U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, Virginia 22313-1450

MANUAL OF PATENT EXAMINING PROCEDURE

Ninth Edition, Latest Revision November 2024

Executive Summary

November 2024 Publication of Revision 01.2024

The November 2024 publication of Revision 01.2024 includes the following changes:

Revisions to MPEP Chapters 200, 300, 400, 500, 600, 700, 900, 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1800, 2100, 2200, 2300, 2400, 2500, 2600, 2700, 2800, 2900, and Chapter FPC (Form Paragraph Book), and updates to the Foreword, Introduction, Subject Matter Index, Appendix II, Appendix L, Appendix R.

<u>Chapter 200</u> was revised to update the process for viewing status inquiries in the USPTO patent electronic filing system; to update the timeline from issue fee payment to patent issue in light of *USPTO Officially Transitions to Issuing Electronic Patent Grants in 2023*, 88 FR 12560 (February 28, 2023) and the best practice for filing continuing applications before the payment of the issue fee; and to clarify when the examiner considers the subject matter of a foreign priority document for determining whether an applicant is entitled to a claim of priority.

<u>Chapter 300</u> was revised to update the name of the Assignment Division and clarify which information in assignment records is considered to affect the integrity of the assignment record when petitioning to expunge information.

<u>Chapter 400</u> was revised to incorporate guidance on the new design patent practitioner bar created by *Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office*, 88 FR 78644 (November 16, 2023) and to clarify limitations on conducting interviews when acting in a representative capacity.

<u>Chapter 500</u> was revised to incorporate guidance from *Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office*, and updated guidance to discuss the fee reductions established in the *Unleashing American Innovators Act of 2022*, Public Law 117-328, division W, sec. 107, 136 Stat. 4459 (December 29, 2022) and implementing regulations.

<u>Chapter 600</u> was revised to incorporate changes from *Applicant-Suggested Drawing Figure in the Publication of Patent Applications*, 1514 OG 107 (September 5, 2023); to include a discussion on the non-DOCX fee; to include a citation to *Nested Bean, Inc. v. Big Beings Pty Ltd.*, IPR2020-01234, Paper 42 (Feb. 24, 2023); and to incorporate changes in how color photographs are stored and published.

<u>Chapter 700</u> was revised to clarify the propriety of final grounds of rejection; to clarify treatment of multiple dependent claims; to update interview practice; and to update discussion of secondary considerations.

<u>Chapter 900</u> was revised to reflect updates to WIPO Standards ST.9 and ST.80; to reflect the replacement of EAST/WEST with PE2E SEARCH; to clarify procedures for utilizing STIC services such as requesting

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translations; to reflect updates to the Classification Home Page; and to clarify the procedure for making classification challenges in CPC after an election.

<u>Chapter 1000</u> was revised to add cross references to MPEP sections to clarify delegations of authority to decide certain petitions; to clarify that petitions to expunge papers in reexamination and supplemental examination proceedings are decided in the Central Reexamination Unit; and to clarify that petitions relating to applications filed under the Hague Agreement are decided by the Director of International Patent Legal Administration.

<u>Chapter 1100</u> was revised to update guidance based on *Applicant-Suggested Drawing Figure in the Publication* of Patent Applications, 1514 OG 107 (September 5, 2023); to clarify guidance in alignment with *Changes To Implement the Preissuance Submissions by Third Parties Provision of the Leahy-Smith America Invents Act,* 77 FR 42150 (July 17, 2012); and to clarify which publications will and will not trigger the <u>37 CFR</u> 1.290(b)(2)(i) time period.

<u>Chapter 1200</u> was revised to incorporate guidance published in the Patent Trial and Appeal Board's (PTAB) Oral Hearing Guide; to add reference to PTAB's pro bono program; and to clarify handling procedures associated with a Pre-Appeal Brief Conference Request.

<u>Chapter 1300</u> was revised to update guidance based on *USPTO Officially Transitions to Issuing Electronic Patent Grants in 2023*, 88 FR 12560 (February 28, 2023); to clarify procedures for an examiner to amend the title; to clarify review of applications under the Quality Assurance program; to update the discussion of a petition for deferment of issue; and to update discussions on withdrawing an application from issue.

<u>Chapter 1400</u> was revised to incorporate the holding of *In re McDonald*, 43 F.4th 1340, 2022 USPQ2d 745 (Fed. Cir. 2022) regarding surrendered subject matter and to incorporate procedures for electronic issuance of all certificates of correction based on *USPTO Transitions to Issuing Electronic Certificates of Correction for Patents*, 1518 OG 588 (January 30, 2024).

Chapter 1500 was revised to incorporate guidance about the new design patent practitioner bar from Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office, 88 FR 78644 (November 16, 2023); to incorporate guidance about computer generated electronic images from Supplemental Guidance for Examination of Design Patent Applications Related to Computer-Generated Electronic Images, Including Computer-Generated Icons and Graphical User Interfaces, 88 FR 80277 (November 17, 2023) and its corrected notice, 89 FR 5506 (January 29, 2024); and to clarify when an examiner may permit claimed inventions to be shifted.

<u>Chapter 1600</u> was revised to incorporate updated guidance previously published on the USPTO's Plant Patent webpage (<u>www.uspto.gov/patents/basics/apply/plant-patent</u>).

<u>Chapter 1800</u> was revised to incorporate changes from *Adoption of Updated WIPO Standard ST.26; Revision to Incorporation by Reference*, 88 FR 34089 (May 26, 2023); to remove references to the Federal Service for Intellectual Property (Rospatent); to clarify the application of fees in a national stage application; and to clarify practice surrounding lack of unity requirements in national stage applications.

<u>Chapter 2100</u> was revised to include additional case law regarding inventorship, claim interpretation, anticipation under <u>35 U.S.C. 102</u>, obviousness under <u>35 U.S.C. 103</u>, written description, enablement, and definiteness requirements under <u>35 U.S.C. 112</u>; to clarify the discussions of the prior art exceptions under <u>AIA 35 U.S.C. 102(b)</u>; and to update the guidance on the enablement requirement consistent with *Guidelines*

for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 FR 1563 (January 10, 2024).

<u>Chapter 2200</u> was revised to incorporate the changes made in the *Advance Notice of Change to MPEP §* 2205 – Correction on supplying copies of cited prior art patents and publications in 35 U.S.C. 301 submissions; to make previously existing example letters for submitting prior art under 37 CFR 1.501 modern and consistent with the first-inventor-to-file prior art regime; and to reiterate that petitions to accept delayed priority or benefit claims filed more than two years after the foreign priority or benefit claim was due require additional explanation.

<u>Chapter 2300</u> was revised to provide an update to the interference search of applications under Secrecy Order and to replace to TC Working Group 3640 with "Licensing and Review."

<u>Chapter 2400</u> was revised to incorporate changes from *Adoption of Updated WIPO Standard ST.26; Revision to Incorporation by Reference*, 88 FR 34089 (May 26, 2023) and to update and clarify overall guidance on WIPO Standard ST.26.

<u>Chapter 2500</u> was revised to delete references to outdated procedures for patentees to request a refund of the surcharge under <u>37 CFR 1.20(h)</u> for payments submitted January 17, 2018, through July 16, 2018; to update maintenance fee payment information in light of the retirement of EFS-Web; to update the process for petitioning to accept unintentionally delayed payment of a maintenance fee; and to add a reference to new SB/460 form "Notification of Loss of Micro Entity Status."

<u>Chapter 2600</u> was revised to remove most of the guidance regarding *inter partes* reexamination because the Office does not accept requests for *inter partes* reexamination filed on or after September 16, 2012; and to add references to previous MPEP publications which contain guidance on the former practices of *inter partes* reexamination.

<u>Chapter 2700</u> was revised to incorporate changes from *Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements*, 88 FR 39172 (June 15, 2023); to include recent court decisions; to incorporate the electronic filing requirement of <u>37 CFR 1.741</u>; to clarify the requirements of an interim patent term extension under <u>35 U.S.C. 156(d)(5)</u>; and to incorporate the electronic issuance of certificates of extension of patent term.

<u>Chapter 2800</u> was revised to update fee reduction percentages for small and micro entities; to clarify guidance on electronically filing supplemental examination requests and "follow-on" papers; and to clarify examples of calculating document size fees.

Chapter 2900 was revised to update the listing of benefits to applicants of filing an international design application directly with the International Bureau through the WIPO's e-filing interface (eHague); to update instructions for electronically filing an international design application through the USPTO as an office of indirect filing; to update the process for submitting reproductions; to reflect the changes to 37 CFR 11.6 in rulemaking Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office, 88 FR 78644 (November 16, 2023); to update the application number format for retrieval of an application via WIPO DAS; and to update the process by which applicant is notified and may make payment of the issue fee to the International Bureau.

Summary of Revision Dates

MPEP Chapters

Each section that has been updated in this revision (published November 2024) has a revision indicator of [R-01.2024], meaning that the section has been updated to include changes based on published guidance documents (e.g., rulemaking, notices, guidelines, and memorandums) that were in effect on or before January 31, 2024.

MPEP Appendices

Appendix II (List of Decisions Cited) includes the decisions cited in this Revision of the Manual.

Appendix R (Patent Rules) includes the rules current as of January 31, 2024.

Appendix L (Patent Laws) includes the laws current as of January 31, 2024.

Appendix AI (Administrative Instructions under the PCT) as in force from July 1, 2022.

Appendix T (Patent Cooperation Treaty and Regulations under the Treaty) as in force from July 1, 2022.

Jeanne Clark, Editor Manual of Patent Examining Procedure

Summary of Changes to MPEP Chapters

For the revised chapters, particular attention is called to the changes in the following sections:

| Passim | Revised to remove references to EFS-Web and private PAIR, or replace with "the USPTO patent electronic filing system" or Patent Center, as appropriate, in all revised sections except MPEP \& 502.05 . |
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| Passim | Updated the reproduction of forms that were revised in revised sections. |
| Passim | Updated website addresses (URLs) where necessary in revised sections. |
| Passim | Revised to use gender neutral language, as appropriate, in revised sections. |
| Passim | Revised to remove references to legacy search systems EAST and WEST and replaced with PE2E-Search, as appropriate, in revised sections. |
| Passim | Replaced "Assignment Division" or "Assignment Branch" with "Assignment Recordation Branch," as appropriate, in revised sections. |

CHAPTER 200:

| 201.01 | Corrected reproduced text of <u>37 CFR 1.9</u> . |
|---------------|---|
| 201.06(d) | In subsections I and II.C, replaced "supervisory applications examiner (SAE)" with "Legal |
| | Instrument Examiner." |
| | In subsection II.E, added text clarifying that in a joint application with no attorney or agent, all |
| | applicants must sign a CPA except when one or more of the joint inventor-applicants is appointed |
| | to represent all of the joint inventor-applicants and added a cross reference to MPEP § 402.02(a), |
| | subsection I. |
| | In subsection II.F, added text clarifying when the Certificate of Mailing procedure under <u>37</u> |
| | <u>CFR 1.8</u> applies to filing a request for CPA. |
| | In subsection IV.B, replaced "Certification Branch" with "Certification Section of the Patent |
| | and Trademark Copy Fulfillment Branch." |
| <u>202</u> | Revised to reflect the current process for examiners to review and correct the bib-data sheet. |
| <u>203.08</u> | In subsection I, updated the process for viewing status inquiries in the USPTO patent electronic |
| | filing system. |
| | In subsection II, deleted the last paragraph. |
| | In subsection III, added a website address (URL) to the e-Office Action program. |
| 211.01(b) | Updated the timeline from issue fee payment to patent issue in light of processing times as a |
| | result of electronic patent grants (eGrants) and the best practice for filing continuing applications |
| | before the payment of the issue fee. |
| <u>211.05</u> | Added a citation to and discussion of Regents of the University of Minnesota v. Gilead Scis., |
| | Inc., 61 F.4th 1350, 2023 USPQ2d 269 (Fed. Cir. 2023). |
| 215.02 | Deleted the specific fee amounts for petitions under <u>37 CFR 1.55(f)</u> . |
| <u>216</u> | Revised to clarify when the examiner considers the subject matter of foreign priority document |
| | for determining whether an applicant is entitled to a claim of priority. |

CHAPTER 300:

| Passim | Replaced "Assignment Services Division" with "Assignment Recordation Branch," as appropriate. |
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| Passim | Replaced "PALM" or "PALM Intranet" with "Patent Data Portal," as appropriate. |
| <u>301</u> | Added a cross reference to MPEP § 325. |
| 301.01 | Replaced "Certification Division" with "Patent and Trademark Copy Fulfillment Branch of the Public Records Division." |
| 302.10 | Revised the reproduced text of <u>37 CFR 1.4</u> . |
| 317 | Changed section title to "Handling of Documents in the Assignment Recordation Branch." |
| 317.02 | Replaced "will be stamped with the original date of receipt" with "will indicate the original date of receipt" |
| 323.01(d) | Added a paragraph clarifying that information in assignment records other than personally identifiable information is considered to affect the integrity of the assignment record when petitioning to expunge assignment records. |
| <u>325</u> | In subsection V, added a cross reference to MPEP § 402. |

CHAPTER 400:

| 401 | Revised "Applicants" to "Interested parties" in the discussion of who may obtain a list of registered patent practitioners. |
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| 402 | Revised the reproduced text of <u>37 CFR 1.32</u> . In subsections II and III, revised to incorporate guidance on or due to the design patent practitioner bar. |
| <u>402.01</u> | Revised the reproduced text of <u>37 CFR 11.9</u> . |
| 402.04 | Added guidance that design patent practitioners acting in a representative capacity may only do so in design patent matters and a cross reference to MPEP \ 1502.02 . |
| 402.06 | Replaced "e-petition" with "ePetition." |
| 402.09 | Revised the reproduced text of <u>37 CFR 11.9</u> . |
| 403 | Added a new paragraph incorporating the guidance on the design patent practitioner bar regarding Customer Number practice. |
| 403.01(a) | Revised the reproduced text of <u>37 CFR 1.33</u> . |
| 405 | Revised to incorporate guidance on the design patent practitioner bar. Clarified limitations on conducting interviews when acting in a representative capacity. |

CHAPTER 500:

| <u>501</u> | Revised the reproduced text of <u>37 CFR 1.1</u> and <u>37 CFR 1.4</u> . In subsection I.A, revised the examples of patent-related correspondence that requires immediate Office attention to include petitions to defer issuance of patent under <u>37 CFR 1.314</u> . In subsection III, updated the address of the Customer Service Window. |
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| 502 | Revised the reproduced text of <u>37 CFR 1.6</u> . In the preamble before subsection I, replaced the reference to the EFS-Web Guidance and Resources with reference to the USPTO Online Filing webpage. In subsection I, revised the title by deleting "(Formerly 'Express Mail')" and deleted the discussion of Express Mail. In subsection II, updated the timeframe for filing post allowance correspondence in light of eGrant. In subsection III, added contact information for the Patent Trial and Appeal Board and updated the listing of types of patent application related correspondence and specific location where they are processed instead of the Customer Service Window. |
| 502.01 | Updated the listing of types of correspondence and specific facsimile numbers to include petitions to defer issuance of patents in item (10). |
| 502.02 | Revised the reproduced text of <u>37 CFR 1.4</u> . In subsections I and II, added guidance on the requirement in <u>37 CFR 1.4</u> that a design practitioner must indicate their design practitioner status when signing correspondence. |
| 502.03 | Revised "Internet email" to "email" in all instances. In subsection VI, revised "Deputy Commissioner for Patent Examination Policy" to "Deputy Commissioner for Patents who oversees the Office of Petitions or assigned staff in the Office of Petitions, the Office of Patent Legal Administration and the MPEP Staff Office." |
| 502.05 | Revised the Editor Note to indicate the retirement of EFS-Web. |
| 503 | In subsection I: -Updated the listing of series codes that are assigned to various applications. -Relocated the paragraph discussing the Electronic Acknowledgement Receipt to after the series codes listing. -Clarified that postcard acknowledgements are only applicable to non-electronic filings. In subsection II: -Clarified that filing receipts no longer include a suggested class in the U.S. Patent Classification System and only includes the art unit if available. -Clarified when a design patent application and a CPA are entitled to a filing date. -Clarified that non-electronically filed applications are processed by OPAP and added to the Office's Image File Wrapper system. |
| <u>505</u> | Revised the reproduced text of <u>37 CFR 1.6</u> . Clarified when correspondence submitted via the USPTO patent electronic filing system is accorded a receipt date. |
| 509 | In subsection I: -Revised the listing of how payments are applied in certain situations upon filing nonprovisional applications to include the non-DOCX fee. -Added a paragraph clarifying that in situations in which a payment of fees has been made in a national stage application prior to the expiration of 30 months from the priority date, but the applicant has not specified a sufficient amount for the payment of the basic national fee, the Office will apply the payment first to the basic national fee regardless of whether the applicant specified the fees to which the payment is to be applied. |

| <u>509.01</u> | In subsection II, replaced the Mail Center with the Customer Service Window and added a cross reference to MPEP § 501, subsection III. |
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| 509.02 | In the preamble before subsection I, updated guidance to discuss the fee reductions established in the Unleashing American Innovators Act of 2022, Public Law 117-328, division W, sec. 107, 136 Stat. 4459 (December 29, 2022) and implementing regulations. In subsection VI, expanded the quotation of 37 CFR 1.27(a)(4)(ii) and added additional guidance regarding government use license arising from an obligation under a cooperative research and development agreement, including quoting from 37 CFR 1.27(a)(4)(iii). |
| 509.03 | Revised the reproduced text of <u>37 CFR 1.27</u> . In subsection II, revised cross references to "paragraph VI. below" with " <u>MPEP § 509.03(a)</u> ." |
| 509.04 | Revised the reproduced text of 35 U.S.C. 123. In the preamble before subsection I: -Revised the background for micro entity discounts, including adding a discussion of the Unleashing American Innovators Act of 2022, Public Law 117-328, division W, sec. 107, 136 Stat. 4459 (December 29, 2022) and implementing regulationsUpdated the fee reduction percentage for micro entitiesAdded the non-DOCX filing surcharge to the listing of fees subject to the micro entity discount. |
| 509.04(e) | Incorporated form USPTO/SB/460 and associated guidance for use. Removed references to EFS-Web document descriptions. |
| <u>511</u> | In subsection I, revised the title by deleting "Express Mail' Renamed" and deleted discussion of Express Mail. |
| 512 | Revised the reproduced text of 37 CFR 1.8. Revised the suggested text for the certificates of transmission by Facsimile and via the USPTO Patent Electronic Filing System, including revising form paragraph 5.02. In subsection III.B, clarified when correspondence submitted via the USPTO patent electronic filing system is accorded a receipt date. |
| <u>513</u> | Deleted discussion of Express Mail. Revised the reproduced text of 37 CFR 1.6. |

