C

SCP/34/6 ADD.
原文：英文
日期：2022 年 7 月 27 日

专利法常设委员会

第三十四届会议
2022 年 9 月 26 日至 30 日，日内瓦

文件 SCP/34/6 摘要：文件 SCP/31/5（关于专利和获取医疗产品与卫生技术的已有研究的回顾报告）更新稿

秘书处编拟

1. 专利法常设委员会（SCP）在 2021 年 12 月 6 日至 9 日于日内瓦举行的第三十三届会议上商定，秘书处将根据文件 SCP/28/9 Rev.中所列的职责范围，在 SCP 第三十四届会议上提交文件 SCP/31/5 的更新稿，其中包含对专利和获取医疗产品与卫生技术已有研究的回顾，并延长回顾期，涵盖 2019 年至 2021 年的期间（见文件 SCP/33/5 第 24 段“专利与卫生”下第一点）。[1]

2. 根据 SCP 的上述决定，秘书处编拟了文件 SCP/31/5 的所述更新稿，载于文件 SCP/34/6 的附件，供将于 2022 年 9 月 26 日至 30 日在日内瓦以混合形式举行的委员会第三十四届会议讨论。根据委员会第三十三届会议的决定，更新稿是按照文件 SCP/28/9 Rev.规定的范围编写的。

3. 鉴于文件 SCP/34/6 的篇幅，编拟了本文件作为该文件的摘要。

4. 按照委员会的授权，回顾报告中包括的研究涉及以下主题：

– 专利及其他相关问题与医疗产品和卫生技术可负担性和可用性之间的关系；[2]

[1] 文件 SCP/28/9 Rev.是阿根廷、巴西、加拿大和瑞士几个代表团的一项关于进行此种审查的提案，供委员会在议程项目“专利与卫生”下审议。

[2] 为本回顾研究的目的，“医疗产品和卫生技术”系指药品、疫苗、诊断用品和医疗器械。

– 专利制度包括专利质量机制在激励和促进新药和卫生技术开发以解决全球疾病负担、促进医疗产品和卫生技术的获取以及确保优质产品供应方面的作用；

– 知识产权制度在医疗产品和卫生技术部门中促进知识溢出和技术转让的作用；

– 强制和自愿许可机制及专利池在促进医疗产品和卫生技术可负担性和可用性方面的作用；

– 基本药物在不受专利保护的国家中的可获取性，考虑供需两方面影响可获得性和可负担性的多种其他因素。

5. 对每份研究报告都概述了分析的事实性概览和研究作者的主要结论与建议。回顾报告中列入的研究报告一览表列于本文件附件。

6. 在进行这次更新时，采用了与编制文件 SCP/31/5 时类似的检索方法。因此，除了世卫组织、产权组织和世贸组织的作品外，还对以下政府间组织编写或委托外部研究人员编写的出版物进行了检索：欧洲联盟、贸发会议、艾滋病署、经合组织、开发署和南方中心等。在学术文献方面，考虑到其领域与授权主题的相关性，对 80 多种经同行评审的期刊进行了检索。

7. 文件SCP/34/6的结构分为三个主要部分：(i)由世卫组织、产权组织、世贸组织和其他相关政府间组织编写的研究报告，包括由这些组织委托外部研究人员编写的研究报告；(ii)经同行评审的学术研究（经济学文献）；(iii)经同行评审的学术研究（法律和一般文献）。

8. 所找到的多数文献与以下主题相关：(i)专利及其他相关问题与医疗产品和卫生技术可负担性和可用性之间的关系；(ii)强制和自愿许可机制及专利池在促进医疗产品和卫生技术可负担性和可用性方面的作用；(iii)专利制度在激励和促进新药和卫生技术开发以解决全球疾病负担方面的作用。尽管与专利许可有关的各种问题都与技术转让有关，但较少的研究关注知识产权制度在医疗产品和卫生技术部门中促进知识溢出和技术转让的作用。有些研究涵盖了一个以上的主题，或者分析了某一特定主题对获得创新产品和创新激励的影响。与文件 SCP/31/5 中所载的第一次回顾结果相比较，在本次更新期间，似乎没有发表专门针对基本药物不受专利保护的国家的基本药物可用性研究，这再次证实了对该主题缺乏研究。

