

世界智慧財產權組織提出有關遺傳資源專利之新揭露義務

草案

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摘要

今 (2023) 年 9 月 13 日世界智慧財產權組織完成「與智慧財產權、遺傳資源及其相關傳統知識有關之國際法律文件草案」的籌備委員會會議，該文件草案旨在對欲申請遺傳資源與相關傳統知識發明專利的公司課予新的揭露義務。其中，文件草案揭示其揭露的適用範圍與需揭露之資訊等。然而，提案的制度中仍有待解決的部分，如專利主管機關在進行可專利性的實質審查時將如何受到專利揭露形式要件的影響，以及其應如何依照專利審查程序公開揭露資訊，又不影響保密性資訊的保護等問題。由於該文件草案就上述問題，並未提供有關形式要件以外的指引，後續發展仍有待觀察。

(取材資料：Bart Van Vooren et al., *WIPO Proposes New Patent Disclosure Obligations on Genetic Resources: What Impact for Companies?*, COVINGTON (Sept. 13, 2023), <https://www.insideeulifesciences.com/2023/09/13/wipo-proposes-new-patent-disclosure-obligations-on-genetic-resources-what-impact-for-companies/#>.)

今 (2023) 年 9 月 13 日世界智慧財產權組織 (World Intellectual Property Organization, WIPO) 完成「與智慧財產權、遺傳資源及其相關傳統知識有關之國際法律文件草案」(以下簡稱文件草案) 的籌備委員會會議¹，該文件草案預計於 2024 年的外交會議上進行討論，並可能於該會議上通過²。其旨在對尋求

¹ World Intellectual Property Organization [WIPO], *Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 1, WIPO Doc. GRATK/PM/5 (Sept. 13, 2023).

² 外交會議 (Diplomatic Conference) 為 WIPO 成員國間的高階會議，旨在完成新條約之談判。若 WIPO 之條約草案已取得足夠進展，得推進至條約通過程序，則 WIPO 大會 (General Assembly) 可決定召開此會議。 *Decision-making and Negotiating Bodies*, WIPO, <https://www.wipo.int/policy/en/index.html#bodies> (last visited Nov. 10, 2023) (“Diplomatic Conferences: If one of the Standing or Permanent Committees determines that sufficient progress has been made to move towards treaty adoption, the General Assembly can decide to convene a Diplomatic Conference. This is a high level meeting of member states, convened with the sole purpose of finalizing negotiations on a new treaty; Standing Committees: These are ad hoc committees of experts established by a decision of the General Assembly for a given purpose; Permanent Committees: Any of the Governing Bodies can constitute committees as required....”); *Diplomatic Conference on*

申請「實質或直接基於」遺傳資源與相關傳統知識之發明專利的公司課予新揭露義務³。此類公司將可能需要揭露有關遺傳資源與相關傳統知識之來源或原產地資訊，作為專利申請的一部分。若無法符合揭露義務，公司的專利申請可能遭拒⁴。

本文先檢視「與智慧財產權、遺傳資源及其相關傳統知識有關之國際法律文件草案」揭露規則的背景，再簡述草案揭露規則之概要，後以文件草案之規則說明其尚待解決的問題，最後為一結論。

壹、揭露規則之背景

事實上，與文件草案相似的揭露規則早在 2008 年討論是否修改《與貿易有關之智慧財產權協定 (Agreement on Trade-Related Aspects of Intellectual Property Rights)》以引入專利申請之強制性揭露要求的會議上，部分會員即提案試圖納入⁵。對於涉及使用遺傳資源與相關傳統知識的發明，會員皆有避免錯誤地授予專利的共識，但就此目標的實現方法，會員間未能達成共識⁶。隨後此項議題亦於有關遺傳資源「取得及利益共享 (Access and Benefit-Sharing)」的《名古屋議定書 (Nagoya Protocol)》談判期間進行討論，但最終未能成功引入強制性的揭露義務⁷。然，印度、西班牙與瑞士等近 30 個國家，業已於各法制中引

Intellectual Property and Genetic Resources, WIPO, <https://www.wipo.int/diplomatic-conferences/en/genetic-resources/index.html> (last visited Nov. 10, 2023).

