

USG Response to WIPO’s December 7, 2023 Request for Input on SCP Documents (Part I)

Document	Input
(i) a draft reference document on the exception regarding extemporaneous preparation of medicines. The inputs may relate to, for example, relevant court cases, challenges faced by Member States in implementing the exception and the results of the national/regional implementation.	The U.S. does not currently have input to this topic.
(ii) a study on various aspects of the unity of invention, including divisional application.	MPEP §§ <a href="#">802-Basis for Restriction Practice in Statute and Rules</a> , <a href="#">803-Restriction – When Proper</a> , <a href="#">806-Determination of Distinctness or Independent of Claimed Inventions</a> , <a href="#">823-Unity of Invention Under the Patent Cooperation Treaty</a> , <a href="#">201.06-Divisional Application</a>
(iii) compilation of laws and practices relating to the patentability of artificial intelligence (AI)-related inventions (update of document SCP/30/5).	In 2022, the Court of Appeal for the Federal Circuit affirmed a USPTO decision denying petitions to name an AI system as an inventor, finding that an inventor must be a natural person. <i>Thaler v. Vidal</i> , 43 F. 4 <sup>th</sup> 1207, 1210 (Fed. Cir. 2022). The court explained, however, that it was not confronted with “the question of whether inventions made by human beings with the assistance of AI are eligible for patent protection.” <i>Id.</i> at 1213. In 2024, pursuant to the “Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence” (October 20, 2023), the USPTO issued <a href="#">inventorship guidance</a> for inventions assisted by artificial intelligence (AI). Among other things, the inventorship guidance explains that: (a) “an inventor must be a natural person, and by extension, any joint inventor must be a natural person”; (b) “the use of an AI system by a natural person(s) does not preclude a natural person(s) from qualifying as an inventor (or joint inventors) if the natural person(s) significantly contributed to the claimed invention”; and (c) “each named inventor in a patent application or patent, including an application or a patent for an AI-assisted invention, must have made a ‘significant contribution’ to the claimed invention.”
(iv) a dedicated webpage on the expedited examination program of Intellectual	Since the publication of WIPO document <a href="#">SCP/35/6</a> , the USPTO has extended the <a href="#">Fast-Track Appeals Pilot Program</a> . NOTE: The USPTO’s

	Property Offices (updating the contents of document SCP/35/6).	COVID-19 Prioritized Examination Pilot Program closed on May 11, 2023.
(v)	a document updating SCP/26/5 (Constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on the access to affordable especially essential medicines for public health purposes in those countries).	The U.S. does not currently have an update to this topic.
(vi)	a document updating SCP/25/4 (compilation of court cases with respect to client-patent advisor privilege).	The U.S. previously provided an update to this topic: <a href="#">Confidentiality of Communication between Clients and their Patent Advisors</a>
(vii)	a document updating SCP/32/6 (patent law provisions that contribute to effective transfer of technology, including sufficiency of disclosure).	The U.S. previously provided an update to this topic: <a href="#">United States of America Intervention on Technology Transfer</a>
(viii)	a study on patent inventorship and ownership issues arising from collaborative research.	MPEP §§ <a href="#">602.09-Joint Inventors</a> , <a href="#">2109-Inventorship</a> , <a href="#">2109.01-Joint Inventorship</a> , <a href="#">2156-Joint Research Agreements</a>