9. 读者应注意，与文件 SCP/31/5 类似，秘书处没有对本更新稿中所包括的找到的出版物和经同行评审的学术研究的内容进行质量评估。此外，根据 SCP 的任务授权，更新稿中没有列入工作文件、草案、博客、评论和观点等，这些不被认为是经过同行审评的学术研究。

[后接附件]

关于专利和获取医疗产品与卫生技术的已有研究的回顾报告更新稿中列入的研究报告一览
（2019-2021）

1. Abbas M. Z. (2020), Treatment of the Novel COVID-19: Why Costa Rica's Proposal for the Creation of a Global Pooling Mechanism Deserves Serious Consideration?, *Journal of Law and the Biosciences*, Vol. 7, No. 1, pp. 1-10.

2. Abbas M. Z. (2021), Parallel Importation as a Policy Option to Reduce Price of Patented Health Technologies, *Journal of Generic Medicines*, Vol. 17, No. 4, pp. 214–219.

3. Abbott F. M. and Reichman J. H. (2020), Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic, *Journal of International Economic Law*, Vol. 23, No. 3, pp. 535–561.

4. Adekola T. A. (2020), Regional Mechanism under Doha Paragraph 6 System – The Largely Untested Alternative Route for Access to Patented Medicines, *Asian Journal of WTO & International Health Law and Policy*, Vol. 15, No. 1, pp. 61-90.

5. Adewopo A. (2021), Access to Pharmaceutical Patents in the COVID-19 Emergency: A Case for Government Use in Nigeria, *Journal of African Law*, Vol. 65, No. S2, pp. 259-286.

6. Baker B. K. (2021), Hamstringing the Health Technology Response to COVID-19: The Burdens of Exclusivity and Policy Solutions, *Northeastern University Law Review*, Vol. 13, No. 2, pp. 689-732.

7. Batista P. H. D., Bryski D., Lamping M. and Romandini R. (2019), IP-based incentives against antimicrobial crisis: a European perspective, *IIC – International Review of Intellectual Property and Competition Law,* Vol. 50, pp. 30–76.

8. Bond Eric and Kamal Saggi (2020): Patent protection in developing countries and global welfare: WTO obligations versus flexibilities, *Journal of International Economics*, Vol. 122.

9. Christie A., Dent C. and Studdert D. M. (2020), Evidence of 'Evergreening' in Secondary Patenting of Blockbuster Drugs, *Melbourne University Law Review*, Vol. 44(2), pp. 537-564.

10. Conti R. (2021), The Determinants of COVID-19 Vaccine Development Success, Commented by Hall S. and Metzger A., Study commissioned by WIPO. Available at: https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_covid_19_ge_22/wipo_gc_covid_19_ge_22_www_572491.pdf.

11. Dai Rong and Jayashree Watal (2021): Product patents and access to innovative medicines, *Social Science and Medicine*, Vol. 291.

12. Dave Chintan V., Michael S. Sinha, Reed F. Bell, and Aaron S. Kesselheim (2020): Estimating the cost of delated generic drug entry to Medicaid, *Health Affairs*, Vol. 39(6), 1011-1017.

13. Ding Yucheng and Xin Zhao (2019): Pay-for-delay Patent Settlement, Generic Entry and Welfare, *International Journal of Industrial Organization*, Vol. 67.

14. Farquhar A. H. (2020), Redefining the TRIPS Agreement to Accommodate en masse Compulsory Licensing of Vaccines & Other Pharmaceuticals for the Treatment of Covid-19, *North Carolina Journal of Law & Technology*, Vol. 22, No. 2, pp. 259-292.

15. Garagancea L. (2021), Access to Medicines: The Interplay between Parallel Imports, Compulsory Licensing, and Voluntary Licensing, *European Pharmaceutical Law Review*, Vol. 5, No. 1, pp. 37-56.

16. Grimes W. (2021), Perverse results from pharmaceutical patents in the United States, *IIC - Review of Intellectual Property and Competition Law,* Vol. 52, pp. 596–605.

17. Groux G. and de Beer J. (2021), Canada: Access to Medicines in High-income Countries. In: Ragavan S. and Vanni A. (eds.) *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals*, Routledge, pp. 189-212.