CHAPTER 600:

| Passim | Replaced "Office's electronic filing system" with "USPTO patent electronic filing system." |
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| 601.03(a) | Revised the reproduced text of <u>37 CFR 1.33</u> . |
| 601.05 | Removed references to electronic submission via EFS-Web or in paper from the discussion of ADS submissions using Fillable Forms. |
| 601.05(a) | In subsection I, incorporated changes from <i>Applicant-Suggested Drawing Figure in the Publication of Patent Applications</i> , 1514 OG 107 (September 5, 2023). In subsection II, revised to explain that any ADS filed after the filing date of the application or the submission of a first ADS is considered a corrected ADS. |
| 601.05(b) | In subsection I, incorporated changes from <i>Applicant-Suggested Drawing Figure in the Publication of Patent Applications</i> , 1514 OG 107 (September 5, 2023). |
| 602.01(c)(1) | In subsection I, clarified that inventorship is established upon the first submission of an application data sheet or inventor's oath or declaration. |
| 606.01 | Replaced the cross reference to "MPEP § 1302.04(a)" with "MPEP § 1302.04." |
| 607 | Added language clarifying that the fee setting authority in section 10 of Public Law 112-29, September 16, 2011 (the Leahy-Smith America Invents Act) has been amended by Public Law 117-328, December 29, 2022 (Unleashing American Innovators Act). In subsection III, clarified that nonelected claims that are withdrawn from consideration will be included in fee determinations unless the claims are cancelled. In subsection IV, removed the specific dollar amount for the non-electronic filing fee and added a new paragraph discussing when the non-DOCX fee is also applicable for non-electronically filed applications. In subsection V, updated the order in which fees are applied when payment for certain filing fees is insufficient and applicant has not specified the fees to which the payment is to be applied to include the non-DOCX fee. |
| 608.01 | In subsection I: -Revised the reproduced text of <u>37 CFR 1.52</u> Emphasized that gray lines and/or a gray background sharply reduce photo reproduction quality by adding "and if present in application papers, will likely result in a notification (e.g. Notice to File Corrected Application Papers) that the papers are not in compliance with <u>37 CFR 1.52</u> ." |
| 608.01(b) | In subsection I.F, revised form paragraph 6.13. |
| 608.01(f) | Revised the reproduced text of <u>37 CFR 1.84</u> . |
| 608.01(n) | In subsection I: -Moved the content of the previous last paragraph of subsection I.B to a new paragraph of subsection IAdded a citation to <i>Nested Bean, Inc. v. Big Beings Pty Ltd.</i> , IPR2020-01234, Paper 42 (Feb. 24, 2023)In subsection I.F, added "(See Example A, below.)" to the second paragraph. |
| 608.01(v) | In subsection II: -Revised form paragraph 6.20Replaced "The Trademark Electronic Search System (TESS)" with "Trademark Search." |
| 608.02 | In subsection V, revised the reproduced text of <u>37 CFR 1.84</u> . In subsection VIII: -Revised the reproduced text of <u>37 CFR 1.84</u> Revised the discussion of how color photographs are stored in the content management system and published in patents. |

| | -Added a reminder that "All issued utility patents are presented with black and white drawings or photographs in the USPTO search systems." -Revised form paragraph 6.24.01. |
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| 608.02(c) | Replaced each instance of "stored in SCORE, and a black and white copy will be stored in IFW along with a SCORE placeholder sheet" with "stored in a content management system, and a black and white copy will be placed in the file wrapper along with a placeholder sheet." |
| 608.05 | Revised the reproduced text of <u>37 CFR 1.52</u> . In subsection II, revised the second paragraph to remove "and the 'Sequence Listing XML' cannot be filed using EFS-Web." In subsection III, revised form paragraphs 6.61.02 and 6.71.02. |
| 608.05(a) | In subsection II, revised form paragraphs 6.64.01 and 6.64.02. |
| 608.05(b) | In subsection II, revised form paragraphs 6.63.01 and 6.63.02. |
| <u>609</u> & <u>609.01</u> | Revised "e-IDS" to "eIDS" in each instance. |
| 609.05(a) | Revised form paragraph 6.49.10. |
| 609.07 | Revised the title to read "IDSs Electronically Submitted (eIDS) Using Patent Center." Replaced "e-IDS" with "eIDS." |

CHAPTER 700:

| 706.04 | Revised to be consistent with MPEP § 904.02 regarding guidance to an examiner when they consider the search of a previous examiner to be incomplete. |
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| | Added cross reference to MPEP § 904.02. |
| 706.07 | Revised form paragraph 7.39.01 and guidance for its use. |
| 706.07(a) | Clarified when a second or subsequent action on the merits will not be made final. Revised the sentence referencing 37 CFR 1.105 to replace "information" with "prior art." Clarified that a dependent claim is treated as amended if the independent claim or any claim it references is amended because a dependent claim incorporates all the subject matter of the referenced claim(s) and added cross references to 35 U.S.C. 112(d) and 37 CFR 1.75. Added guidance from MPEP § 821.04 regarding when an Office action may be made final where there is a rejoinder after the first action on the merits, including a cross reference to MPEP § 821.04 et seq. |
| 706.07(b) | Revised to provide clarifying guidance on instances when claims may or may not be finally rejected in the first Office action or in the action immediately subsequent to the filing of an RCE. Revised form paragraphs 7.41, 7.41.03, and 7.42.09. |
| 706.07(h) | In subsection VI, revised item (B) to state that applicants cannot file an RCE to obtain continued examination on the basis of claims that lack unity of invention with the claims previously elected and examined as a matter of right. Revised form paragraph 7.42.09. |
| <u>707</u> | Revised form paragraphs 7.100, 7.101, and 7.102. |
| 707.05 | Clarified that examiners should cite of interest all material "disclosures having a prior art date" after the filing date of the U.S. parent application or the foreign priority application but before the actual filing date of the application being examined. |
| 707.05(a) | Revised form paragraph 7.82.03. |
| 707.07(i) | Added a paragraph clarifying "When the application includes multiple dependent claims, treat each version of the multiple dependent claim separately in the Office action. See MPEP § 608.01(n) , subsection I.F and Nested Bean, Inc. v. Big Beings Pty Ltd., IPR2020-01234, Paper 42 (Feb. 24, 2023)." |
| 707.08 | Revised form paragraphs 7.100, 7.101, and 7.102 and guidance on their use. |
| 708 | Deleted ", whether amended or new," after "docket." |
| <u> </u> | Replaced "effective filing date" or "effective U.S. filing date" with "oldest date for which domestic benefit is claimed," "a domestic benefit claim to an earlier filing date" or "claimed domestic benefit date." |
| 708.01 | Revised the reproduced text of <u>37 CFR 1.102</u> . Revised item (E) to replace "effective filing" with "earliest claimed domestic benefit." |
| 708.02 | Revised the reproduced text of <u>37 CFR 1.102</u> . Replaced "effective United States filing dates" with "filing dates in view of any domestic benefit claimed." |
| 708.02(a) | Revised form paragraphs 7.126.AE, 7.42.08.AE, 7.51.AE, 7.71.AE, 7.84.AE, 7.95.AE, 8.26.AE, and 19.02.AE. |
| 708.02(b) | Revised the reproduced text of <u>37 CFR 1.102</u> . In subsection I.B.4, clarified that an application must be filed with the basic filing fee, the search fee, and the examination fee by deleting ", any excess claims fees, and any application size fee." |
| <u>709</u> | Replaced each occurrence of "denied" with "dismissed." |
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| | In subsection I.A, revised form paragraphs 7.56 and 7.56.01. In subsection I.C, clarified the example on requesting deferral of examination under 37 CFR 1.103(d) that the action is deferred for 36 months from the filing date of the foreign application, at which point the application will be automatically added to the docket based upon the order in which the application was filed in the USPTO. |
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| 710.02(e) | Updated the fee reduction percentages for small and micro entities. Revised to add the word "Service" in "Customer Service Window" and replaced the address of the Customer Service Window with a cross reference to MPEP \ 501 , subsection III. |
| 710.06 | Clarified what errors in an Office action may affect the ability of the applicant to reply. Clarified guidance on the interaction between an Office Customer and the Office regarding participation in the Patent Electronic Business Center e-Office Action program. |
| 711.01 | In the preamble, switched the order of items (A) and (B). |
| 711.03(c) | In subsection II.A.2, clarified the procedures for paying timely filed issue fees in the event of an entity status change, including a cross reference to MPEP § 1303. |
| 713.01 | In subsection I, updated guidance on when interviews should be conducted on campus. In subsection IV: -Clarified guidance on scheduling and conducting examiner interviewsRevised "EFS-Web Guidance and Resources" to "Patent Center Resource." |
| 713.04 | -Revised 'EFS-web Guidance and Resources' to 'Patent Center Resource.' In the preamble: -Added "or mailed" after "given" in the guidance for providing applicant/applicant's representative with a copy of the Interview Summary formUpdated to change the order of interview formats in item (E). |
| 713.05 | Replaced "proper authority" with "proper authorization." Updated procedures for registered practitioners acting in a representative capacity to have authorization to conduct interviews, including guidance on using the Applicant Initiated Interview Request Form (PTOL-413A). |
| 714.10 | Added clarification how nonelected claims that are withdrawn from consideration are treated for determining fees and a cross reference to MPEP § 607, subsection III. |
| 714.13 | In subsection III: -Clarified guidance for when the primary examiner finds the final rejection to have been premature, including adding cross references to MPEP §§ 706.07(d) to 706.07(f). -Updated examiner procedures for annotating amendments after a final rejection. In subsection IV and V, added multiple instances of the word "Service" in "Customer Service Window" and replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. |
| 714.16(d) | In the preamble: -Replaced "(unless specifically)" with "(including if specifically)." -Revised to add the word "Service" in "Customer Service Window" and replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. In subsection III: -Revised to state that amendments required by the Office of Data Management that are going to be hand-delivered must be delivered to the Customer Service WindowReplaced the old address of the Office of Data Management with a cross reference to MPEP § 501, subsection III. |
| <u>715</u> | Clarified that the effective filing date is of the claimed invention. In subsection II: -Revised item (E) to replace "parent application or an International Convention proved filing date" with "claimed invention." |

| | -Revised item (F) to "Where the reference U.S. patent or U.S. patent application publication claims the same invention and the claimed invention under examination is subject to statutory double patenting. See MPEP § 804." -Revised item (G) to replace "reference" with "rejection." In subsection III.A, clarified the date to be overcome under 37 CFR 1.131(a). Revised form paragraph 7.64.fti . |
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| 715.01(a) | Revised to more clearly articulate guidance when there is a joint inventor or sole inventor and to reflect AIA definitions of applicant and inventor. Added "traversing the rejection" following "37 CFR 1.132" in the first sentence. Clarified the discussion of <i>EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.</i> , 859 F.3d 1341, 123 USPQ2d 1146 (Fed. Cir. 2017). |
| 715.01(b) | Clarified guidance by replacing "shows" with "discloses" and "it" with "subject matter," and adding "under examination" after "and the application." |
| 715.01(c) | In subsection I: -Revised to more clearly articulate guidance when there is a joint inventor or sole inventor and to reflect AIA definitions of applicant and inventorClarified the discussion of <i>EmeraChem Holdings</i> , <i>LLC v. Volkswagen Grp. of Am., Inc.</i> , 859 F.3d 1341, 123 USPQ2d 1146 (Fed. Cir. 2017). |
| 715.02 | Replaced instances of "35 U.S.C. 103" with "35 U.S.C. 103(a)." Revised to reflect AIA definitions of applicant and inventor. In the preamble, replaced "If the affidavit contains in the activity" with a quote from and citation to <i>In re Clarke</i> , 356 F.2d 987, 148 USPQ 665 (CCPA 1966). In subsection I, clarified that references have a "prior art date" and to add "the inventor's" prior to "possession." In subsection II, revised to clarify that the reference has a prior art date. |
| 715.03 | In the preamble, clarified that references have a prior art date. In subsection I.B, added "the inventor's" before "prior possession." In subsection I.C: -Deleted "as opposed to species of a claimed genus." -Added a quotation from and citation to <i>In re DaFano</i> , 392 F.2d 280, 157 USPQ 192 (CCPA 1968). In subsection II: -Revised the discussion of <i>In re Shokal</i> to a direct quotation. -Replaced "skilled" with "of ordinary skill" and corrected the citation to <i>In re Schaub</i> . |
| 715.04 | In subsection I, revised to more clearly articulate guidance when there is a joint inventor or sole inventor and to reflect AIA definitions of applicant and inventor. |
| 715.05 | Replaced "35 U.S.C. 103" with "pre-AIA 35 U.S.C. 103(a)." Replaced "domestic reference" with "U.S. patent or patent application publication." |
| 715.07(a) | Deleted "or inventors" in the first paragraph. Added "of the reference as prior art" after "effective date" in discussing conception. Revised to reflect AIA definitions of applicant and inventor. Deleted "due" prior to "diligence." |
| 715.10 | Clarified that the effective filing date is of "the claimed invention" in the application or patent. |
| 716.01(b) | Replaced "To be given" with "If the evidence is to be given." Added a citation to <i>Yita LLC v. MacNeil IP LLC</i> , 69 F.4th 1356, 2023 USPQ2d 667 (Fed. Cir. 2023). Clarified who bears the burden of establishing a nexus and added a citation to <i>In re Huang</i> , 100 F.3d 135, 140 (Fed. Cir. 1996). |

| | Added a discussion of and citation to <i>Volvo Penta of the Americas, LLC v. Brunswick Corp.</i> , 81 F.4th 1202, 2023 USPQ2d 1000 (Fed. Cir. 2023). |
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| 716.01(c) | In subsection II: -Revised the title by replacing "ATTORNEY ARGUMENTS" with "ARGUMENTS BY APPLICANT." -Replaced "The arguments of counsel" with "Arguments presented by the applicant." -Added a citation to <i>In re De Blauwe</i> , 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984). |
| 716.01(d) | Added citation to and discussion of <i>Volvo Penta of the Americas, LLC v. Brunswick Corp.</i> , 81 F.4th 1202, 2023 USPQ2d 1000 (Fed. Cir. 2023). |
| 716.02 | Added citation to and quote from UCB, Inc. v. Actavis Labs, UT, Inc., 65 F.4th 679, 2023 USPQ2d 448 (Fed. Cir. 2023). |
| 716.03 | In subsection I: -Revised the title to "BURDEN OF PRODUCTION FOR EVIDENCE OF COMMERCIAL SUCCESS AND NEXUS." -Clarified guidance on the burden of production for evidence of commercial success by removing the discussion of nexus. |
| 716.03(b) | In subsection I: -Revised the title by replacing "DERIVED FROM" with "ATTRIBUTABLE TO." -Replaced "directly derived from" with "a result of." -Added a citation to <i>UCB</i> , <i>Inc. v. Actavis Labs, UT, Inc.</i> , 65 F.4th 679, 2023 USPQ2d 448 (Fed. Cir. 2023)Replaced "accorded substantial" with "given any" prior to the citation to <i>In re Huang</i> . |
| 717.01 | In subsection III, revised item (B) to add "and does not name anyone else" after "examination." |
| 717.01(b)(2) | In subsection IV, revised to add specific references to <u>35 U.S.C. 102(b)(1)(B)</u> or <u>35 U.S.C. 102(b)(2)(B)</u> , to generically refer to disclosure, and to add a parenthetical regarding prior disclosure of the genus. |
| 717.01(c) | In subsection I: -Clarified who should file the affidavit or declaration under 37 CFR 1.130Added a cross reference to MPEP § 2155.05. |
| 717.02(a) | In subsection I.B: -Added "The statement must be signed in accordance with 37 CFR 1.33(b)." -Deleted "of record" after "representative(s)." |
| 717.02(b) | In subsection III: -Added "The statement must be signed in accordance with 37 CFR 1.33(b)." -Deleted "of record" after "representative(s)." -Replaced two instances of "attorney or agent of record" with "patent practitioner." -Clarified that the effective filing date is of the claimed invention in the application. |
| 724.02 | Revised to add the word "Service" in "Customer Service Window" and replaced the address of the Customer Service Window with a cross reference to MPEP \ 501 , subsection III. |

