

## 专利法常设委员会

### 第三十一届会议

2019年12月2日至5日，日内瓦

#### 文件 SCP/31/5“关于专利和获取医疗产品与保健技术的已有研究的回顾报告”摘要

##### 秘书处编拟的文件

1. 专利法常设委员会（SCP）在2018年12月3日至6日和2019年6月24日至27日分别于日内瓦举行的第二十九届会议和第三十届会议上商定，秘书处将按文件 SCP/28/9 Rev. 所载，在 SCP 第三十一届会议上提交关于专利和获取医疗产品与保健技术的已有研究的回顾报告（见文件 SCP/29/7 第 22 段和文件 SCP/30/10 第 23 段）。文件 SCP/28/9 Rev. 是阿根廷、巴西、加拿大和瑞士代表团提交的提案，建议进行此项回顾工作供委员会在“专利与卫生”议程项目下审议。
2. 根据 SCP 的上述决定，秘书处编拟了所述回顾报告，载于文件 SCP/31/5 “关于专利和获取医疗产品与保健技术的已有研究的回顾报告”，并将其提交给将于 2019 年 12 月 2 日至 5 日在日内瓦举行的委员会第三十一届会议讨论。
3. 鉴于文件 SCP/31/5 的篇幅，编拟了本文件作为该文件的摘要。
4. 按照 SCP 的上述决定，回顾工作是根据文件 SCP/28/9 Rev. 中所载的提案进行的。具体而言，回顾工作是由秘书处与世卫组织和世贸组织秘书处协商开展的，并列入了这些组织以及其他相关政府间组织编拟的研究报告。回顾工作中还列入了由这些组织委托外部研究人员编拟的研究报告，以及经过同行审评的学术研究。
5. 按照委员会的授权，秘书处在进行上述回顾工作时，主要检索了关于以下主题的研究报告：

- 专利及其他相关问题与医疗产品和保健技术可负担性和可用性之间的关系；<sup>1</sup>
- 专利制度包括专利质量机制在激励和促进新药和保健技术开发以解决全球疾病负担、促进医疗产品和保健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保健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保健技术可负担性和可用性方面的作用；
- 基本药品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。

6. 该回顾涵盖了 2005 年至 2018 年间所完成的工作。对每份研究报告都以大约半页的篇幅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。

7. 关于政府间组织制作的作品，除了产权组织、世卫组织、世贸组织的作品和这些组织委托的外部研究人员的作品之外，还对欧洲联盟、贸发会议、艾滋病署、经合组织、开发计划署、国际贸易和可持续发展中心及南方中心等组织制作的出版物进行了检索。

8. 对 80 多份经过同行审评的期刊进行了学术文献检索，考虑期刊领域与得到授权主题的相关性。读者应注意下述事实，即尽管本回顾报告列入了所有与上述主题相关的经过同行审评的学术研究报告，但是秘书处尚未对其内容进行质量评估。此外，根据 SCP 的任务授权，回顾报告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。

9. 对于上述每一项得到授权的主题，都已找到了不同数量的研究报告。所找到的大多数经济和法律文献与以下主题相关：（i）专利制度在激励和促进新药和保健技术开发以解决全球疾病负担方面的作用；（ii）专利制度在医疗产品和保健技术部门中促进知识溢出和技术转让的作用；（iii）专利与医疗产品和保健技术可负担性和可用性之间的关系；及（iv）强制许可机制在促进医疗产品和保健技术可负担性和可用性方面的作用。已找到的与基本药品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）主题相关的文献量较少。这反映出在经济学、法律或其他领域都缺乏有关该主题的已发表研究。

[后接附件]

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<sup>1</sup> 为回顾目的，“医疗产品和保健技术”系指医药、疫苗、诊断方法和医疗器械。

关于专利和获取医疗产品与保健技术的已有研究的回顾报告中列入的研究报告一览表：

1. 具有历史意义的突破性创新，《世界知识产权报告》第二章，世界知识产权组织（2015年）。
2. 《与流感病毒及其基因相关的专利问题：概述》，生命科学计划，产权组织（2007年）。世界卫生组织委托编制的工作文件。可在以下网址查阅：  
[https://www.wipo.int/export/sites/www/policy/en/global\\_health/pdf/influenza.pdf](https://www.wipo.int/export/sites/www/policy/en/global_health/pdf/influenza.pdf)。
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[https://www.who.int/phi/publications/Increasing\\_Access\\_to\\_Diagnostics\\_Through\\_Technology\\_Transfer.pdf](https://www.who.int/phi/publications/Increasing_Access_to_Diagnostics_Through_Technology_Transfer.pdf)。
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