jurisdiction ends under 37 CFR 41.35. Petitions for fast-track status may be filed for ex parte appeals regardless of whether the appeal is newly docketed or was docketed previously. If the petition complies with the formal requirements (*i.e.,* signature, identification of application, certification that the application claims a product or process subject to an applicable FDA approval for COVID–19 use), the appeal will be given fast-track status in accordance with current procedures, including the overall program threshold described above.

*(3) Hearings*

Inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 may be requested for ex parte appeals in which the appellant seeks an oral hearing before the PTAB (heard appeals), as well as those appeals for

which no oral hearing is requested (on-brief appeals). Hearings in ex parte appeals accorded fast-track status under the pilot program will be conducted according to the ordinary PTAB hearing procedures. Appellants seeking an oral hearing should submit with the request for oral hearing any preferences as to the time, date, or location of the hearing. The PTAB will make its best efforts to schedule a hearing in accordance with such preferences, consistent with the goals of the pilot program. If the PTAB is unable to accommodate an appellant's preferences, the PTAB will schedule the hearing in an available hearing room at any office, including a regional office, and at a time and date best suited to meeting the goals of the pilot program. If no such hearing room is available, the PTAB will schedule a hearing to be conducted by videoconference or telephone.

Because an appellant seeks a faster decision and hearing room availability is limited, an appellant in an ex parte appeal accorded fast-track status may not seek to relocate (to a different office) the hearing after receiving a Notice of Hearing. An appellant who does not wish to attend the hearing at the designated location may, however, request to attend the hearing by videoconference or telephone, in accordance with current PTAB hearing procedures. An appellant may also waive the hearing and continue under the Fast-Track Pilot Program for Appeals Related to COVID–19 for consideration and decision on the briefs.

An appellant may not reschedule the date or time of a hearing and remain in the Fast-Track Pilot Program for Appeals Related to COVID–19. If an appellant in an ex parte appeal accorded fast-track status must reschedule the date or time of a hearing and is not willing to waive the oral hearing, then the appellant may opt out of the Fast-Track Pilot Program for Appeals Related to COVID–19, thereby regaining the ability to reschedule or relocate the hearing as per ordinary PTAB hearing procedures.

*(4) Termination of Fast-Track Status Under the Fast-Track Pilot Program for Appeals Related to COVID–19*

Fast-track status will be maintained in an ex parte appeal from the date at which the petition for inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 is granted until the PTAB's jurisdiction ends under 37 CFR 41.35(b). Activities subsequent to an appellant's withdrawal from the pilot program or the PTAB's decision, including any reopened prosecution, will not be treated as subject to fast-track status, nor will filing a petition for inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 cause an application to be accorded fast-track status outside the jurisdiction of the PTAB. Additionally, any request by an appellant that causes a delay in the conduct of the appeal, such as for an extension of time under 37 CFR 1.136(b), or for additional briefing, will be cause for the removal of fast-track status.

**Status of the Pilot Program**

The Fast-Track Pilot Program for Appeals Related to COVID–19 is being adopted on a temporary basis until 500 appeals have been accorded fast-track status under the program. The USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may discontinue the pilot program depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

The USPTO will notify the public when the threshold of 500 granted petitions for the Fast-Track Pilot Program for Appeals Related to COVID–19 is about to be reached, and with any further relevant information, on the PTAB web page at *www.uspto.gov/PTABCOVIDFastTrack.*

**Andrew Hirshfeld,**

*Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2021–07704 Filed 4–14–21; 8:45 am]

**BILLING CODE 3510–16–P**

## CONSUMER PRODUCT SAFETY COMMISSION

**[Docket No. CPSC–2020–0027]**

## Agency Information Collection Activities; Submission for OMB Review; Comment Request; Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice.

**SUMMARY:** As required under the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) announces that CPSC has submitted to the Office of Management and Budget (OMB) a new proposed collection of information for a survey that will evaluate consumer awareness of infant sleep product warning labels. On December 21, 2020, the CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of this collection of information. After reviewing and considering the comments, the Commission announces that it has submitted to the OMB a request for approval of this collection of information. A copy of the proposed survey, ''Revised Supporting Statement'' titled *Consumer Product Safety Commission: Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments,* is available at: *www.regulations.gov* under Docket No. CPSC–2020–0027, Supporting and Related Material.

**DATES:** Submit written or electronic comments on the collection of information by May 17, 2021.

**ADDRESSES:** Send written comments and recommendations for the proposed information collection within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting, ''Currently under 30-day Review—Open for Public Comments,'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2020–0027.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

**SUPPLEMENTARY INFORMATION:**

**A. Background**

Under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency data-collection studies. The PRA establishes procedures agencies must follow to obtain OMB approval of a collection of information, including notice and a review of comments, among other procedures. Agencies must provide notice of the proposed collection of information in the **Federal Register**, and provide a 60-day comment period, before submitting the collection to OMB for approval. 44 U.S.C. 3506(c)(2)(A). Agencies then must evaluate any public