CHAPTER 900:

| 901.05(b) | In subsection I, updated the reproduction of WIPO Standard ST.9. In subsection II, updated the reproduction of WIPO Standard ST.80. |
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| 001.05(a) | Revised the list of sources for examiners to obtain foreign patents. |
| 901.05(c) | Added a discussion of the Foreign Image and Text (FIT) database available in PE2E SEARCH. |
| 901.05(d) | Clarified the process for requesting machine and human translations. |
| | Corrected the name of the STIC's "Foreign Patent Service Center" by deleting "and Scientific |
| | Literature." |
| 901.06(a) | In the preamble, updated the address of the STIC Library. |
| | In subsection I.A: |
| | -Clarified the types of publications available from STIC and the process for discovering them |
| | -Updated the process for submitting a request to purchase a publication not currently available |
| | from STIC. |
| | In subsection I.B, clarified the types of STIC periodicals available and the process for discovering |
| | them. |
| | In subsection I.D, revised the processing for locating NPL Services for Examiners on the USPTO |
| | intranet. |
| | In subsection II, clarified how to use the STIC online catalog. |
| | In subsection III, clarified the process for requesting materials from other libraries. |
| | In subsection IV.A, deleted instances of "Reference Desk" and "STIC Reference Desk." |
| | In subsection IV.B: |
| | -Updated names of forms used to request litigation or patent family searches. |
| | -Removed an instance of "Reference Desk." |
| | -Replaced "STIC's Digital Resources Division" with "the USPTO Learning Center." |
| | In subsection IV.C, deleted reference to the Foreign Patent Access System (FPAS) in |
| | EAST/WEST. |
| | In subsection IV.D, clarified the available languages for which oral translations are available |
| | and added a website address (URL) where examiners may review a list of available translators. |
| | In subsection IV.E, clarified the process for obtaining materials from other libraries. |
| 901.06(c) | Removed reference to the database for U.S. A.P.C. bib data. |
| 902.02 | Removed the statement that class definitions are archived to CD-ROM. |
| | Replaced "Main STIC" with "Main Library of STIC." |
| 902.03(a) | Updated the discussion of Office of Patent Classification Home Page. |
| 902.03(b) | Deleted the discussion of the Patent Classification Retrieval System. |
| 902.03(e) | Replaced a reference to the Patent Search Room with a website address (URL) to the Patent Public Search tool (PPUBS). |
| 903.03 | Deleted a reference to the Foreign Patent Access System (FPAS). |
| 203.03 | Replaced "Main STIC" with "Main Library of STIC." |
| 903.07 | Corrected two instances of the name of "Examiner Handbook on the Use of the U.S. Patent |
| <u> </u> | Classification System." |
| | Replaced three instances of "IFW issue classification form" with "issue classification sheet." |
| 000 01(1) | ^ |
| 909.01(d) | In subsection II: |
| | Revised the procedure for making a classification challenge after a restriction requirement. |
| | Added a cross reference to MPEP § 812. |
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CHAPTER 1000:

| 1002.02(b) | In item 4, deleted "For utility and plant applications filed on or after November 29, 2000." In item 5, replaced "right of priority under 37 CFR 1.55(c)" with "right of foreign priority, 37 CFR 1.55(c) and MPEP § 213.03, subsection III." In item 6, replaced "priority papers under 37 CFR 1.55(f)" with "certified copy of foreign application, 37 CFR 1.55(f) or (g), as applicable, and MPEP § 215.02." In item 7, deleted "For utility and plant applications filed on or after November 29, 2000." In item 8, replaced "a domestic benefit claim under 37 CFR 1.78(b) or (e)" with "the benefit of a provisional application, 37 CFR 1.78(b) and MPEP § 211.01(a), subsection II." In item 10, added a cross reference to 37 CFR 1.313(c)(3). In item 13, added "in the regulations." In item 31, added a cross reference to MPEP § 710.02(e). |
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| | In item 35, removed "or patent files." In item 47, added "and 1.29" to incorporate the correction of an error in establishing micro entity status. Added new item 49 for petitions to issue a corrected patent under 37 CFR 1.322(b). Added new item 50 for requests for a certificate of correction that affects related U.S. application data or foreign priority data. |
| 1002.02(c) | In item 2, clarified that petitions under 37 CFR 1.144 involving restriction practice include those involving a finding that a national stage application lacks unity of invention and to add cross references to 37 CFR 1.499 and MPEP § 1893.03(d). In item 15, removed "or patent files." In item 20, replaced "37 CFR 1.103, MPEP § 709" with "37 CFR 1.103(a), MPEP § 709, regardless of which rule the first or prior request for suspension was based on." |
| 1002.02(c)(4) | In item 4, added "in reexamination and supplemental examination proceedings." |
| 1002.02(1) | Deleted item 2 and renumbered item 3 as item 2. |
| 1002.02(p) | In item 13, clarified which decisions to withdraw an examiner's action are decided by the Director of International Patent Legal Administration. Added new item 22 for requests for a certificate of correction that affects related U.S. application data or foreign priority data in a patent resulting from an application under 35 U.S.C. 371 or which claims the benefit of or priority to an international application filed under the PCT. Added new item 23 for the late filing of a certified copy of foreign application under 37 CFR 1.55(f) dealing with PCT related issues. |
| | Added new item 24 for decisions to withdraw national stage applications from issue for failure to comply with 35 U.S.C. 371(c). Added new items 25-30 clarifying that petitions relating to issues under the Hague Agreement are decided by the Director of International Patent Legal Administration. |
| 1002.02(q) | In item 4, deleted "the Office of Initial Patent Examination or where the nonprovisional application is before." |
| 1002.02(t) | Replaced "Office of Patent Information Management" with "Office of Information Technology for Patents" in the title and the body of the section. |
| 1003 | Deleted item 1.c. |

CHAPTER 1100:

| Passim | Revised to replace references to Image File Wrapper (IFW) with "image file wrapper" or "file wrapper" as appropriate in revised sections. |
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| <u>1121</u> | Revised the reproduced text of <u>37 CFR 1.215</u> and <u>pre-AIA 37 CFR 1.215</u> . |
| | In subsection I.A, corrected the reference to <u>37 CFR 1.63(d)(1)(iii)</u> by adding "pre-AIA." |
| <u>1125</u> | Deleted "- Patent Publication Branch" after "Office of Data Management." |
| 1126 | Added asterisks to the reproduced text of <u>37 CFR 1.211</u> to indicate the existence of text not reproduced. Replaced "Office of Data Management – Patent Publication Branch" with "Office." |
| 1128 | Added asterisks to the reproduced text of <u>37 CFR 1.14</u> to indicate the existence of text not reproduced. In subsection I, replaced references to the Image File Wrapper (IFW) system with "Patent Center" and deleted an occurrence of "via Patent Center." |
| 1129 | Revised the reproduced text of <u>37 CFR 1.219</u> . |
| 1130 | Revised the reproduced text of 37 CFR 1.221. In subsection I, replaced "EFS-Web Legal Framework" with "Legal Framework for Patent Electronic System." In subsection II.A: -Revised "(effective) filing date" to "filing date." -In item (D), replaced "first sentences" with "first sentence(s)." |
| | In subsection II.B: -Updated situations in which applicants should not file a request for a corrected publication and which situations are not an Office error based on <i>Applicant-Suggested Drawing Figure in the Publication of Patent Applications</i> , 1514 OG 107 (September 5, 2023); -In item (C), deleted reference to the first sentence of the specification for applications filed on or after September 16, 2012. |
| <u>1132</u> | Revised the reproduced text of <u>37 CFR 1.217</u> . |
| 1133 | Revised the reproduced text of <u>37 CFR 1.221</u> . Replaced "EFS-Web Legal Framework" with "Legal Framework for Patent Electronic System." |
| 1134 | Changed "While" to "For example," before "37 CFR 1.290 limits printed publications." Inserted "while" before "37 CFR 1.291 provides publications." Corrected the cross reference to subsection V of MPEP § 1901.06. Clarified that a concise explanation for a protest under § 1.291(c)(2) allows for arguments against patentability, in alignment with <i>Changes To Implement the Preissuance Submissions by Third Parties Provision of the Leahy-Smith America Invents Act</i> , 77 FR 42150 (July 17, 2012). |
| 1134.01 | In subsection I, clarified which publications will and will not trigger the 37 CFR 1.290(b)(2)(i) time period. In subsection I.B, clarified that the web-based interface for preissuance submissions is in Patent Center. |
| | In subsection II, replaced "statements" with "a statement" in item (E). In subsection II.B.1: |
| | -Moved the cross reference to subsection IV.F up within the same paragraphClarified that, whether filing electronically or in paper, concise descriptions of relevance may be combined into a single paper. |
| | In subsection II.B.3, corrected the teaching of element B to appear in the Publication Y column in the example in the last claim chart. |
| | In subsection II.F.3, updated the instructions for paying the small entity fee when submitting a third-party submission via the USPTO patent electronic filing system. |
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In subsection II.F.4, updated the small entity fee amounts.

Submission" with "Request email notification."

In subsection IV.E:

- -Updated the website address (URL) and instructions for filing a third-party submission via the dedicated web-based interface in the USPTO patent electronic filing system.
- -Added guidance stating that applicant papers filed via the dedicated web-based interface for third-party submissions will not be entered into the application file and an applicant must become a registered user of the USPTO patent electronic filing system to file papers electronically in their application.

In subsection IV.F:

- -Updated the website address (URL) and instructions for filing a third-party submission in paper. -Clarified that the dedicated web-based interface is "for third-party submissions in the USPTO
- patent electronic filing system."

 In subsection V, deleted references to the AIA help telephone number and email address.

 In subsection VI.A.1, replaced "Request for Notification Regarding Third-Party Preissuance

CHAPTER 1200:

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| <u>1201</u> | Added information concerning the Patent Trial and Appeal Board Pro Bono Program. |
| <u>1204</u> | In subsection IV, removed reference to Form PTO/SB/31. |
| 1204.02 | Clarified that any amendment filed under 37 CFR 1.116 filed on the same day as a Pre-Appeal Brief Conference Request will be treated as accompanying the request. Clarified the procedural handling when a notice of appeal, Pre-Appeal Brief Conference Request and Request for Continued Examination are filed on the same day. |
| 1204.04 | Replaced reference to PTO/SB/08a or 08b with PTO/SB/08. |
| 1206 | Clarified the handling of amendments filed on the same date as or after a non-compliant appeal brief. |
| 1209 | Added reference to the Patent Trial and Appeal Board's Oral Hearing Guide. Revised to be consistent with the guidance in the Patent Trial and Appeal Board's Oral Hearing Guide. |
| 1214.01 | Clarified that the provisions of <u>37 CFR 41.50(b)(1)</u> apply to an examiner's rejection after an amendment in response to a new ground of rejection by the Board, even if such rejection is not final. |
| 1214.04 | Clarified that an examiner is expected to bring a prior art search up-to-date prior to allowance on an application. |
| | Revised to provide guidance to an examiner when they consider the search of a previous examiner to be incomplete. |
| | Clarified that when an examiner is proposing a new rejection for any reason of any appealed claim as to which the examiner was reversed, the proposed rejection must be submitted to the TC or CRU Director unless an exception applies. |
| 1216.02 | Updated to reflect that a copy of a complaint and summons in a civil action under <u>35 U.S.C. 145</u> or <u>146</u> must be served in a timely manner to the U.S. Attorney for the Eastern District of Virginia. |

CHAPTER 1300:

| Passim | Replaced references to Image File Wrapper (IFW) with "image file wrapper" or "file wrapper" |
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| rassim | as appropriate in revised sections. |
| 1302.01 | Clarified that if a satisfactory title is not supplied by the applicant, the examiner may require a change to the title on or after allowance. |
| 1302.04 | Added an exception that an examiner may amend the title to correspond with the claim where the Office has established the title as described in MPEP \sigma 2920.04(a) in an examiner's amendment without approval from applicant. Clarified the review of applications under the Quality Assurance program and added a cross reference to MPEP \sigma 1308.03 . |
| 1302.08 | Updated the examples of performing an interference search to include a classified search or a combination of text search and classified search. |
| 1302.14 | In subsection III, in item (D), clarified "effective filing date" by adding "the claims of" this application "are entitled to." In subsection IV, clarified that any comments filed by applicant on the examiner's statement of reasons for allowance "must be filed" no later than payment of the issue fee. |
| 1303 | Deleted the sentence reminding applicants to transmit an extra copy of the PTOL-85B when payment of the issue fee is by way of authorization to debit a Deposit Account and the cross reference to MPEP \ 509.01 . |
| <u>1306</u> | Updated the fee reduction percentages for small and micro entities. |
| 1306.01 | Revised the discussion of a petition for deferment of issue by adding details of timely consideration and means for filing and confirming receipt of the petition. |
| 1306.03 | Updated guidance based on <i>USPTO Officially Transitions to Issuing Electronic Patent Grants in 2023</i> , 88 FR 12560 (February 28, 2023). |
| <u>1307</u> | Removed and reserved. |
| 1308 | In subsection I.B, added a statement about the procedure for withdrawing a design application from issue and revised to reflect the changes in practice for petitions to withdraw an application from issue under 37 CFR 1.313(c). |
| | In subsection II, revised the discussion on the authority to withdraw an application from issue, added cross references to MPEP § 1002.02(p), and replaced "Deputy Commissioner for Patent Examination Policy" with "Deputy Commissioner Who Oversees the Office of Petitions." In subsection II.A, deleted reference to "status code 091 (Withdraw From Issue – Awaiting Action)." |
| | In subsection II.B, deleted reference to "status code 066 (Previous Action Withdrawn – Awaiting Further Action) by using transaction code 1040." |
| 1308.03 | Clarified the review of applications under the Quality Assurance program. |
| 1309 | Updated to add guidance based on <i>USPTO Officially Transitions to Issuing Electronic Patent Grants in 2023</i> , 88 FR 12560 (February 28, 2023), including new subsection IV. Added cross references to 37 CFR 1.9(k) and MPEP § 2128, subsection II, for electronically issued patents are considered printed patents and to MPEP Chapter 1400 for information on the correction of an issued patent. |

CHAPTER 1400:

1412.02 In the preamble before subsection I, updated to include citations to *In re McDonald*, 43 F.4th 1340, 2022 USPQ2d 745 (Fed. Cir. 2022) and *In re Youman*, 679 F.3d 1335, 102 USPQ2d 1862 (Fed. Cir. 2012). In subsection I: -Clarified that, in the context of recapture case law, claims are considered canceled if they were replaced by other claims that are more specific than the canceled claims in at least one aspect in order to overcome a rejection. -Corrected the pin citation for MBO Laboratories, Inc. v. Becton, Dickinson & Co., 602 F.3d 1306, 94 USPQ2d 1598 (Fed. Cir. 2010). -Added citations to In re McDonald, 43 F.4th 1340, 2022 USPQ2d 745 (Fed. Cir. 2022). -Clarified that an SGL or surrendered subject matter can be by presentation of new/amended claims or an argument/statement to obviate a rejection based on other grounds than a prior art In subsection II.B, changed subsection title to "The Second Step - Does Any Broadening Aspect of the Reissue Claim Relate to Surrendered Subject Matter?" In subsection II.B.1: -Added a citation to *In re McDonald*, 43 F.4th 1340, 2022 USPQ2d 745 (Fed. Cir. 2022). -Clarified that reliance by applicant can be created by presentation of new/amended claims or arguments/statements to obviate rejections based on other grounds than a prior art rejection. In subsection II.C: -Defined the acronym "(SGL)." -Revised "two possibilities" to "several possibilities" before the situational examples provided. -Revised the titles of the situational examples to clarify the purpose of each example. -Moved the citation of *In re Mostafazadeh*, 643 F.3d 1353, 98 USPQ2d 1639 (Fed. Cir. 2011). -Added a citation to and quotation from In re Youman 679 F.3d 1335, 102 USPQ2d 1862 (Fed. Cir. 2012) to clarify that even if the retained portion of a modified limitation is not well known, there may still be impermissible recapture. -Added "for example" in the first sentence of the last paragraph. In subsection III, clarified that surrendered subject matter can be created when overcoming rejections other than those based on prior art during prosecution of an original patent. In subsection III.B.2, deleted "Note" prior to the citation to *In re Clement*. In subsection III.B.4, expanded the discussion of *In re Youman* 679 F.3d 1335, 102 USPQ2d 1862 (Fed. Cir. 2012). In subsection VI, revised form paragraph 14.17. In subsection VIII, revised the flowchart for reissue recapture to more clearly show the process for determining the presence or absence of recapture and add cross references to corresponding sections of the MPEP. 1444 In subsection IV, revised "request the submission of the supplemental oath/declaration by EFS-Web or fax" to "request submission of the supplemental oath/declaration." 1451 Revised the example of suggested language for cross referencing multiple reissue applications resulting from a single patent. 1453 In subsection III: -Revised form paragraph 14.21.01.