³ *Draft Text on Genetic Resources and Associated Traditional Knowledge: Executive Summary*, WIPO, <https://www.wipo.int/export/sites/www/diplomatic-conferences/en/docs/executive-summary-draft-text-on-genetic-resources-and-associated-traditional-knowledge.pdf> (last visited Nov. 10, 2023).

⁴ WIPO, Decisions on Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, art. 6.1, WIPO Doc. WIPO/GRTKF/IC/SS/GE/23/4 (Sept. 8, 2023) [hereinafter *The Decisions*].

⁵ Trade Negotiations Committee, *Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products Other than Wines and Spirits and Those Related to the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, WTO Doc. WT/GC/W/591, TN/C/W/50, paras. 6, 10 (June 9, 2008).

⁶ *Id.* para. 5 (“There is important common ground on key underlying objectives, notably ... the avoidance of erroneous patents for inventions that involve the use of genetic resources...However, the work continues to be characterized by different approaches to meeting these objectives...”).

⁷ 「取得及利益共享」係指遺傳資源可能的取得方式，以及因使用這些資源而產生的利益是如何在使用資源者與提供資源者間分享。SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, INTRODUCTION TO ACCESS AND BENEFIT-SHARING 2 (2010); Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Oct. 12, 2014, 3008 U.N.T.S. 3; UNCTAD, THE CONVENTION ON BIODIVERSITY AND THE NAGOYA PROTOCOL: INTELLECTUAL PROPERTY IMPLICATIONS 47 (Oct. 1, 2014) (“[D]elegates at Nagoya were also unable to resolve whether such a requirement should or should not be included in the final treaty text, and the Nagoya Protocol therefore contains no mandatory disclosure obligation, leaving it up to the Parties to decide whether or not they wished to incorporate such a requirement in their national laws.”).

入此類揭露義務⁸。因此，此刻 WIPO 這份文件草案意在全球範圍下引入此種揭露義務，並試圖對不合規者進行制裁，未揭露者甚至可能導致其專利申請被拒絕⁹。

貳、草案揭露規則之概要

就本文件草案之揭露規則，以下介紹此規則之適用範圍、揭露義務的觸發時機與需揭露之資訊，後針對違反揭露義務之效果予以說明。

一、揭露規則之適用範圍

新的揭露規則明確涵蓋以下三類資訊：「遺傳資源¹⁰」、「相關傳統知識¹¹」與「國家管轄範圍以外地區取得之遺傳資源¹²」。

該文件草案尚未解決的問題是，其是否尚包含遺傳資源的數位序列資訊 (Digital Sequence Information, DSI)¹³。雖然在目前的文件草案中並未明確提及 DSI，但在較早的提案中明確要求申請人應具有遺傳資源的「實體樣本」¹⁴。不過，這些文字最終因觀點不同而被移除，使這個問題並未有所定論¹⁵。這種不確

⁸ Brendan Tobin, *Monitoring Compliance Under an International ABS Regime: The Role of an International Certificate Scheme*, 10(3) ASIAN BIOTECHNOLOGY AND DEV. REV. 95, 104 (2008).

⁹ *Draft Text on Genetic Resources and Associated Traditional Knowledge: Executive Summary*, *supra* note 3.

¹⁰ The Decisions, *supra* note 4, arts. 3.1-3.2.

¹¹ *Id.*

¹² WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 10, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022) (“Sub paragraphs 3.1(b) and/or 3.2(b) apply in those cases ... For example, GRs in areas beyond national jurisdiction such as the high seas.”).

¹³ 數位序列資訊係指在國際談判中有關共享遺傳資源利益所產生的數位生物資料，目前尚未就其定義達成共識；其可限於遺傳基因資訊，或包括所有相關的數位生物資料，甚至相關傳統知識。在生物多樣性締約方大會，締約方之間體認到《生物多樣性公約》架構下有關遺傳資源數位序列資訊的定義與範圍，仍具有不同觀點。United Nation Environment Programme [UNEP], Conference of the Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity*, at 1, U.N. Doc. CBD/COP/DEC/15/9; UK PARLIAMENT, DIGITAL SEQUENCE INFORMATION 1 (2020).

¹⁴ Submitted by the European Community and Its Member States, *Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications*, at 2-3, WIPO Doc. WIPO/GRTKF/IC/8/11 (May 17, 2005) (“[I]f the country of origin is unknown, the applicant should declare the source of the specific genetic resource to which the inventor has had physical access and which is still known to him....”).

