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SUMMARY: STUDY ON THE ROLE OF PATENT SYSTEMS IN PROMOTING INNOVATIVE MEDICINES, AND IN FOSTERING THE TECHNOLOGY TRANSFER NECESSARY TO MAKE GENERIC AND PATENTED MEDICINES AVAILABLE IN DEVELOPING COUNTRIES AND LEAST DEVELOPED COUNTRIES

Document prepared by the Secretariat

INTRODUCTION

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twentieth session held in Geneva from January 27 to 31, 2014, document SCP/21/8 entitled "Study on the role of patent systems in promoting innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in developing countries and least developed countries (LDCs)" was submitted by the Secretariat to the twenty-first session of the SCP. The study is confined to fact-finding, and was drawn up based on a thorough review of relevant literatures on the topic. Due to the complexity and multifaceted nature of the topic, the study may not exhaust all relevant issues, which could be subject to further research. In accordance with the WIPO language policy, document SCP/21/8 is available only in English due to its volume. This document is a summary of document SCP/21/8, which will be available in six languages.

MEASURING THE RELATIONSHIP BETWEEN PATENT SYSTEMS AND INNOVATION AND TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL SECTOR

2. The first section of the paper explains issues implicated in empirically measuring the relationship between patent systems and innovation or technology transfer in the pharmaceutical sector.

Indicators of Innovation and Technology Transfer in the Pharmaceutical Sector

3. This section first discusses the indicators commonly used to assess the relationship between a patent system and innovation or technology transfer in the pharmaceutical sector, and issues that arise from the use of such indicators. For example, numerous studies have used R&D activities to examine the impact of changes in patent protection on pharmaceutical R&D, including the level of R&D expenditures, composition of R&D, and private returns to R&D using the market value of a pharmaceutical firm's stock, debts and assets. However, obtaining reliable data on R&D expenditures, receipt of payment for contract R&D, venture capital investments and other forms of R&D expenditures might be challenging, and its utility may be limited due to changes in a country's definition of what constitutes R&D.

4. Patent grants, patent applications and patent citations have also been used to measure innovation or transfer of technology in the pharmaceutical sector. Patenting activity has been identified as a quantitative indication of the innovation process. The use of patenting activity as an indicator is not free from challenges. For example, the value of a pharmaceutical innovation may not be captured by merely counting the patent or patent application. In addition, a number of studies on the role of patent systems in pharmaceutical innovation have used survey data to assess the relationship between patent protection and the R&D/commercialization of pharmaceuticals. In countries in which domestic R&D capabilities are underdeveloped, however, surveys of domestic pharmaceutical industry participants may not be an informative indicator of innovation. In addition, some studies have used market outcome data and trade data, including licensing payments, to assess the relationship between patent protection and the diffusion of pharmaceuticals and pharmaceutical technology. With regards to licensing agreements, unless publicly disclosed, such information may be difficult to obtain.

Challenges in Measuring the Effect of Patent System on Innovation and Technology Transfer in the Pharmaceutical Sector

5. Two challenges have been noted across numerous studies on measuring the relationship between patent systems and pharmaceutical R&D or technology transfer. The first is that the patent law reform, or IPR reform more generally, was often an endogenous policy choice. In other words, a country's adoption or enhancement of patent protection is a response to the needs of domestic industries that have acquired greater innovative capacity. This would present difficulties in attributing increased pharmaceutical innovation or technology transfer to strengthened patent protection. Numerous studies have claimed that developing countries and LDCs had to introduce IPR reform and adopt a higher level of IP protection as a result of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement). Consequently, many studies converge on the view that in general, a developing country's reform of its patent laws subsequent to the TRIPS Agreement may be regarded as having an external cause; therefore, changes to patent laws to comply with the TRIPS Agreement can, in certain cases, provide a natural experiment to understand the effect of IP protection on innovative activities. A second challenge is the influence of non-patent based initiatives, laws or policies on innovation or the market for technology. Such factors can affect observed trends in data on the effect of patent systems on pharmaceutical innovation or technology transfer. To account for any influence in the analysis, statistical studies have tried to control for such factors in various ways depending on the data and methodology used.