18. Gurgula O. (2021), Drug Prices, Patents and Access to Life-Saving Medicines: Changes Are Urgently Needed in the COVID-19 Era, *European Intellectual Property Review*, Vol. 43, No. 6, pp. 381-387.

19. Gurgula O. and Lee W. H. (2021), COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?, *Journal of Generic Medicines*, Vol. 17, No. 2, pp. 61–70.

20. Gurgula O. and Hull J. (2021), Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer, *Journal of Intellectual Property Law &Practice*, Vol. 16, Issue 11, pp. 1242-1261.

21. Houston A. R. and Beall R. F. (2019), Could the Paragraph 6 Compulsory License System be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime, *McGill Journal of Law and Health*, Vol. 12, No. 2, pp. 227-246.

22. Hu Y., Eynikel D., Boulet P. and Krikorian G. (2020), Supplementary protection certificates and their impact on access to medicines in Europe: Case studies of sofosbuvir, trastuzumab and imatinib, *Journal of Pharmaceutical Policy and Practice*, Vol. 13, No. 1.

23. Huneycutt B., Lurie N., Rotenberg S., Wilder R. and Hatchett R. (2020), Finding equipoise: CEPI revises its equitable access policy, *Vaccine,* Vol. 38, pp.2144-2148, Elsevier.

24. Islam M. D., Kaplan W. A., Trachtenberg D., Thrasher R., Gallagher K. P. and Wirtz V. J. (2019), Impacts of Intellectual Property Provisions in Trade Treaties on Access to Medicine in Low and Middle Income Countries: A Systematic Review, *Globalization and Health*, Vol. 15, No. 1.

25. Khachigian L. M. (2020), Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent, *Drug Discovery Today*, Vol. 25, No. 7, pp. 1135-1141.

26. Kianzad B. and Wested J. (2021), 'No-one is Safe Until Everyone is Safe' – Patent Waiver, Compulsory Licensing and COVID-19, *European Pharmaceutical Law Review*, Vol. 5, No. 2, pp. 71-91.

27. Le V. A. and Samson L. (2021), Are IPRs and Patents the Real Barriers to COVID-19 Vaccine Supplies?, *Manchester Journal of International Economic Law*, Vol. 18, No. 2, pp. 192-204.

28. Long D. E. (2021), Innovation Policies: Roadblocks to Establishing Sustainable Pharmaceutical Innovation Policies. In: Ragavan S. and Vanni A. (eds.) Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals. *Routledge*, pp. 405-430.

29. McMahon A. (2020), Patents, Access to Health and COVID-19 – The Role of Compulsory and Government-Use Licensing in Ireland, *Northern Ireland Legal Quarterly*, Vol. 71, No. 3, pp. 331-358.

30. McMahon A. (2021), Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance, *Journal of Medical Ethics*, Vol. 47, No. 3, pp. 142-148.

31. Mercurio B. (2021), From TRIPS to Access to Medicines: What's There in Between? In: Ragavan S. and Vanni A. (eds.) *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals*. *Routledge*, pp. 82-93.

32. Mike J. H. (2019), A Re-Evaluation of the Framework for the Protection of Patents, Women's Health in Nigeria and the Issue of Accessing Pharmaceutical Innovation in Africa: Designing Strategies for Medicines, *Journal of World Intellectual Property*, Vol. 22, No. 3-4, pp. 162-204.

33. Motari Marion, Jean-Babtiste Nikiema, Ossy M.J. Kasilo, Stanislav Kniazkov, Andre Loua, Aissatou Sougou, and Propser Tumusiime (2021): The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement, *BMC Public Health*, Vol. 21.

34. Napolitano S. (2021), From TRIPS to Access to Medicines: What's There in Between?. In: Ragavan S. and Vanni A. (eds.) *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals*. *Routledge*, pp. 66-81.

35. Organization for Economic Co-operation and Development (2020), Treatments and a vaccine for COVID-19: the need for coordinating policies on R&D, manufacturing and access, OECD Policy Responses to Coronavirus (COVID-19). Available at: https://read.oecd-ilibrary.org/view/?ref=133_133372-v717pcul4c&title=Treatments-and-a-vaccine-for-COVID-19-the-need-for-coordinating-policies-on-RD-manufacturing-and-access.