1480.01 Added a reference to Notification of Approval-in-part form PTOL-404 to notify patentees of

-Replaced "PTO-303" with "PTOL-303" in the last paragraph.

partial acceptance of a request for a certificate of correction.

Clarified how assignment data is captured for printing on a patent.

| 1485 | In the preamble prior to subsection I: -Removed or replaced references to "the person making the request" with "patentee," as applicableRemoved reference to PTO/SB/44 in the sentence discussing partial approval. In subsection I, incorporated <i>USPTO Transitions to Issuing Electronic Certificates of Correction for Patents</i> , 1518 OG 588 (January 30, 2024). |
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| 1490 | In subsection II: -Clarified that the filing of a terminal disclaimer may affect any patent term adjustment provided under 35 U.S.C. 154(b). -Added a citation to <i>In re Cellect, LLC</i> , 81 F.4th 1216, 2023 USPQ2d 1011 (Fed. Cir. 2023). In subsection V.B, clarified how terminal disclaimers other than eTDs are processed. In subsection VI.A, added additional specific situations in which a contingent terminal disclaimer is improper. In subsection VIII, clarified that a recorded terminal disclaimer may only be withdrawn if a petition under 37 CFR 1.182 is granted before a patent or reexamination certificate issues, as applicable. |

CHAPTER 1500:

| 1502.02 | Added a new section titled "Design Patent Practitioner Bar" which incorporates guidance from |
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| | Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office, 88 FR 78644 (November 16, 2023). |
| <u>1503.01</u> | In subsection I, deleted language discussing the preamble being printed on a patent. |
| 1503.02 | Revised form paragraph 15.48. In subsection V, clarified how to represent color in black and white line drawings, and added cross references to 37 CFR 1.84(a)(1) and 1.84(n) and MPEP § 608.02, subsection IX. |
| <u>1504</u> | Clarified that an applicant for a design patent application can employ a design patent practitioner registered under 37 CFR 11.6(d) or a patent practitioner registered under 37 CFR 11.6(a)-(c). |
| 1504.01(a) | Revised to replace "icons" with "electronic images" in numerous instances, including in the section title, the preamble before subsection I, the titles of subsection I and subsection I.B, and the preamble before subsection I.A and subsection I.B. In subsections I.A and I.B, revised to incorporate guidance from <i>Supplemental Guidance for Examination of Design Patent Applications Related to Computer-Generated Electronic Images, Including Computer-Generated Icons and Graphical User Interfaces</i> , 88 FR 80277 (November 17, 2023) (hereinafter Supplemental Guidance). Added a new subsection I.C titled "Examples" which incorporates examples 1 and 3-5 in the corrected <i>Supplemental Guidance for Examination of Design Patent Applications Related to Computer-Generated Electronic Images, Including Computer-Generated Icons and Graphical User Interfaces</i> , 89 FR 5506 (January 29, 2024) (hereinafter Corrected Supplemental Guidance). Deleted subsection II and renumbered subsequent existing subsections as conforming changes. In renumbered subsection III, revised the title to replace "icons" with "electronic images," replaced "Computer generated icons including images" with "Computer-generated electronic images" in the first sentence, and revised to incorporate example 2 in the Corrected Supplemental Guidance. |
| 1504.03 | Replaced the address for the Customer Service Window with a cross reference to MPEP § 501, subsection III. In subsection I.D, added a cross reference to subsection III of this section and MPEP § 716 et seq. for more information on evaluating secondary considerations. In subsection III: -Added a cross reference to MPEP § 2145. -Added a citation to Campbell Soup Co. v. Gamon Plus, Inc., 10 F.4th 1268, 2021 USPQ2d 875 (Fed. Cir. 2021) and a cross reference to MPEP § 716.01(b). |
| 1504.04 | In subsection I.B, revised form paragraph 15.51.01. In subsection I.C.2: -Clarified that claims for priority to or benefit of an earlier-filed application are claiming the "filing date" of the earlier-filed applicationAdded a cross reference to MPEP § 1504.10. In subsection I.C.3, revised form paragraphs 15.51 and 15.51.01. |
| 1504.05 | In the preamble, clarified when an examiner may permit a claimed invention to be shifted and added a cross reference to MPEP \ 819 . Revised form paragraph 15.33. |
| 1504.30 | Replaced the address for the Customer Service Window with a cross reference to MPEP § 501, subsection III. |

CHAPTER 1600

| <u>1601</u> | Revised to add apomictic seeds, bulbs, division, slips, rhizomes, runners, corms, tissue culture, and |
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| | nucellar embryos as examples of asexual reproduction means. |

Added a citation to S. Rep. No. 71-315 (1930).

Revised to incorporate the plain meaning of the term "plant" and to further reiterate that invention in a plant patent is a two-step process.

Revised to reiterate that a plant patent is limited to one plant or genome and to further explain that a sport or mutant is unlikely to have the same genome as the original plant.

Clarified that plant patent applications are examined with respect to the same statutory provisions as other national applications with a cross reference to MPEP § 1608.

Added cross references to MPEP §§ 324, 325 and 402.

- 1604 Added cross reference to MPEP § 602.01(a).
 - Added guidance on how a person may qualify as an inventor or joint inventor in a plant application.
- 1606 Revised to indicate that watercolor renderings are a type of drawing.

CHAPTER 1800:

| Passim | Revised to remove references to the Federal Service for Intellectual Property (Rospatent). |
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| 1805 | Replaced the address for hand delivery of international applications with a cross reference |
| 1000 | to MPEP § 501, subsection III. |
| | Added "subsection III" to the cross reference to MPEP § 1834. |
| 1809 | Changed the section title to "Access to the USPTO patent electronic filing system." |
| | Updated the process for obtaining status information relating to patent applications via |
| | Patent Center. |
| | Updated the process for associating a new international application with an existing customer |
| | number. |
| <u>1823</u> | Added a citation and website address (URL) to Section 204 of the Administrative Instructions |
| | (in effect before July 1, 2022). |
| | Clarified that for international applications having an international filing date on or after |
| | July 1, 2022, where applicable, the description shall include a sequence listing as a separate |
| | part of the description complying with the standard provided for in the PCT Administrative |
| | Instructions. Added cross references to MPEP § 1823.02 and MPEP § 1823.01. |
| 1922 02 | |
| <u>1823.02</u> | Revised the section Editor Note to clarify that the rules reproduced in this section apply to national phase applications. |
| | In subsection I: |
| | -Revised the Editor Note to clarify that the rules reproduced in this subsection apply to |
| | national phase applications. |
| | -Revised to update and clarify overall guidance on WIPO Standard ST.26. |
| | In subsection II: |
| | -Revised the Editor Note to clarify that the rules reproduced in this subsection apply to |
| | national phase applications. |
| 1840.04 | Removed and reserved. |
| <u>1848</u> | Revised the section Editor Note to clarify that the rules reproduced in this section apply to |
| | national phase applications. |
| | In subsection I: |
| | -Revised subsection title to add "STANDARD" in the parenthetical. |
| | -Revised the Editor Note to clarify that the rules reproduced in this subsection apply to |
| | national phase applications. |
| | -Revised to update and clarify overall guidance on WIPO Standard ST.26Deleted a cross reference to MPEP § 1823.02. |
| | In subsection II: |
| | -Revised the Editor Note to clarify that the rules reproduced in this subsection apply to |
| | national phase applications. |
| | -Added a cross reference to MPEP § 1823.02, subsection II. |
| 1851 | In the discussion of country codes, replaced a reference to "Annex A, Section I" with "Annex |
| | I" and two references to "Annex B" with "Annex II." |
| <u>1857</u> | Corrected the reproduction of PCT Rule 48.2. |
| <u>1865</u> | Replaced the address for hand delivery of the Demand with a cross reference to MPEP § |
| | 501, subsection III. |
| | Replaced "e-filers" with "users." |
| 1893.01(a)(1) | Moved a sentence discussing when a copy of an international application is not required |
| | from the first paragraph to the fourth paragraph. |

| 1893.01(c) | Added a paragraph clarifying that in situations in which a payment of fees has been made in a national stage application prior to the expiration of 30 months from the priority date, but the applicant has not specified a sufficient amount for the payment of the basic national fee, the Office will apply the payment first to the basic national fee regardless of whether the applicant specified the fees to which the payment is to be applied. |
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| 1893.03(a) | Updated the process for identifying an application as a national stage submission under 35 U.S.C. 371 when filing an application via the USPTO patent electronic filing system. Updated the discussion of when conflicting instructions may be present in an initial submission under 35 U.S.C. 371. |
| 1893.03(d) | Clarified that unity of invention analysis is applicable in national stage applications submitted under 35 U.S.C. 371. Added cross references to 37 CFR 1.143, 1.144, 1.499, and MPEP § 1002.02(c) regarding review of a lack of unity requirement. Clarified that the examiner may make a lack of unity requirement in a national stage application even if no such requirement was made by the ISA or IPEA. |
| 1893.03(e) | In subsection II, added "lack of unity of invention" after "non-binding opinion regarding." |
| <u>1896</u> | In subsection III, added a cross reference to MPEP § 1893.03(d). |

CHAPTER 2100:

| Passim | Replaced "the time the invention was made" with "the relevant time," as appropriate, in revised sections. Clarified that the effective filing date is of "the claimed invention" in the application or patent. |
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| 2106.07(a)(1) | Added a reminder that it is not necessary to identify a single statutory category into which a claim falls so long as it is clear that the claim falls into at least one statutory category, including a cross reference to MPEP \struct 2106.03 . Revised form paragraph 7.05.01. |
| 2109 | In subsection VII, revised to include additional case law regarding inventors and joint inventors having to be natural persons with citations to and discussions of <i>Thaler v. Vidal</i> , 43 F.4th 1207 (Fed. Cir. 2022); <i>Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V.</i> , 734 F.3d 1315, 107 USPQ2d 1989 (Fed. Cir. 2013); and <i>Beech Aircraft Corp. v. EDO Corp.</i> , 990 F.2d 1237, 26 USPQ2d 1572 (Fed. Cir. 1993). |
| 2111.01 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection I, revised to include citations to and discussion of <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) and <i>Salazar v. AT&T Mobility LLC</i> , 64 F.4th 1311, 2023 USPQ2d 412 (Fed. Cir. 2023). In subsection II, revised to include a citation to and discussion of <i>Sisvel Int'l S.A. v. Sierra Wireless, Inc.</i> , 81 F.4th 1231, 2023 USPQ2d 1030 (Fed. Cir. 2023). In subsection III, revised to include an additional citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) regarding consulting extrinsic evidence and new citations to and discussions of <i>Malvern Panalytical Inc. v. TA Instruments-Waters LLC</i> , 85 F.4th 1365, 2023 USPQ2d 1297 (Fed. Cir. 2023) and <i>Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc.</i> , 85 F.4th 1167, 2023 USPQ2d 1314 (Fed. Cir. 2023). In subsection IV, revised to include a citation to <i>CCS Fitness, Inc. v. Brunswick Corp.</i> , 288 F.3d 1359, 62 USPQ2d 1658 (Fed. Cir. 2002). In subsection IV.A, revised to include a citation to and discussion of <i>Apple Inc. v. Corephotonics, Ltd.</i> , 81 F.4th 1353, 2023 USPQ2d 1056 (Fed. Cir. 2023). In subsection V, replaced "special definition" with "meaning provided by the specification" in the last paragraph. |
| 2111.03 | In subsection I, revised to include a citation to and discussion of <i>Amgen Inc. v. Amneal Pharmaceuticals LLC</i> , 945 F.3d 1368, 2020 USPQ2d 3197 (Fed. Cir. 2020) and a cross reference to MPEP § 2117. In subsection II: -Revised to include a citation to and discussion of <i>Amgen Inc. v. Amneal Pharmaceuticals LLC</i> , 945 F.3d 1368, 2020 USPQ2d 3197 (Fed. Cir. 2020)Relocated the last paragraph as the second paragraph. |
| 2112 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| 2112.02 | In subsection II, clarified that the applied prior art in <i>In re May</i> disclosed the same compounds "as well as a method of using them." |
| 2113 | In subsection I, revised to include citations to and discussions of <i>Biogen MA Inc. v. EMD Serono, Inc.</i> , 976 F.3d 1326, 2020 USPQ.2d 11129 (Fed. Cir. 2020) and <i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , 74 F.4th 1360, 2023 USPQ2d 862 (Fed. Cir. 2023). |

| 2117 | In subsection I, revised to include a citation to and discussion of <i>Amgen Inc. v. Amneal Pharmaceuticals LLC</i> , 945 F.3d 1368, 220 USPQ2d 3197 (Fed. Cir. 2020). |
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| 2120 | In subsection I, revised to clarify in item (C) that an exception in a <u>37 CFR 1.130</u> affidavit or declaration may be of attribution or prior public disclosure and move the pre-AIA guidance from item (C) to new item (E) to clarify how prior art could be antedated under pre-AIA law. In subsection II, deleted "effective" from "a different effective publication date." |
| 2121 | In subsection III, added that the quote in <i>Impax Labs. Inc. v. Aventis Pharm. Inc.</i> is citing to <i>Rasmusson v. SmithKline Beecham Corp.</i> , 413 F.3d 1318, 75 USPQ2d 1297 (Fed. Cir. 2005). |
| 2121.02 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| 2121.03 | Corrected the wording in the court's holding in <i>In re Elsner</i> , 381 F.3d 1125, 72 USPQ2d 1038 (Fed. Cir. 2004) by deleting "claimed" after "identifies" and changing "experimentation to" to "experimentation by." |
| 2122 | Added that the quote in <i>Impax Labs. Inc. v. Aventis Pharm. Inc.</i> is citing to <i>Rasmusson v. SmithKline Beecham Corp.</i> , 413 F.3d 1318, 75 USPQ2d 1297 (Fed. Cir. 2005). |
| 2124.01 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| 2127 | In subsection I, clarified the discussion of <i>In re Lund</i> , 376 F.2d 982, 153 USPQ 625 (CCPA 1967). In subsection IV, clarified that <u>37 CFR 1.14(a)</u> applies to all pending U.S. "patent" applications and that rejections may be made when copending applications have "at least one" inventor in common or differ by at least one "joint" inventor. |
| <u>2128</u> | In subsection II.B, replaced "Prior art disclosures" with "Electronic publications." |
| | In subsection II.E, clarified guidance regarding the Wayback Machine [®] . |
| 2131.01 | In subsection II, revised to include a citation to and discussion of <i>Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc.</i> , 85 F.4th 1167, 2023 USPQ2d 1314 (Fed. Cir. 2023). |
| 2131.03 | In subsection I, revised to include a citation to and discussion of <i>UCB</i> , <i>Inc. v. Actavis Labs. UT, Inc.</i> , 65 F.4th 679, 2023 USPQ2d 448 (Fed. Cir. 2023). |
| <u>2133</u> | In subsection I, revised to streamline guidance regarding the provisions of 35 U.S.C. 21(b). |
| 2133.03 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| 2136 | Revised to include a citation to and discussion of <i>Becton, Dickinson & Co. v. Baxter Corp. Englewood</i> , 998 F.3d 1337, 2021 USPQ2d 586 (Fed. Cir. 2021). |
| 2136.03 | In subsection III, added an explanation that <i>Dynamic Drinkware</i> only applies to applications and patents subject to <u>pre-AIA 35 U.S.C. 102</u> and does not apply to <u>AIA 35 U.S.C. 102(d)</u> and added a cross reference to <u>MPEP § 2154.01(b)</u> . |
| 2137 | Made clarifying edits in the preamble, such as replacing "inventor(s)" with "inventorship," "proper inventors" with "proper inventor," and "by way of affidavit" with "by way of an affidavit or declaration." |
| <u>2138</u> | Revised Editor Note to clarify when the AIA and pre-AIA law applies. |
| 2138.01 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. In subsection I: -Deleted outdated reference to the United States having a first to invent patent system. |