¹⁵ *E.g.*, *Amended Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, WIPO (May 14, 2022), https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_43/wipo_grtkf_ic_43_non_paper.pdf (“[T]he issue of inclusion of derivatives and digital sequencing information (DSI) was raised. An issue that also relates directly to the trigger. On this latter issue, it was clear during consultations, that there was no consensus. Also, it was noted that discussions on derivatives and DSI are ongoing in other forums, notably the CBD.”).

定性或許是因為 DSI 利益共享的全球機制在「生物多樣性公約第十五屆締約方大會 (COP 15)」後正處設立階段¹⁶，WIPO 可能希望待 COP 15 確立該機制後，將揭露規則與其保持一致。

二、揭露義務之觸發時機

文件草案中存在的另一項重要問題是缺乏明確的觸發條件。由於 WIPO 成員觀點各異，該文件草案目前規定，只有當發明「實質或直接基於」遺傳資源或相關傳統知識時，才會觸發揭露義務¹⁷。意即，就申請專利範圍所主張之發明而言，遺傳資源與相關傳統知識係為必要或具實質影響，且該發明需仰賴遺傳資源或相關傳統知識之特殊性質¹⁸。

實質上，此揭露條件顯示發明與遺傳資源之間必須存在因果關係。而相關利害關係人，例如企業最關切的可能是研究工具的使用，比如動物與植物、酵母、細菌、質體 (plasmids) 及病毒載體¹⁹，均可能被視為遺傳資源²⁰。然而，根據文件草案之解釋文件，可能涉及發明之研發但對發明不具實質影響的遺傳資源，不會觸發揭露義務²¹。這尤其包括通常為標準耗材且可自商業型供應商購買之研究工具，該等物品並不為申請專利範圍所主張之發明的一部分，因此無需揭露²²。

值得一提的是，國家為保護公共利益的特殊情況，在國內層級得對揭露制度設立正當例外與限制²³。但該文本並未在解釋文件中針對所謂「特殊情況」是否應包含公共衛生緊急情況，提供進一步的指引，因此，針對造成疫情嚴峻之病原體的疫苗、診斷與治療方法專利申請是否應涵蓋其中，依舊存在不確定性。

三、需揭露之資訊

一旦觸發揭露義務，專利申請人即需揭露「遺傳資源的原產地國家」或

¹⁶ UNEP, Conference of the Parties to the Convention on Biological Diversity, *Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity*, para. 16, U.N. Doc. CBD/COP/DEC/15/9.

¹⁷ *Draft Text on Genetic Resources and Associated Traditional Knowledge: Executive Summary*, *supra* note 3.

¹⁸ The Decisions, *supra* note 4, art. 2.

¹⁹ 質體 (plasmid) 係一種小型的圓狀 DNA 分子，存在於細菌與微生物中。PLASMID, NAT'L HUMAN GENOME RSCH. INST. (Oct. 4, 2023), <https://www.genome.gov/genetics-glossary/Plasmid>.

²⁰ WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 9, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022).

²¹ *Id.*

²² *Id.*

²³ The Decisions, *supra* note 4, art. 4 (“In complying with the obligation set forth in Article 3, Contracting Parties may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest....”).

「提供相關傳統知識的原住民族或當地社群」。若申請人無法獲取上述資訊，則需提供「遺傳資源的來源」或「遺傳資源相關傳統知識的來源」²⁴。

該文件草案將「遺傳資源的來源」定義為：「申請人獲得遺傳資源的任何來源，例如研究中心、基因庫、《糧食與農業植物遺傳資源國際條約 (International Treaty on Plant Genetic Resources for Food and Agriculture, ITPGRFA)》的多邊系統，抑或是其他任何遺傳資源的移地 (ex situ) 收集或存放處²⁵。」而「遺傳資源相關傳統知識的來源」則被定義為：「申請人獲得與遺傳資源相關傳統知識之任何來源，例如科學文獻、可公開取得的資料庫、專利申請案及專利出版品²⁶。」

這些定義相當廣泛，草案也並提供一未盡臚列的清單，說明遺傳資源與相關傳統知識可能來自何處。如果這些資訊皆不可得，申請人可提交一份聲明，以此證明其係因正當緣由導致其無法獲知相關資訊，則仍然允許其申請專利²⁷。然而，此為例外情況，且只適用於非常特殊的情形，例如因不可抗力因素致使相關文件毀損，而無法再指出遺傳資源的來源²⁸。