36. Owoeye O. (2019), Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access, *Routledge*.

37. Reisinger Markus, Lluis Sauri, and Hans Zenger (2019): Parallel imports, price controls, and innovation, *Journal of Health Economics*, Vol. 66, pp. 163-179.

38. Sampat Bhaven and Heidi L. Williams (2019): How do patents affect follow-on innovation? Evidence from the human genome, *American Economic Review*, Vol. 109(1), pp. 203-236.

39. South Centre (Research Paper 85, 2019), Access to medicines: experiences with compulsory licenses and government use – the case of Hepatitis C. Available at: https://www.southcentre.int/wp-content/uploads/2019/04/RP85_Access-to-Medicines-Experiences-with-Compulsory-Licenses-and-Government-Use-The-Case-of-Hepatitis-C_EN-1.pdf.

40. South Centre (Research Paper 100, 2019), Medicines and Intellectual Property: 10 Years of the WHO Global Strategy,. Available at: https://www.southcentre.int/wp-content/uploads/2019/12/RP100_Medicines-and-Intellectual-Property-10-Years-of-the-WHO-Global-Strategy-_EN.pdf.

41. South Centre (Research Paper 101, 2019), Second Medical Use Patents - Legal Treatment and Public Health-Issues. Available at: https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf.

42. South Centre (Research Paper 103, 2020), Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa. Available at: https://www.southcentre.int/wp-content/uploads/2020/02/RP103_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-HealthTRIPS-Flexibilities-in-Africa_EN.pdf.

43. South Centre (Research Paper 114, 2020), Equitable Access to COVID-19 related health technologies: A global priority. Available at: https://www.southcentre.int/wp-content/uploads/2020/06/RP-114.pdf.

44. South Centre (Research Paper 127, 2020), Revisiting the questions of extending the limits of protection of pharmaceutical patents and data outside the EU – the need to rebalance. Available at: https://www.southcentre.int/wp-content/uploads/2020/12/RP-127.pdf.

45. South Centre (Research Paper 129, 2021), The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines. Available at: https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf.

46. South Centre (Research Paper 132, 2021), Interpreting the Flexibilities under the TRIPS Agreement. Available at: https://www.southcentre.int/wp-content/uploads/2021/06/RP-132.pdf.

47. South Centre (Research Paper 141, 2021), Utilising Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions. Available at: https://www.southcentre.int/wp-content/uploads/2021/11/RP141_Utilising-Public-Health-Flexibilities-in-the-Era-of-COVID-19_EN.pdf.

48. South Centre (Training Papers 1, 2019), Intellectual property and access to medicines: An introduction to key issues – some basic terms and concepts. Available at: https://www.southcentre.int/wp-content/uploads/2019/12/TP1_Intellectual-Property-and-Access-to-Medicines_EN-1.pdf.

49. Urias Eduardo and Shyama V. Ramani (2020), Access to medicines after TRIPS: is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence, *Journal of International Business Policy*, Vol. (3), pp. 367-384.

50. Walsh K., Wallace A., Pavis M., Olszowy N., Griffin J. and Hawkins N. (2021), Intellectual property rights and access in crisis, *IIC - International Review of Intellectual Property and Competition Law,* Vol. 52, pp. 379–416.

51. World Health Organization, World Intellectual Property Organization and World Trade Organization (2020), Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2nd edition. World Health Organization, Geneva (WHO ISBN 978-92-4-000827-4 (print) / ISBN 978-92-4-000826-7 (electronic version)). Available at: https://apps.who.int/iris/handle/10665/333552.

52. World Health Organization, World Intellectual Property Organization and World Trade Organization (2021) Intersections between public health, intellectual property and trade: Promoting Access to Medical Technologies and Innovation, 2nd edition, updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic (2021). World Health Organization, Geneva (WHO ISBN 978-92-4-003635-2 (print) / ISBN 978-92-4-003634-5 (electronic version). Available at: http://apps.who.int/iris/handle/10665/346780.

53. World Trade Organization (2020), Staff Working Paper ERSD-2020-12, Patent-related actions taken in WTO Members in response to the COVID-19 Pandemic. Available at: https://www.wto.org/english/res_e/reser_e/ersd202012_e.pdf.

54. World Trade Organization (2020), the TRIPS Agreement and COVID-19, Information Note (2020). Available at: https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

[附件和文件完]