| | -Moved the citation to <i>Paulik v. Rizkalla</i> and corrected the pinpoint pages. In subsection IV, added "pre-AIA" in front of "35 U.S.C. 102" and "35 U.S.C. 103." |
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| 2138.02 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. |
| 2138.03 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. |
| 2138.04 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. In subsections I and II, replaced "inventors" with "inventor." |
| 2138.05 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. In subsection V, replaced "inventors" with "inventor." |
| 2138.06 | Revised Editor Note to clarify when the AIA and pre-AIA law applies. In subsection II, corrected citation to <i>Rieser v. Williams</i> . |
| 2139.02 | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. In subsection I, revised to streamline guidance regarding the provisions of 35 U.S.C. 21(b). In subsection IV, replaced "inventor(s)" with "inventor." |
| 2141 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| | In subsection I, added citations to <i>Novartis Pharms</i> . <i>Corp. v. West-Ward Pharms</i> . <i>Int'l Ltd.</i> , 923 F.3d 1051, 2019 USPQ2d 171676 (Fed. Cir. 2019); <i>Apple Inc. v. Samsung Elecs. Co.</i> , 839 F.3d 1034, 120 USPQ2d 1400 (Fed. Cir. 2016); and <i>Aventis Pharma S.A. v. Hospira</i> , <i>Inc.</i> , 675 F.3d 1324, 102 USPQ2d 1445 (Fed. Cir. 2012). |
| | In subsection II.A.2, added cross references to MPEP § 1504.03. |
| | In subsection II.C, added a cross reference to MPEP § 2141.03, subsection II. |
| | In subsection III, added citations to and discussions of <i>Intel Corp. v. Qualcomm Inc.</i> , 21 F.4th 784 (Fed. Cir. 2021); <i>In re Ethicon, Inc.</i> , 844 F.3d 1344, 121 USPQ2d 1139 (Fed. Cir. 2017); and <i>Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.</i> , 25 F.4th 1354, 2022 USPQ2d 144 (Fed. Cir. 2022). |
| | In subsection IV: |
| | -Replaced "have established the Graham factual findings and concluded" with "have issued a rejection that establishes the Graham factual findings and concludes." |
| | -Added a new last paragraph on guidance that an applicant's reply may establish that a disclosure is not prior art or is disqualified as prior art, including cross references to MPEP88.2146 , 2153.01, 2154.02, and 2155. |
| 2141.01 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection I, added citations to and discussions of <i>In re Wertheim</i> , 646 F.2d 527, 209 USPQ 554 (CCPA 1981) and <i>In re Hoeksema</i> , 399 F.2d 269, 158 U.S.P.Q. 596 (CCPA |
| | In subsection III, clarified that although the AIA changed the relevant time focus, the observations made by the Federal Circuit in <i>W.L. Gore & Associates, Inc. v. Garlock, Inc.</i> , 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) continue to apply. In subsection IV, edited the discussion of relying on pre-AIA 35 U.S.C. 103(c) to overcome an obviousness rejection to be more concise. |
| 2141.01(a) | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection I: -Revised the subsection title by replacing "Prior Art" with "Art To The Claimed Invention." |

| | -Clarified that when more than one prior art reference is used as the basis of an obviousness rejection, it is not required that the references be analogous art to each other but to the claimed invention and added citations to <i>Sanofi-Aventis Deutschland GMbH v. Mylan Pharms. Inc.</i> , 66 F.4th 1373, 2023 USPQ2d 552 (Fed. Cir. 2023) and <i>Corephotonics, Ltd. v. Apple Inc.</i> , 84 F.4th 990, 2023 USPQ2d 1202 (Fed. Cir. 2023). -Added quotations from and citations to <i>Netflix, Inc. v. DivX, LLC</i> , 80 F.4th 1352, 2023 USPQ2d 1057 (Fed. Cir. 2023) and <i>Wyers v. Master Lock Co.</i> , 616 F.3d 1231, 95 USPQ2d 1525 (Fed. Cir. 2010). In subsection II, corrected the <i>In re Ellis</i> quote to include "disclosed in the references" after "inventions." |
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| | In subsection V, deleted "rate" from "frequency rate." In subsection VI, deleted the discussion of analogous art in design applications. |
| 2141.02 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection V, clarified that presence of a result-effective variable is one, but not the only, motivation for a person of ordinary skill in the art to experiment to reach another workable product or process and added a cross reference to MPEP § 2144.05, subsection II.B. |
| 2141.03 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection I: -Split the final paragraph into two paragraphs. |
| | -Clarified that references which are not prior art may be relied upon to demonstrate the level of ordinary skill in the art at or around the relevant time. -Added citations to and discussions of <i>In re Merck & Co., Inc.,</i> 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) and <i>Ecolochem, Inc. v. S. California Edison Co.,</i> 227 F.3d 1361, 56 USPQ2d 1065 (Fed. Cir. 2000) regarding evidence of simultaneous inventions. -As a conforming change, revised the last paragraph to discuss that references not available as prior art may be relevant to establish motivation by deleting "because the documents were not accessible to the public may be used to demonstrate the level of ordinary skill in the art." |
| 2142 | Clarified that applicants may submit rebuttal arguments, in addition to or as an alternative to evidence, in response to a <i>prima facie</i> conclusion of obviousness produced by the examiner. |
| 2143 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection I.C, added quotation from and citation to <i>Intel Corp. v. PACT XPP Schweiz AG</i> , 61 F.4th 1373, 2023 USPQ2d 297 (Fed. Cir. 2023). |
| 2143.01 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). Added a citation to and discussion of <i>Axonics, Inc. v. Medtronic, Inc.</i> , 73 F.4th 950, 2023 USPQ2d 795 (Fed. Cir. 2023). In subsection V, clarified that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, there "may be" no suggestion or motivation to make the proposed modification. |
| 2143.02 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |

| | Deleted the preamble text before subsection I. In subsection I: -Added a statement that the reasonable expectation of success requirement refers to the likelihood of success in combining or modifying prior art disclosures. -Added citations to and discussions of <i>Elekta Ltd. v. ZAP Surgical Sys., Inc.</i> , 81 F.4th 1368, 2023 USPQ2d 1100 (Fed. Cir. 2023) and <i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> , 821 F.3d 1359, 119 USPQ2d 1171 (Fed. Cir. 2016). -Added a cross reference to MPEP § 2143. -Clarified the explanation of <i>In re Merck & Co., Inc.</i> , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). -Added citation to and discussion of <i>Eli Lilly & Co. v. Teva Pharms. Int'l GmbH</i> , 8 F.4th 1331, 2021 USPQ2d 862 (Fed. Cir. 2021). |
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| 2143.03 | In the preamble: -Added a citation to and discussion of <i>Axonics, Inc. v. Medtronic, Inc.</i> , 73 F.4th 950, 2023 USPQ2d 795 (Fed. Cir. 2023). -Clarified that a claim depending from a nonobvious independent claim may not be nonobvious when the effective filing date of a dependent claim is later than the effective filing date of an independent claim from which the dependent claim depends. -Added cross references to MPEP §§ 2133.01 and 2152.01. In subsection II, added a quotation from and citation to <i>In re Miller</i> , 441 F.2d 689, 169 USPQ 597 (CCPA 1971). |
| 2144 | In subsection III: -Added a discussion of "sufficiently similar" in the context of relying on a prior legal decision, including an example of applying the rationales from KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007). -Added cross references to MPEP § 2143, subsection I.A and MPEP § 2145, subsection X.E. |
| 2144.03 | In subsection A: -Reorganized and clarified the discussion of official notice and <i>In re Ahlert</i> , 424 F.2d 1088, 165 USPQ 418 (CCPA 1970)Clarified that it is not advisable to rely on official notice when an examiner can find a prior art disclosure to support the fact at issue. In subsection E, as a reminder, repeated a statement from subsection A that official notice should be rarely used when an application is under final rejection or action under 37 CFR 1.113. |
| 2144.05 | In subsection I: -Moved the citation to <i>In re Bergen</i> , 120 F.2d 329, 49 USPQ 749 (CCPA 1941) from the second paragraph to the first, and added an explanation. -Deleted citations to <i>In re Waite, In re Swenson, Gentiluomo v. Brunswick Bowling and Billiards Corp</i> , and <i>In re Jones</i> . -Added parentheticals to the citations of <i>In re Dreyfus</i> , 73 F.2d 931, 24 USPQ 52 (CCPA 1934) and <i>In re Baird</i> , 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994). In subsection II.A, added parentheticals to the citations of <i>Merck & Co. Inc. v. Biocraft Lab. Inc.</i> , 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.1989), cert. denied, 493 U.S. 975 (1989); <i>In re Kulling</i> , 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and <i>In re Geisler</i> , 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In subsection III.A, added a citation and parenthetical to <i>UCB, Inc. v. Actavis Labs, UT, Inc.</i> , 65 F.4th 679, 2023 USPQ2d 448 (Fed. Cir. 2023). In subsection III.B, added parentheticals to the citations of <i>Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.</i> , 567 F.3d 1314, 90 USPQ2d 1865 (Fed. Cir. 2009); <i>Allergan, Inc. v.</i> |

| | Sandoz Inc., 796 F.3d 1293, 115 USPQ2d 2012 (Fed. Cir. 2015); and In re Brandt, 886 F.3d 1171, 126 USPQ2d 1079 (Fed. Cir. 2018). |
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| 2144.06 | In subsection I, added a citation to <i>In re Couvaras</i> , 70 F.4th 1374, 2023 USPQ2d 697 (Fed. Cir. 2023). |
| 2144.07 | Deleted a quotation from <i>Sinclair & Carroll Co. v. Interchemical Corp.</i> , 325 U.S. 327, 65 USPQ 297 (1945). |
| 2144.08 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection II.A: -Clarified that Office personnel must consider the factors in <i>Graham v. John Deere</i> in order to establish a <i>prima facie</i> case of obviousness. -Added cross references to MPEP §§ 714.12, 714.13 and 715.09. In subsection II.A.1, clarified that each reference "to be applied as the basis for an obviousness rejection" must qualify as prior art and must also be analogous art "to the claimed invention." In subsection II.A.4, updated the title by changing "Been Motivated" to "Had a Reason." In subsection II.A.5, clarified that fact-findings should state a rationale, as required by <i>KSR</i> , that supports a conclusion that the claimed invention would have been obvious. |
| 2144.09 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In subsection II, clarified the parenthetical of <i>In re Mills</i> , 281 F.2d 218, 126 USPQ 513 (CCPA 1960). |
| 2145 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). In the preamble: -Added reminder statements about applicant's presentation and examiners' consideration of rebuttal evidence and arguments. -Clarified where rebuttal arguments can be presented, including deleting the citations to <i>In re Chu</i> , 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995) and <i>In re Huang</i> , 100 F.3d 135, 40 USPQ2d 1685 (Fed. Cir. 1996) and adding a citation to <i>In re Schulze</i> , 346 F.2d 600, 145 USPQ 716 (CCPA 1965) and cross references to MPEP § 714 to 716 et seq. -Added citations to and discussion of <i>In re Kao</i> , 639 F.3d 1057, 98 USPQ2d 1799 (Fed. Cir. 2011); <i>Leo Pharm. Prod., Ltd. v. Rea</i> , 726 F.3d 1346, 107 USPQ2d 1943 (Fed. Cir. 2013); and <i>In re Cyclobenzaprine Hydrochloride Extended- Release Capsule Patent Litig.</i> , 676 F.3d 1063, 102 USPQ2d 1760 (Fed. Cir. 2012). -Clarified the discussion of <i>In re Hoeksema</i> , 399 F.2d 269, 158 USPQ 596 (CCPA 1968). -Added a citation to and quotation from <i>Volvo Penta of the Americas, LLC v. Brunswick Corp.</i> , 81 F.4th 1202, 2023 USPQ2d 1000 (Fed. Cir. 2023). -Clarified that evidence pertaining to secondary considerations must be taken into account whenever "it has been properly presented." -Revised Example 2 to clarify that the case was examined under pre-AIA 35 U.S.C. 103. -Revised Example 3 to clarify the types of declarations that may be filed under AIA and pre-AIA law. -Added a new Example 4. -Added cross references to MPEP § 715 et seq., 716 et seq., 716.01(b), 2155, 2136.05(a) and 2136.05(b). In subsection I: |

| | -Deleted "attorney" and "of counsel" to clarify that applicant arguments are not limited to |
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| | attorney arguments. |
| | -Added a citation to <i>In re De Blauwe</i> , 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984). In subsection III: |
| | -Added a citation to and quotation from <i>In re Mouttet</i> , 686 F.3d 1322 (Fed. Cir. 2012). |
| | -Moved the citation to <i>In re Keller</i> , 642 F.2d 413, 208 USPQ 871 (CCPA 1981). |
| | -Revised the citation of MPEP § 2143.01 to include "subsection VI." |
| | In subsection X.A, added two quotations from and citations to KSR Int'l Co. v. Teleflex Inc., |
| | 550 U.S. 398, 127 S. Ct. 1727 (2007). |
| | In subsection X.C, clarified that a teaching, suggestion, or motivation to combine references that is found in the prior art is an appropriate rationale for determining obviousness and added a citation to KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S. Ct. 1727 (2007). |
| | In subsection X.D, revised the citation of MPEP § 2143.01 to include "subsection VI." |
| | In subsection X.D.1, added citations to and discussion of <i>UCB, Inc. v. Actavis Labs, UT, Inc.</i> , 65 F.4th 679, 2023 USPQ2d 448 (Fed. Cir. 2023) and <i>Schwendimann v. Neenah, Inc.</i> , 82 F.4th 1371, 2023 USPQ2d 1173 (Fed. Cir. 2023). |
| | In subsection X.E, added a cross reference to MPEP § 2143.02. |
| <u>2146</u> | Replaced instances of "35 U.S.C. 103" with " <u>35 U.S.C. 103(a)</u> ." |
| | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. |
| 2146.01 | In the preamble, deleted the last paragraph pertaining to guidance for AIA 35 U.S.C. 102(c). |
| 2146.01 | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. Replaced instances of "35 U.S.C. 103" with "35 U.S.C. 103(a)." In subsection I: |
| | -Consolidated a sentence identifying the application types subject to 35 U.S.C. 103(c)(1) into |
| | a parenthetical in the preceding sentence. |
| | -Deleted two sentences describing the applicability of 1999 and 2004 changes to <u>pre-AIA</u> |
| | 35 U.S.C. 103(c). |
| | -Deleted a sentence contrasting current 35 U.S.C. 102(c). |
| 2146.02 | -Deleted cross references to MPEP §§ 2156 and 2159. |
| 2146.02 | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. Replaced instances of "35 U.S.C. 103" with "35 U.S.C. 103(a)". |
| | Replaced instances of "double patenting" with "nonstatutory double patenting." |
| | In subsection I: |
| | -Deleted a sentence discussing the burden of establishing common ownership under <u>pre-AIA</u> |
| | 35 U.S.C. 103(c). |
| | -Revised example 3 for clarity. |
| | In subsection II, deleted "of record" following "representative(s)." |
| <u>2146.03</u> | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. |
| | Replaced instances of "35 U.S.C. 103" with "35 U.S.C. 103(a)." Replaced instances of "double patenting" with "nonstatutory double patenting." |
| 2146.03(a) | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. |
| 2140.03(a) | In item (E), clarified that disqualification under pre-AIA 35 U.S.C. 103(c) includes showing |
| | "common ownership" as well as joint research agreement disqualification. |
| | Replaced an instance of "35 U.S.C. 103" with "35 U.S.C. 103(a)." |
| | Replaced several instances of "double patenting" with "nonstatutory double patenting" in |
| | the examples. |
| 2147 | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. Replaced instances of "35 U.S.C. 103" with "35 U.S.C. 103(a)." |
| 2151 | Revised to streamline guidance regarding the provisions of <u>35 U.S.C. 21(b)</u> . |