一旦申請專利之公司已盡其揭露義務，專利主管機關將毋須驗證資訊的真實性²⁹。不過，根據各國專利審查程序，這些資訊將會公開發布，並且在該文件草案下將創建一特殊的遺傳資源與相關傳統知識資訊系統，締約方宜確保專利主管機關可取得此資訊系統，以作為專利申請的搜尋及審查使用³⁰。

四、違反揭露義務之效果

如果申請人未能揭露所需資訊，其專利申請是否將遭駁回？答案將取決於各國國內法律的執行方式。締約方將建立「適當、有效且相稱的法律、行政或

²⁴ *Id.* arts. 3.1-3.2.

²⁵ 移地 (ex situ) 係指外部、離開原地點或遠離自然所在地。Ex Situ, OXFORD UNIVERSITY PRESS, <https://www.oxfordreference.com/display/10.1093/oi/authority.20110810104854504> (last visited Nov. 10, 2023); The Decisions, *supra* note 4, art. 2.

²⁶ The Decisions, *supra* note 4, art. 2.

²⁷ WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 10, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022); *Draft Text on Genetic Resources and Associated Traditional Knowledge: Executive Summary*, *supra* note 3.

²⁸ WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 10, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022).

²⁹ The Decisions, *supra* note 4, art. 3.5.

³⁰ *Id.* arts. 7.2-7.3 (art. 7.2 “Contracting Parties should ... make such information systems accessible to Offices for the purposes of search and examination of patent applications....”).

政策措施」³¹，其中可能包含專利權授予前制裁或核准後制裁³²。不過，該文件草案至少明確指出，該等已獲准之專利，除非申請人故意不揭露資訊，否則主管機關不得僅因其未能揭露資訊而做成專利不可執行之決定³³。

參、文件草案尚待解決的問題

文件草案之規則中尚有許多部分留下疑問，如專利揭露之形式要件將對專利主管機關進行可專利性的實質審查有何影響？該文件草案的其中一項根本目標即是，在欠缺新穎性或進步性的情況下，避免主管機關錯誤地授予專利予有關遺傳資源及相關傳統知識的專利申請³⁴，從而增進法律明確性與專利的品質³⁵。然而，在專利審查程序中，主管機關將如何使用申請人揭露的資訊？本文件草案中除了形式要件外，並未提供任何實質要件的指引。

此外，將如何處理保密性問題仍尚待解決。根據文件草案，專利主管機關需按照專利審查程序公開揭露資訊³⁶，但這不影響對保密性資訊的保護。然值得玩味的是，專利申請人需要提供何種事由使相關專利主管機關維持其保密性，尚不得而知，在文件草案中亦並未進一步討論該規範。

肆、結論

此份文件草案將在 2024 年由全體 WIPO 成員於外交會議上進行討論。一旦文件草案於該會議通過，其文本將開放各國簽署，並在達二十國簽署後之三個月內生效³⁷。儘管文件草案揭示其揭露的適用範圍、揭露義務的觸發條件與需揭露之資訊，然而，在提案的制度下，不論是揭露規則的涵蓋範圍、觸發條件，又或是專利申請過程中，專利主管機關使用申請人所揭露之資訊的實質要件，以及對於資訊的保密性又該如何處理，皆留下諸多問題，因而吾人對後續

³¹ *Id.* art. 6.1.

³² WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, at 15, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022) (“The measures could include pre-grant sanctions, such as suspending the further processing of a patent application until the disclosure requirement is met, or withdrawing/lapsing the application if the applicant fails or refuses to provide the minimum information required in Article 3 within a time period as determined at the national level. These measures could also include post-grant sanctions, such as fines for wilfully failing to disclose the required information or intentionally providing incorrect information as well as the publication of judicial rulings.”).

³³ The Decisions, *supra* note 4, art. 6.3.

³⁴ *Id.* art. 1(b).

³⁵ *Id.* art. 1(a).

³⁶ *Id.* art. 3.6.

³⁷ WIPO, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, art. 16, WIPO Doc. WIPO/GRTKF/IC/43/5 (June 3, 2022).

發展仍有待持續關注。