| | Replaced an instance of "35 U.S.C. 103" with "35 U.S.C. 103(a)." Replaced an instance of "common ownership" with "deemed common ownership." |
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| 2152.05 | Revised Editor Note to expand on the cross references for guidance on when the AIA applies. In subsection I: -Replaced instances of "Potential references" with "A disclosure in a potential prior art |
| | reference" or "Disclosures in potential prior art references." -Clarified that the exception under 35 U.S.C. 102(b)(1)(A) may apply if the disclosure was |
| | the inventor's, or at least one joint inventor's, own work. -Clarified that the exception under 35 U.S.C. 102(b)(1)(B) may apply if the reference discloses which matter that was "proviously" published disclosed. |
| | subject matter that was "previously" publicly disclosed. In subsection II: |
| | -Clarified the discussion regarding when a reference qualifies as prior art under <u>35 U.S.C.</u> <u>102(a)(2)</u> . |
| | -Replaced "Potential references" with "Disclosures in potential prior art references." -Clarified that 35 U.S.C. 102(b)(2)(A) limits the use of an inventor's or at least one joint inventor's own work as prior art. |
| | -Replaced the last instance of "prior art" with "disclosures that are commonly owned or deemed commonly owned." |
| 2153.01 | Clarified that the exception under <u>AIA 35 U.S.C. 102(b)(1)(A)</u> limits the use of an inventor's or at least one joint inventor's own work as prior art. |
| 2153.01(a) | Clarified that an inventor-originated disclosure "made within the grace period" is not prior art under AIA 35 U.S.C. 102(a)(1). |
| | Clarified the discussion of how to show that a grace period inventor-originated public |
| | disclosure is not prior art under <u>35 U.S.C. 102(a)(1)</u> , including clarifying that the format specified in <u>37 CFR 1.77(b)(6)</u> may not be used after the filing date of the application. Revised to streamline guidance regarding the provisions of <u>35 U.S.C. 21(b)</u> . |
| 2153.02 | Clarified the discussion of what disclosures may be excepted as prior art under <u>AIA 35 U.S.C.</u> 102(b)(1)(B) in the first paragraph. |
| | Added a new paragraph discussing how applicants can include statements regarding inventor-originated public disclosures in the specification upon filing and after filing. Revised to streamline guidance regarding the provisions of 35 U.S.C. 21(b). |
| 2154.01(a) | Clarified by adding ", unless an exception under AIA 35 U.S.C. 102(b)(2) applies" after "is prior art under AIA 35 U.S.C. 102(a)(2)." |
| 2154.01(b) | Added citations to <i>Penumbra, Inc. v. RapidPulse, Inc.</i> , 2023 USPQ2d 292, IPR2021-01466, Paper 34 (March 10, 2023) and related discussion of prior art determinations under <u>AIA 35</u> |
| | U.S.C. 102. Replaced "common inventor" with "common inventor or joint inventor" in the first paragraph. Added that the requirement in <i>Dynamic Drinkware</i>, <i>LLC</i>, v. National Graphics, Inc., 800 F.3d 1375, 116 USPQ2d 1045 (Fed. Cir. 2015) does not apply to AIA 35 U.S.C. 102(d). |
| 2154.01(d) | Revised the titles of subsections I and II to replace "COMMON INVENTOR" with "COMMON (JOINT) INVENTOR." In subsection II, replaced "patent is published" with "patent has issued." |
| 2154.02(a) | Replaced two instances of "inventor's own work" with "inventor's or at least one joint inventor's own work." |
| | Added "of attribution under <u>37 CFR 1.130(a)</u> " after two instances of affidavit(s) or declarations(s). |
| | Added a new paragraph discussing how applicants can include statements regarding inventor-originated public disclosures in the specification upon filing and after filing. |

| 2154.02(b) | Added a new paragraph discussing how applicants can include statements regarding inventor-originated public disclosures in the specification upon filing and after filing. |
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| 2154.02(c) | Replaced "prior art" with "disclosures that are commonly owned or deemed commonly owned" in the second paragraph. Replaced instances of "representative of record" with "representative." |
| 2155.02 | |
| 2155.03 | Deleted reference to 102(b)(1)(B) and 102(b)(2)(B) in the first paragraph. Made minor clarifications to the discussion of grace period disclosures and deleted the reference to an affidavit or declaration under 37 CFR 1.130(a). |
| 2155.05 | Clarified when an applicant or their representative must be the party that files an affidavit or declaration under 37 CFR 1.130. Added a cross reference to MPEP § 717.01(c). |
| 2155.06 | Replaced an instance of "an inventor" with "the inventor or a joint inventor." Clarified when the provisions of <u>37 CFR 1.130</u> are not available. |
| 2156 | Made minor clarifications to the discussion of the three conditions under AIA 35 U.S.C. 102(a)(2) that must be met and added a cross reference to MPEP § 717.02(b), subsection IV. Clarified the guidance on invoking the joint research agreement exception by: -Replacing an instance of "representative of record" with "representative." -Adding that the statement should be on or begin on a separate page and a cross reference to MPEP § 717.02(a)(1), subsection II. -Adding guidance about when the processing fee is required to amend the specification to include the names of the parties to the joint research agreement. Clarified that the Office will not request corroborating evidence unless independent evidence raises doubt as to the existence "or nature" of the joint research agreement. |
| | Clarified that the AIA 35 U.S.C. 102(b)(2)(C) exception does not apply to certain non-public sales and added a cross reference to MPEP § 2133.03. |
| 2157 | Deleted instances of "or joint inventors" to clarify the discussion of the actual or named inventor. Added cross references to MPEP §§ 2155.01 and 2155.02. Replaced two instances of "inventor" with "inventor or a joint inventor" and deleted "to name the actual inventor." |
| 2159.02 | Reorganized by moving the last sentence into the previous paragraph and made minor clarifying amendments. |
| 2159.03 | Added that the cross reference to MPEP § 2138 is for guidance on pre-AIA 35 U.S.C. 102(g). |
| 2163 | In subsection I, replaced "benefit of an earlier priority date or effective filing date" with "benefit of or priority to an earlier filing date." In subsection II.A.3.b, added a citation to and discussion of <i>Regents of the Univ. of Minnesota v. Gilead Scis.</i> , <i>Inc.</i> , 61 F.4th 1350, 2023 USPQ2d 269 (Fed. Cir. 2023). |
| 2163.03 | In subsection II, added a citation to and discussion of <i>Regents of the Univ. of Minnesota v. Gilead Scis.</i> , <i>Inc.</i> , 61 F.4th 1350, 2023 USPQ2d 269 (Fed. Cir. 2023). In subsection V, added cross references to MPEP \section 2163 , subsection I.A and MPEP \section 2163 , subsection II.A.3(a). |
| 2163.05 | In subsection II: -Clarified the parenthetical of <i>Fujikawa v. Wattanasin</i> , 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996)Added a citation to <i>Regents of the Univ. of Minnesota v. Gilead Scs., Inc.</i> , 61 F.4th 1350, 2023 USQ2d 269 (Fed. Cir. 2023). Removed citation to <i>Regelicki v. Chiang</i> , 590 Fed. App'v 990 (Fed. Cir. 2014). |
| 0164.01 | -Removed citation to <i>Rozbicki v. Chiang</i> , 590 Fed.App'x 990 (Fed. Cir. 2014). |
| <u>2164.01</u> | Removed the second citation to <i>In re Wands</i> , 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). |

| | Added cross references to MPEP § 2164.06. Updated to incorporate guidance from Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 FR 1563 (January 10, 2024). Updated the subsection title to "Quantity of Experimentation." |
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| 2164.01(a) | Updated to incorporate guidance from Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 FR 1563 (January 10, 2024). |
| 2164.02 | In subsections I and III, added citations to and quotations from <i>Amgen Inc. et al. v. Sanofi et al.</i> , 598 U.S. 594, 2023 USPQ2d 602 (2023), consistent with <i>Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al.</i> , 89 FR 1563 (January 10, 2024). |
| 2164.05(b) | Added a citation to and discussion of <i>United Therapeutics Corp. v. Liquidia Techs., Inc.,</i> 74 F.4th 1360, 2023 USPQ2d 862 (Fed. Cir. 2023). |
| 2164.06 | Added a citation to and quotation from <i>Amgen Inc. et al. v. Sanofi et al.</i> , 598 U.S. 594, 2023 USPQ2d 602 (2023). In subsection II, added a citation to and discussion of <i>Amgen Inc. v. Sanofi, Aventisub LLC</i> , 987 F.3d 1080 (Fed. Cir. 2021), consistent with <i>Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al.</i> , 89 FR 1563 (January 10, 2024). |
| 2164.08 | Updated to incorporate guidance from <i>Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al.</i> , 89 FR 1563 (January 10, 2024). Added a citation to and discussion of <i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , 74 F.4th 1360, 2023 USPQ2d 862 (Fed. Cir. 2023). |
| 2173.02 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |
| 2173.05(b) | In the preamble and subsection I, added citations to and discussions of <i>Clearone, Inc. v. Shure Acquisition Holdings, Inc.</i> , 35 F.4th 1345, 2022 USPQ2d 509 (Fed. Cir. 2022). In subsection IV, clarified that the examiner should determine whether the specification supplies some objective standard for measuring the scope of a subjective term used in the claim. |
| 2173.05(e) | In the preamble, replaced the second instance of "components" with "elements." |
| 2173.05(h) | In subsection I, added a citation to and discussion of <i>In re Kiely</i> , 2022 USPQ2d 532 (Fed. Cir. 2022). |
| <u>2175</u> | Revised form paragraph 7.35. |
| 2183 | Revised Editor Note to clarify that this section is applicable regardless of whether an application is examined under the AIA or under pre-AIA law and to remove the citation to <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). |

CHAPTER 2200:

| on supplying copies of cited prior art patents and publications in 35 U.S.C. 301 submissions. Revised to make language more consistent with 35 U.S.C. 301 and 37 CFR 1.501, and added citations to 37 CFR 1.501. Updated the example letters for submitting prior art under 37 CFR 1.501 and made consistent with the first-inventor-to-file prior art regime. Added a cross reference to MPEP § 2226 for information regarding citing prior art or written statements via the USPTO patent electronic filing system. 2206 In the preamble text before subsection I: -Replaced "eFilers" with "users of the USPTO patent electronic filing system." -Added the word "electronically" and deleted "via EFS." -Clarified that submissions under 37 CFR 1.501 will be forwarded to the Technology Center that currently examines the technology where the patent is classified, and to no longer refer to "class and subclass." In subsection II.A: -Clarified that the USPTO patent electronic filing system only allows a third party submitter to request notification of an improper submission using an email address. -Deleted "in the interface." 2210 Replaced "eFilers" with "users of the USPTO patent electronic filing system." Added the words "electronic" and "electronically" and deleted "via EFS." Clarified that the Office may refer third-party inquiries, requests, or submissions that are improperly submitted via the USPTO patent electronic filing system must be submitted as a new request, and not as a follow-on paper into the patent. Clarified that the Office may refer third-party inquiries, requests, or submissions that are improperly submitted via the USPTO patent electronic filing system by registered practitioners to the Office of Enrollment and Discipline. 2215 Revised the reproduced text of 37 CFR 1.20. Added cross reference to MPEP § 325 for information on establishing an assignee's right to take action when submitting a power of attorney. Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection | | |
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| -Replaced "eFilers" with "users of the USPTO patent electronic filing system." -Added the word "electronically" and deleted "via EFS." -Clarified that submissions under 37 CFR 1.501 will be forwarded to the Technology Center that currently examines the technology where the patent is classified, and to no longer refer to "class and subclass." In subsection II.A: -Clarified that the USPTO patent electronic filing system only allows a third party submitter to request notification of an improper submission using an email addressDeleted "in the interface." 2210 Replaced "eFilers" with "users of the USPTO patent electronic filing system." Added the words "electronic" and "electronically" and deleted "via EFS" and "EFS." Clarified that a request for reexamination submitted via the USPTO patent electronic filing system must be submitted as a new request, and not as a follow-on paper into the patent. Clarified that the Office may refer third-party inquiries, requests, or submissions that are improperly submitted via the USPTO patent electronic filing system by registered practitioners to the Office of Enrollment and Discipline. 2215 Revised the reproduced text of 37 CFR 1.20. 2226 Added cross reference to MPEP § 325 for information on establishing an assignee's right to take action when submitting a power of attorney. 2224 Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. Revised form paragraph 22.73. Revised the reproduced text of 37 CFR 1.52. In subsection II, updated fees for filing a petition in an ex parte reexamination when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 211.02. In subsection II, added cross reference to MPEP § 211.03. In subsection | 2205 | Revised to make language more consistent with 35 U.S.C. 301 and 37 CFR 1.501, and added citations to 37 CFR 1.501. Updated the example letters for submitting prior art under 37 CFR 1.501 and made consistent with the first-inventor-to-file prior art regime. Added a cross reference to MPEP § 2258. Clarified that the example letters are written for either mail or hand-delivery, and added a cross reference to MPEP § 2206 for information regarding citing prior art or written statements via the |
| Added the words "electronic" and "electronically" and deleted "via EFS." and "EFS." Clarified that a request for reexamination submitted via the USPTO patent electronic filing system must be submitted as a new request, and not as a follow-on paper into the patent. Clarified that the Office may refer third-party inquiries, requests, or submissions that are improperly submitted via the USPTO patent electronic filing system by registered practitioners to the Office of Enrollment and Discipline. Revised the reproduced text of 37 CFR 1.20. Added cross reference to MPEP § 325 for information on establishing an assignee's right to take action when submitting a power of attorney. Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. Revised form paragraph 22.73. Revised the reproduced text of 37 CFR 1.52. Z250.03 In subsection II, updated fees for filing a petition in an ex parte reexamination proceeding. In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. In subsection II, added cross reference to MPEP § 211.04. | 2206 | -Replaced "eFilers" with "users of the USPTO patent electronic filing system." -Added the word "electronically" and deleted "via EFS." -Clarified that submissions under 37 CFR 1.501 will be forwarded to the Technology Center that currently examines the technology where the patent is classified, and to no longer refer to "class and subclass." In subsection II.A: -Clarified that the USPTO patent electronic filing system only allows a third party submitter to request notification of an improper submission using an email address. |
| Added cross reference to MPEP § 325 for information on establishing an assignee's right to take action when submitting a power of attorney. Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. Revised form paragraph 22.73. Revised the reproduced text of 37 CFR 1.52. In subsection II, updated fees for filing a petition in an ex parte reexamination proceeding. In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information | 2210 | Added the words "electronic" and "electronically" and deleted "via EFS" and "EFS." Clarified that a request for reexamination submitted via the USPTO patent electronic filing system must be submitted as a new request, and not as a follow-on paper into the patent. Clarified that the Office may refer third-party inquiries, requests, or submissions that are improperly submitted via the USPTO patent electronic filing system by registered practitioners to the Office |
| Added cross reference to MPEP § 325 for information on establishing an assignee's right to take action when submitting a power of attorney. Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. Revised form paragraph 22.73. Revised the reproduced text of 37 CFR 1.52. In subsection II, updated fees for filing a petition in an ex parte reexamination proceeding. In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information | 2215 | • |
| subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. Revised form paragraph 22.73. Revised the reproduced text of 37 CFR 1.52. In subsection II, updated fees for filing a petition in an <i>ex parte</i> reexamination proceeding. In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information | | Added cross reference to MPEP § 325 for information on establishing an assignee's right to take |
| 2250.03 In subsection II, updated fees for filing a petition in an <i>ex parte</i> reexamination proceeding. 2258.02 In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. 2268 In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information | 2224 | subsection III. Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. |
| In subsection II, updated fees for filing a petition in an <i>ex parte</i> reexamination proceeding. In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP § 211.04. In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information | 2246 | 1 0 1 |
| In subsections I.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP \ 214.02 . In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP \ 211.04 . In subsection II, added cross reference to MPEP \ 211.04 . | <u>2250</u> | 1 |
| to accept a delayed priority claim is filed more than two years after the date the foreign priority claim was due and to include a cross reference to MPEP \sigma 214.02 . In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the benefit claim was due and to include a cross reference to MPEP \sigma 211.04 . In subsection II, added cross reference to MPEP \sigma 711.03(c) , subsection II for more information | 2250.03 | In subsection II, updated fees for filing a petition in an ex parte reexamination proceeding. |
| | 2258.02 | claim was due and to include a cross reference to MPEP § 214.02. In subsections II.A.1 and 2 and II.B.1 and 2, incorporated the requirement for additional explanation when a petition to accept a delayed benefit claim is filed more than two years after the date the |
| | 2268 | In subsection II, added cross reference to MPEP § 711.03(c), subsection II for more information about petitions under 37 CFR 1.137. |

In subsection VI, corrected a typographical mistake in the last paragraph by adding the word "appealable."

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CHAPTER 2300:

| 2301.04 | Replaced "current" with "AIA" before "35 U.S.C. 102." |
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| 2304.01 | Changed section title to "Preparation of an Application for Interference." |
| 2304.01(a) | Revised "nucleotide or peptide sequence" to "nucleotide and/or amino acids sequence." Clarified the interference search of applications under Secrecy Order. Replaced references to TC Working Group 3640 with "Licensing and Review." |
| 2304.01(c) | Changed the reference from <u>37 CFR 1.55(a)(4)</u> to <u>37 CFR 1.55(g)(3)(i)</u> and <u>41.154(b)</u> . |

CHAPTER 2400:

| Passim | Revised Editor Note for sections subject to WIPO Standard ST.26 (2412-2412.06 and 2413-2419.03) to more clearly set forth the applicability. |
|------------|---|
| 2401 | Revised to reference both WIPO ST.25 and WIPO ST.26, with the relevant CFR sections. |
| 2412 | Revised to more closely follow language in WIPO Standard ST.26 regarding nucleotide and/or amino acid sequences. Deleted discussion of International Nucleotide Sequence Database Collaboration (INSDC) identifiers. Revised reproduced text 37 CFR 1.839 in accordance with Adoption of Updated WIPO Standard ST.26; Revision to Incorporation by Reference, 88 FR 34089 (May 26, 2023). |
| 2412.01 | Clarified the application of the sequence listing rules implementing WIPO Standard ST.26. Added when sequences and associated sequence information are considered to be part of the disclosure in both U.S. applications and international applications. |
| 2412.02 | Revised reproduced text of 37 CFR 1.831. Revised to more closely follow language in WIPO Standard ST.26 regarding nucleotide and/or amino acid sequences. Deleted discussion of the presentation of the sequence data associated with nucleotide and/or amino acid sequences as a separate part of the disclosure as an ASCII plain text file, as PDF sheets of the specification, or on physical sheets of paper for applications with a filing date before July 1, 2022. |
| 2412.02(a) | Added a cross reference to the Guidance portion of WIPO Standard ST.26, Annex VI, page 3.26.vi.2 for a discussion of "enumeration of its residues" and page 3.26.vi.18-19, 51, 53 for examples. |
| 2412.03 | Deleted "the data associated with" in the first and second paragraphs. In the third paragraph, replaced "nucleotides" with "nucleotide" and "acids" with "acid sequences" in the first sentence and "sequences" with "sequence" in the second sentence. |
| 2412.03(a) | Replaced paragraph "3k" with "3(k)." In Tables 1 and 3, clarified that "n" and "X" are used in a conventional manner. |
| 2412.03(b) | Revised to clarify that an amino acid, in accordance with WIPO Standard ST.26 can be represented by any of the symbols shown in Annex I, Table 3: List of Amino Acids Symbols Added a cross reference to MPEP \sigma 2413.01(g) , subsection I, for discussion of a "feature table." Moved the second paragraph and Table 4 to MPEP \sigma 2412.03(c) . |
| 2412.03(c) | Added a new paragraph discussing how modified amino acids, including D-amino acids, should be represented. Added a paragraph and table 4 previously located in MPEP § 2412.03(b) and further revised the moved paragraph to add cross references to MPEP § 2413.01(g), subsection I and MPEP § 2413.01(g), subsections II and III, and to indicate that feature key "SITE" together with the qualifier "note" should be used when the modified amino acid is not a post-translationally modified amino acid. |
| 2412.03(d) | Revised first sentence to more closely follow language in WIPO Standard ST.26. |
| 2412.03(e) | Revised first sentence to replace "identifies" with "provides." |
| 2412.04 | Revised title to "Use of Sequence Identifiers to Denote Sequences Disclosed in the Description, Drawings or Claims." Revised to more closely follow language in WIPO Standard ST.26. Added cross references to 37 CFR 1.832(a) and MPEP § 2412.05(a). Clarified the guidance regarding the requirements of 37 CFR 1.831(c). |

| <u>2412.05</u> | Replaced "additional format" with "XML formatting representations." |
|----------------|---|
| 2412.05(a) | Revised to more closely follow language in WIPO Standard ST.26 in discussing the definition in 37 CFR 1.831(b). |
| | Revised to add a cross reference to MPEP § 2412.02 for further description of a "sequence." Revised final paragraph to clarify "intentionally skipped sequences" as set forth in WIPO Standard ST.26, paragraphs 58 and 59. |
| 2412.05(b) | In subsection I, revised to more closely follow language in WIPO Standard ST.26, including replacing "its residues" with "the residues." |
| | In subsection II, added "relative to a primary sequence" after "i.e., alternative, deletions, insertions or substitutions." |
| | In subsection III: |
| | -Deleted "in subsection IV" from the first paragraphDeleted "provided in accordance with 37 CFR 1.832(b)(4)" and the cross reference to MPEP § 2413.01(g) and instead noted that the "feature table" is as described in subsection IV of this section. |
| | -Added new cross references regarding use of a feature key and use of a qualifierMoved Table 2, which was previously in subsection IV, to subsection III. |
| | In subsection IV, revised to remove Table 2 and updated the cross references in the paragraph. |
| 2412.05(c) | Replaced "specifically defined to meet" with "meeting," in first sentence. Revised to state that "Where a variant sequence is disclosed as a single sequence with enumerated alternative residues at one or more positions, it must be included" Added a new cross reference to MPEP § 2413.01(g). |
| 2412.05(d) | In subsection II: |
| | -Revised to further describe Table 3 and its location. |
| | -Updated or added cross references to MPEP sections. |
| | -Revised to more closely follow language in WIPO Standard ST.26, such as adding "enumerated" before "amino acid" and "sequence contained in a" before "Sequence Listing XML." |
| | -Deleted prior reference to paragraph 7 of WIPO Standard ST.26 and the text regarding element INSDSeq and WIPO Standard ST.26, paragraph 29. |
| | In subsection III, revised to more closely follow language in WIPO Standard ST.26 such as changing the last paragraph to read "The feature key 'SITE' together with the qualifier 'note' should be used when the modified amino acid is not a post-translationally modified amino acid." |
| | In subsection IV, revised to more clearly set forth that the text pertains to "feature keys" and added cross references for further information. |
| 2412.05(e) | Revised to update and add cross references. |
| 2412.06 | Revised to more closely follow language in WIPO Standard ST.26, including replacing "nucleic acid" with "a nucleotide sequence" and "sequences that fall within the definition set forth" with "sequence(s) by enumeration of its residues, as defined" in the first sentence. |
| <u>2413</u> | Revised the title to add an "a" before "Sequence Listing XML." Revised to add "XML file" to the end of the paragraph. |
| 2413.01 | Revised to replace "37 CFR 1.833" with "37 CFR 1.839." |
| 2413.01(a) | Clarified that 37 CFR 1.833 requires the entire "Sequence Listing XML" to be presented as a single file and that WIPO Standard ST.26 specifies that the file meet certain other restrictions. Deleted reference to Annex IV in item (2) in the restriction list. Added a cross reference to MPEP § 2413.01(g) regarding the "general information part" and the "sequence data part." |
| | Added a cross reference to WIPO Standard ST.26 regarding "numeric character references." |

| 2413.01(b) | Clarified the discussion of the DTD requirement in accordance with <u>37 CFR 1.833(b)(1)</u> and specified that Annex II of WIPO Standard ST.26 provides further guidance on a compliant document. |
|------------|---|
| 2413.01(c) | Revised to state that "WIPO Standard ST.26, paragraph 39(a), specifies that the first line of the XML instance must contain the XML declaration" |
| 2413.01(d) | Revised Editor Note to more clearly set forth the applicability of WIPO Standard ST.26. |
| 2413.01(e) | Revised to state that "WIPO Standard ST.26, paragraph 43, prescribes the root element of an XML instance to have the following attributes" |
| 2413.01(f) | Revised to more closely follow language in WIPO Standard ST.26, such as clarifying that "WIPO Standard ST.26 prescribes that the general information part of the sequence listing must contain the following bibliographic elements" and replacing "application identification" with "application number" in the second row of the reproduced table from paragraph 45 of WIPO Standard ST.26. |
| | |

2413.01(g) Revised to more closely follow language in WIPO Standard ST.26 with specific examples given below.

In the preamble before subsection I:

- -Replaced "associates all relevant biological sequence information for" with "contains."
- -Added "together with sequence-associated data" in the first paragraph.
- -Revised and reformatted the "List of INSDSeq Dependent Elements" table to be more consistent with the table found at paragraph 52 of WIPO Standard ST.26.
- -Added a cross reference to MPEP § 2412.05(a) regarding intentionally skipped sequences. In subsection II, revised the first sentence to add "that Annex I contains" following "specifies" and deleting later instance of "in Annex I."

In subsection IV:

- -Revised the second paragraph to add "and operators" after "descriptors."
- -Replaced "Table 10" with "Tables (a)-(c)."
- -Deleted the cross reference to paragraph 66 of WIPO Standard ST.26.
- -In the first paragraph following the table in (c), revised to replace "location" with "combination of locations."
- -In the second paragraph following the table in (c), added a cross reference to WIPO Standard ST 26
- -In the last paragraph, added ", '<' and '>', respectively."

In subsection V:

- -Revised item (a) to add and update cross references.
- -Clarified that Section 6 of Annex I and Section 8 of Annex I contains the exclusive listing of qualifiers and their specified value formats, if any, for nucleotide sequence key feature and amino acid sequence key feature, respectively.

In subsection VI:

- -Revised to delete "for nucleotide sequences and amino acid sequences."
- -Added a reference to Annex I of WIPO Standard ST.26, Sections 5 and 7, for listings of feature keys with mandatory qualifiers."

In subsection VII:

- -Revised the second sentence, to add "and one optional attribute," following "elements."
- -Revised "List of INSDQualifier Dependent Elements" table consistent with changes in WIPO Standard ST.26.

In subsection VIII:

-Revised the title (ORGANISM AND MOL_TYPE QUALIFIERS) and moved it to immediately following the table WIPO cross reference, which now incorporated the last two paragraphs of subsection VII.

-Revised to add cross references to Annex I, section 6, of the WIPO Standard ST.26 for the organism qualifier. -Incorporated text from former subsection IX. -Removed the reference to paragraph 84 of WIPO Standard ST.26. Renumbered former subsection X to IX. In renumbered subsection IX: -Clarified that for each qualifier other than the "translation" qualifier, the free text must not exceed 1000 characters. -Clarified references to Annex I. -Deleted the cross reference to MPEP § 2413.01(d). Renumbered former subsection XII to XI. In renumbered subsection XI: -Updated the cross references from MPEP § 2412.05(a) to MPEP § 2412.03. -Deleted references to paragraph 7 of WIPO Standard ST.26. -Added cross references to MPEP §§ 2412.03, 2412.05(b) and 2412.05(d). -Updated reference to the tables in Annex I. 2413.01(h) Revised the title to replace "Qualifiers" with "Qualifier Values." Revised to more closely follow language in WIPO Standard ST.26. For example, clarified that the term "language-dependent free text" means the free text value of certain qualifiers that may require translation for international, national or regional procedures and that for each qualifier other than the "translation" qualifier, the free text must not exceed 1000 characters. Deleted the third and fourth paragraphs regarding qualifier elements and the element INSDFeature quals. Updated cross references to WIPO Standard ST.26 and other MPEP sections to be more specific. In Table 5, revised the second column heading to read "Language-Dependent Free Text Qualifier" added the following row: "6.21-frequency." In Table 6, revised the second column to read "Language-Dependent Free Text Qualifier." Revised to more closely follow language in WIPO Standard ST.26, such as changing "List 2413.01(i) of Patent Application Information Elements (reproduced in MPEP § 2413.01(f))" to "the table of elements of the general information part (reproduced in MPEP § 2413.01(f) from WIPO Standard ST.26, paragraph 45)" and "need not be in English" to "must be in the language of filing." Revised to add cross reference to MPEP § 2413.01(h) regarding language-dependent free 2413.02 Revised to read "In order for the USPTO to be able to process the 'Sequence Listing XML' .xml file, all characters must be encoded using Unicode UTF-8." Revised the second paragraph to delete "For applications filed on or after July 1, 2022." 2413.03 Revised to indicate that domestic applications filed after the ST.26 applicability date will receive a notice from the Office of Patent Application Processing (OPAP) when failing to comply with 37 CFR 1.831 through 1.834. Revised to indicate that sequence submissions via read-only optical disc should be enclosed in a hard case should be placed in a protective mailer. Revised to more specifically set forth the labeling requirements. Revised the end of the first paragraph to add "The incorporation by reference statement 2413.04 identifies: (i) the name of the file; (ii) the date of creation of the file; and (iii) the size of the file in bytes Note that this requirement pertaining to applicant submission of a 'Sequence Listing XML' does not apply to a sequence listing that is part of an international application and communicated to the USPTO under PCT Article 20, for a national phase application."

| | Revised the third paragraph after "reference paragraph" to add "in the context of a substitute specification under <u>37 CFR 1.125</u> ." Revised the last sentence of the third paragraph to delete "by identifying: (i) the name of the |
|---------|--|
| | file; (ii) the date of creation of the file; and (iii) the size of the file in bytes." |
| 2413.05 | Revised Editor Note to more clearly set forth the applicability of WIPO Standard ST.26. |
| 2414 | Revised the first sentence to add "under 35 U.S.C. 111(a) having a filing date on or after July 1, 2022, or an application which entered the national stage, having an international filing date" after "filed" and to change "disclosures of nucleotides" to "disclosure of nucleotide." Revised the third sentence by deleting "an added initial 'Sequence Listing XML' if the 'Sequence Listing XML' or a replacement." Added cross references to additional form paragraphs to the last sentence. |
| 2414.01 | Clarified the second sentence by replacing "acids" with "acid sequences" and replaced "filed" with "having a filing date." |
| 2414.02 | Revised to more closely follow language in WIPO Standard ST.26. For example, replaced "nucleotides" with "nucleotide" and "acids" with "acid sequences." Added a cross reference to 37 CFR 1.835. Revised the second paragraph, item (1), to indicate that read-only optical discs may be hand-delivered to the Office. |
| 2414.03 | Revised to more closely follow language in WIPO Standard ST.26, such as replacing "nucleotides" with "nucleotide" and "acids" with "acid sequences." Clarified that if a previously submitted "Sequence Listing XML" contains errors and/or the application fails to comply with 37 CFR 1.831 - 1.834, a notice indicating the deficiencies will be issued to the applicant. Clarified that an examiner can identify outstanding requirements regarding errors and/or instances of noncompliance with 37 CFR 1.831 - 1.834 that might not have been identified by pre-examination staff. In item (1), revised to indicate that read-only optical discs may be hand-delivered to the Office. |
| 2414.04 | Revised the first paragraph to state "Thus, any 'Sequence Listing XML' that contains one or more qualifiers having a free text value that is language-dependent must comprise an 'INSDQualifier_value' element containing text in the English language, otherwise a translation of the 'Sequence Listing XML' is required." Revised the second paragraph to replace "elements" with "values" and add "in a new 'Sequence Listing XML'" after "English." |
| 2414.05 | Revised to clarify that <u>PCT Rule 5.2</u> requires that the description shall include a sequence listing part of the description complying with the standard provided for in the Administrative Instructions (AI) and in accordance with Section 208, any sequence listing, whether forming part of the international application or not, shall comply with Annex C of the AI. Revised to more closely follow language in WIPO Standard ST.26, including replacing references to "Sequence Listing XML" with "sequence listing." |
| 2414.06 | Revised the title to "Amendment of a 'Sequence Listing XML' in a Patent." Deleted "granted patent containing a." Added "contained in a patent" after each occurrence of "Sequence Listing XML." |
| 2415 | Added "sequences and" before "associated." Replaced "filed" with "having a filing date." Added that for national phase applications submitted under 35 U.S.C. 371, the relevant date is the international filing date. |
| 2415.01 | Revised the first paragraph to more clearly set forth which applications are required to provide a "Sequence Listing XML" in accordance with <u>37 CFR 1.831 -1.835</u> . Added cross reference to <u>MPEP § 1893.03(b)</u> . |

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| 2415.02 | Revised to replace "nucleotides" with "nucleotide" and "acids" with "acid sequences." Revised the last sentence to replace "a provisional application" with "the application." |
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| 2415.03 | Revised the title to "Improper Submissions of 'Sequence Listing' under 1.821(c) When a 'Sequence Listing XML' was Required." Revised to more closely follow language in WIPO Standard ST.26, including adding "WIPO Standard" before the first occurrence of "ST.26." Clarified requirements for a petition under 37 CFR 1.182 when an improper submission of a "Sequence Listing" under 1.821(c) was filed. |
| <u>2416</u> | Revised form paragraphs 24.17.26, 24.19.26, and 24.20.26. |
| 2417 | Added new section "Helpful Hints for Sequence Rules Compliance under WIPO Standard ST.26" to provide further guidance for Sequence Rules Compliance under WIPO Standard ST.26. |
| 2418 | Revised to provide updated information on the WIPO sequence tool, which includes the Sequence Validator, after initial implementation of WIPO Standard ST.26. |
| 2419 | Clarified that the USPTO uses a style sheet to transform a "Sequence Listing XML" file of less than 1 GB in size into an ASCII text file, which will be used to present the sequence information in a format that is more easily read. |
| <u>2419.01</u> - <u>02</u> | Revised Editor Note to more clearly set forth the applicability of WIPO Standard ST.26. |
| 2419.03 | Revised to replace "one gigabyte" with "1GB." |
| <u>2427</u> | Revised form paragraphs 24.01, 24.08, and 24.09. |

CHAPTER 2500:

- 2504 In subsection I, deleted subsection I.D and the discussion referring to outdated procedures for patentees to request a refund of the surcharge under 37 CFR 1.20(h) for payments submitted January 17, 2018, through July 16, 2018.
- In subsection I, clarified the options for making maintenance fee payments via the internet. In subsections II and IV, replaced the Mail Center with the Customer Service Window and added a cross reference to MPEP § 501, subsection III.
- 2520 Updated the fee reduction percentages for small and micro entities.
- Deleted outdated procedures for making an entity status change in Private PAIR.

 In subsection II, added a cross reference to MPEP § 509.03(b) and included a reference to new SB/460 form "Notification of Loss of Micro Entity Status."
- 2575 Subsection I, changed subsection title to "STANDARD NOTICES."
- 2590 In subsection I:
 - -Updated the process for petitioning to accept unintentionally delayed payment of a maintenance fee
 - -Deleted reference to the EFS-Web version of the SB/66 form.

CHAPTER 2600:

| 2601 | Revised to remove most of the guidance and provide a short history of <i>inter partes</i> reexamination. Further revised to state that <i>ex parte</i> reexamination is still available and to cross reference MPEP §§ 2209 to 2296 for guidance on the procedures for <i>ex parte</i> reexamination proceedings. |
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| 2602 | Revised to remove guidance except for the previous last paragraph, which was updated to explain that while citations of prior art continue to be allowed under 37 CFR 1.501, any filed citation of prior art under 37 CFR 1.501 will only be processed in accordance with 37 CFR 1.902 in an <i>inter partes</i> reexamination request filed prior to September 16, 2012, and to refer to revision 07.2022 of the 9th Edition of the MPEP for guidance on the former practice. |
| All other sections | Guidance was removed and replaced with references to previous MPEP publications which contain guidance on the former practices of <i>inter partes</i> reexamination. Removed reproduction of form paragraphs 26.01 to 26.80. |

CHAPTER 2700:

| 2701 | In subsection V, added "In contrast, patent term adjustment under 35 U.S.C. 154(b) does not extend the patent term beyond the expiration date specified in the disclaimer. See 35 U.S.C. 154(b)(2)(B) and 37 CFR 1.703(g)." |
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| 2730 | In subsection III: -Revised the Editor Note with updated applicability datesRevised the reproduced text of 37 CFR 1.704Added a new paragraph describing the procedure for filing 37 CFR 1.704(d) statements on or after July 17, 2023, in accordance with 37 CFR 1.704(d)(3). |
| 2731 | In subsection V, added a new paragraph including discussions of and citations to <i>SawStop Holding LLC v. Vidal</i> , 48 F.4th 1355, 2022 USPQ2d 836 (Fed. Cir. 2022) and <i>Chudik v. Hirshfeld</i> , 987 F.3d 1033, 2021 USPQ2d 149 (Fed. Cir. 2021). |
| 2732 | Revised the Editor Note with updated applicability dates. Revised the reproduced text of 37 CFR 1.704. In subsection IV, revised to describe the procedure for filing 37 CFR 1.704(d) safe harbor statements on or after July 17, 2023, in accordance with 37 CFR 1.704(d)(1) and clarified which communications are included in the provisions of 37 CFR 1.704(d). |
| 2734 | In subsection I, replaced reference to "37 CFR 1.136" with "37 CFR 1.136(a)." Removed subsection III and the reproduction of form PTO/SB/132. Renumbered previous subsection IV as subsection III. Further revised renumbered subsection III to incorporate changes from <i>Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements</i> , 88 FR 39172 (June 15, 2023). |
| <u>2750</u> | Added a cross reference to MPEP § 2754.01. |
| 2751 | In subsection I, added a discussion of and citation to <i>Novartis AG v. Ezra Ventures LLC</i> , 909 F.3d 1367, 128 USPQ2d 1752 (Fed. Cir. 2018). In subsection II: -Corrected the name of the Animal and Plant Health Inspection Service. -Added a new quote from and citation to <i>Biogen Int'l GmbH v. Banner Life Scis. LLC</i> , 956 F.3d 1351, 2020 USPQ2d 10385 (Fed. Cir. 2020) regarding the definition of an active ingredient. In subsection IV, clarified that devices reviewed under the Humanitarian Device Exemption are considered to be reviewed under section 515. |
| 2752 | Clarified that a power of attorney may be filed as a limited power of attorney specifying that the power is limited to prosecution of the application for patent term extension and the procedure for doing so. Revised "there must be an agency relationship" to "there must have been an agency relationship." |
| 2753 | Revised the reproduced text <u>37 CFR 1.740</u> . Clarified that any extension granted from an application is based on review of a product as either a medical device or a drug product rather than a combination of those separate products. Added cross references to <u>MPEP §§ 2754.01</u> , <u>2752</u> , and <u>2001.06(e)</u> . Clarified that the expiration date of a patent with a patent term adjustment is subject to any terminal disclaimer that could further limit the term. Clarified how to change a correspondence address in a patent file and how the information provided under <u>37 CFR 1.740(a)(15)</u> is used by the Office. Deleted the discussion regarding the requirement for copies pursuant to <u>37 CFR 1.740(b)</u> . |
| <u>2754</u> | Revised the reproduced text of <u>37 CFR 1.741</u> . In subsection I, revised to incorporate the electronic filing requirement of <u>37 CFR 1.741</u> . |

| 2754.01 | Revised to clarify how the sixty-day period for filing an application for patent term extension under <u>35 U.S.C. 156</u> is determined. |
|----------------|---|
| <u>2754.02</u> | Revised to state that interim extensions should be filed using USPTO patent electronic filing |
| | system. |
| | Added citation to <u>37 CFR 1.791</u> . |
| | Added "under 35 U.S.C. 156(d)(5)" after "a new request for interim extension." |
| 2755 | Revised to indicate that patent extension eligibility "will normally be made" to "may be made." Added a reference to <u>37 CFR 1.750</u> in the discussion that further information may be required. Added an explanation that "The USPTO patent electronic filing system includes the document description 'Response to request for information sent under <u>37 CFR 1.750</u> ' (document code TERM.INF.RES) which is to be used for responses to requests for information under <u>37 CFR 1.750</u> ." Added that a single request for reconsideration of a final determination may be extended under |
| | the provisions of 37 CFR 1.136(a). |
| 2755.01 | Added "under 35 U.S.C. 156(e)(2)" after "request for an interim extension by the application." Deleted "where those patents expire on the same day," after "37 CFR 1.785." Replaced "would be" with "are" after 35 U.S.C. 156(e)(2). |
| <u>2755.02</u> | Revised the reproduced text of <u>37 CFR 1.790</u> . |
| | Clarified the requirements of an interim patent term extension under 35 U.S.C. 156(d)(5). Revised "an interim extension pursuant to the provisions of 35 U.S.C. 156(e)(2) would be granted, provided the patent owner" to "an interim extension pursuant to the provisions of 35 U.S.C. 156(e)(2) can be granted, provided that the patent owner" |
| 2756 | In the preamble before subsection I, clarified that "The Animal and Plant Health Inspection Service of the United States Department of Agriculture approves veterinary biological products and is responsible for both (i) assisting the Office in determining the eligibility for term extension of a patent which claims a veterinary biological product that has been subject to review under the Virus-Serum-Toxin Act (21 U.S.C. 151-59) and (ii) determining the regulatory review period of the veterinary biological product." In subsection I, in item (D), revised "Office determination" to "determination." In subsection II, revised "mailed to the regulatory agency" to "sent to the regulatory agency." |
| <u>2758</u> | In the preamble before subsection I, added ", and in view of any applicable terminal disclaimer" after "(for applications filed on or after May 29, 2000)." |
| <u>2759</u> | Revised to incorporate the electronic issuance of certificate of extensions for patent term. |
| 2760 | Added "If the USPTO receives a submission in accordance with the procedures of this section and MPEP § 724.02, the USPTO will, on its own initiative, waive the electronic filing requirement under 37 CFR 1.740(b) for the submission." |
| <u>2761</u> | Clarified how multiple applications for extension of patent term are handled. Deleted the discussion on circumstances where extensions of multiple patents have been sought based on a single regulatory review period as per 37 CFR 1.785. |
| 2762 | Added "The USPTO patent electronic filing system includes the document description 'Disclosure Under <u>37 CFR 1.765</u> in a Patent Term Extension Application' (document code TERM.PTE.DIS) for disclosures to the USPTO under <u>37 CFR 1.765</u> ." |
| 2764 | Revised the reproduced text of <u>37 CFR 1.770</u> . Revised to note an exception for the timing of filing a request for withdrawal filed in response to a requirement for election. Deleted information on the distinction from the situation as compared to <u>MPEP § 2761</u> . |

| <u>2765</u> | Added reference to "under 35 U.S.C. 156(e)(1)" regarding instances where the Office is ready to issue a Notice of Final Determination and grant a certificate of extension, but unresolved issues relating to the patent remain. |
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| <u>2766</u> | Revised "reviewed by the Office of Patent Legal Administration" to "decided by the Office of Patent Legal Administration." |

CHAPTER 2800

| <u>2801</u> | Revised flowchart of the Supplemental Examination Procedure in two instances to no longer refer to PAIR when discussing electronic issuance of the Supplemental Examination Certificate. |
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| 2803 | Added cross reference to MPEP § 325 for more information regarding how all parties having an interest in a patent must act together in proceedings before the USPTO. |
| 2806 | In subsection I: -Clarified who can electronically file an initial supplemental examination request and "follow-on" papers and to refer to the "Patent Center User Guide" and the Patent Electronic Business Center for how to electronically file requests for supplemental examination and "follow on" papers. -Clarified that a corrected request filed in response to a Notice of Noncompliant Supplemental Examination Request and any paper submitted in a reexamination proceeding which resulted from a supplemental examination should be filed as "follow-on" paper(s). In subsection II: -Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. -Clarified that whether the correspondence is mailed, delivered, or hand-carried, it is strongly recommended to place the Mail Stop information on the first page of each paper filed. |
| 2810 | Updated fee reduction percentages for small and micro entities. Replaced citations to <i>Setting and Adjusting Patent Fees</i> , 78 Fed. Reg. 4212 (January 18, 2013) and <i>Changes to Implement Micro Entity Status for Paying Patent Fees</i> , 77 Fed. Reg. 65019 (December 19, 2012) with <i>Reducing Patent Fees for Small Entities and Micro Entities Under the Unleashing American Innovators Act of 2022</i> , 88 FR 17147 (March 22, 2023). |
| 2810.01 | Clarified examples of calculating document size fees. Deleted instances of "EFS-Web Filers" and "EFS-Web Quick Start Guide to Filing a Supplemental Examination Request." |
| <u>2811</u> | In subsection IX, added cross reference to MPEP § 325 for more information regarding how all parties having an interest in a patent must act together in proceedings before the USPTO. |
| 2811.01 | In subsection III, clarified in multiple instances that it is "the claimed invention" in a patent that has an effective filing date. |
| 2816.02 | In subsection II, clarified in multiple instances that it is "the claimed invention" in a patent that has an effective filing date. |
| 2816.03 | In subsection II.C, clarified that it is "the claimed invention" in a patent that has an effective filing date. |

CHAPTER 2900

| <u>2905</u> | Updated the listing of benefits to applicants of filing an international design application directly with the International Bureau through the WIPO's e-filing interface (eHague). |
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| <u>2905.01</u> | Replaced the address of the Customer Service Window with a cross reference to MPEP § 501, subsection III. Updated instructions for electronically filing an international design application through the USPTO as an office of indirect filing in light of the retirement of EFS-Web. |
| <u>2906</u> | Updated the text of Hague Rule 14. Updated the cross reference from Hague Rule 14(1) to Hague Rule 14(1)(a) and (b) as a conforming change. |
| <u>2907</u> | Updated the cross reference from Hague Rule 14(1) to Hague Rule 14(1)(a) and (b) as a conforming change. |
| 2909 | In subsection II, corrected "(iii) a claim, and/or," to "and/or a claim, and," to clarify the additional mandatory contents. In subsection IV, replaced "Description of the Reproductions (Legends) of the Industrial Designs" with "Legends (<i>optional</i>)." |
| 2909.01 | Corrected "'How to Submit an International Application to the International Bureau' of the Hague Guide for Users" to "'How to Submit an International Application to the International Bureau – e-filing or form DM/1' of the Guide to the Hague System." |
| 2909.02 | Corrected "Hague Guide for Users" to "Guide to the Hague System." |
| 2909.02(a) | Changed section title to "Reproductions Submitted Through the USPTO Patent Electronic Filing System." Updated the process for submitting reproductions in light of the retirement of EFS-Web. |
| 2909.03 | Replaced "Annex V (for submitting a priority document) are specific to the designation of the Republic of Korea" with "Annex V (for submitting a document concerning a priority claim) are specific to certain other designations as specified in the respective annex." |
| <u>2910</u> | Revised the reproduced text of <u>37 CFR 1.1031</u> . |
| <u>2911</u> | Replaced "37 CFR 11.6" with "including design patent practitioners registered under 37 CFR 11.6(d)" to reflect the changes to the rule in <i>Representation of Others in Design Patent Matters Before the United States Patent and Trademark Office</i> , 88 FR 78644 (November 16, 2023). Added a cross reference to new section MPEP § 1502.02. |
| 2920.01 | Replaced "signed" with "corrected" regarding an application data sheet filed with a request to correct the inventorship. Corrected references to "37 CFR 1.41(f)" with "37 CFR 1.48(f)." |
| 2920.05(d) | Deleted "as discussed in MPEP § 215.02(a), by submitting Form PTO/SB/38 (Request to Retrieve Electronic Priority Application(s)), where applicable." Updated the application number format for retrieval of an international design application via WIPO DAS. Added a reference to the USPTO webpage for the application number format needed for retrieval of other types of foreign applications via WIPO DAS. |
| 2920.06 | Updated the process by which applicant is notified and may make payment of the issue fee to the International Bureau. |

CHAPTER FPC:

Chapter FPC provides a consolidated listing of the form paragraphs found in the numbered chapters of the MPEP. The FPC sections within Chapter FPC are organized by form paragraph number and do not necessarily correspond to the chapters of the MPEP in which the form paragraphs appear. The Subject Matter Index may be consulted to locate the MPEP section(s) wherein a given form paragraph is reproduced. An indication of the form paragraphs being revised, deleted, or added are indicated in the summary of changes organized by MPEP sections above.