THE ROLE OF PATENT SYSTEMS IN PROMOTING INNOVATIVE MEDICINES

6. The second section reviews empirical studies that measure the role of patent systems as a whole in promoting pharmaceutical innovation and subsequently reviews literature considering the role of relevant elements of the patent system in pharmaceutical innovation.

Empirical studies

7. The review of empirical literature on the role of patent systems as a whole in pharmaceutical innovation demonstrates there is no single effect of patent protection on pharmaceutical innovation across all countries. Statistical studies that measure the role of patent systems in promoting pharmaceutical innovation have noted that any observed increases in pharmaceutical innovation are not exclusively attributable to patent protection, and that factors such as education level, country income level, the size of the market, among other factors, play a role in influencing pharmaceutical innovative activities.

8. Numerous studies surveying pharmaceutical industry participants have indicated that patent protection is critical for incentivizing pharmaceutical R&D. In this regard, various survey-based studies of pharmaceutical industries in developed countries have concluded that in the absence of patent protection, many of the pharmaceutical inventions would not have been developed or commercially introduced. One of the main arguments put forward with respect to the need for strict protection of IPRs is the high cost of R&D for new medical products. On the basis of a systematic overview of publications on the cost of developing pharmaceuticals, the WTO, WIPO, WHO study, Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade (the Trilateral Study) noted that estimations of R&D costs varied from $92 million US dollars ($161 million US dollars capitalized) to $883.6 million US dollars ($1.8 billion US dollars capitalized). In providing this information, however, the Trilateral Study explained that such data are difficult to verify and that the estimations are based on multiple variables. On the issue of measuring the cost/investment of pharmaceutical R&D, there is no concordance of views on the appropriate methodology to measure the cost/investment required to develop pharmaceuticals. However, some commentators have claimed that three attributes of pharmaceutical development are indisputable: (i) that the fixed costs of pharmaceutical development are extremely large in relation to the marginal costs of production; (ii) the development project failure rate is high; and (iii) imitation costs are small in relation to development costs.

9. Statistical studies on the impact of patents in pharmaceutical innovation in developed countries have tended to indicate that patent protection in developed countries is positively related with pharmaceutical innovative activities. For instance, in a study of the impact of 1987 Canadian legislation strengthening patent protection on pharmaceutical R&D efforts, Pazderka (1999) found an increase in pharmaceutical R&D spending in Canada beginning around 1987. Similarly, Qian (2007) found that patents had a positive effect on pharmaceutical R&D in more developed countries with higher levels of education. In addition, Kyle et al. (2012) concluded that with respect to diseases that affect high-income countries, patent protection in such countries was associated with greater pharmaceutical R&D efforts.

10. In contrast to evidence on the impact of patents in pharmaceutical innovation in developed countries, the evidence on the effect of patent protection in developing countries or on R&D for pharmaceuticals to treat diseases found predominantly in developing countries or LDCs has not indicated a consistent trend. Lanjouw et al. (2001) discovered an increase in the inventive activity on at least some pharmaceuticals directed at LDC markets as a result of the TRIPS Agreement and free trade agreements with IP provisions. Lanjouw et al. (2005) concluded similarly, reporting an apparent increase in the early 2000s of patenting activity and bibliometric citations relating to diseases for which there was still a need of good, low-cost treatment. Lanjouw et al. (2005) remarked, however, that it could be too early to determine whether such increase would continue. Kyle et al. (2012) found that unlike in high income countries, patent protection in developing countries and LDCs did not stimulate greater R&D efforts in treatments for neglected diseases.

11. Numerous studies have focused on the impact of patent protection on pharmaceutical innovation in India. Dutta et al. (2008) found trends of increased pharmaceutical R&D in India

by Indian firms on the basis of data spanning from 1989 to 2005. Similarly, Arora et al. (2008) discovered that in anticipation of the implementation of pharmaceutical patent protection in India, large Indian pharmaceutical firms had increased their innovative activity and had shifted to R&D-intensive business models. Haley et al. (2012) found that the growth of pharmaceutical innovation in India had declined in its product-patent regime and thus concluded that the notion that product-patent regimes incentivize innovation was unsupported by patent data from India's pharmaceutical industry. Regarding the type of diseases toward which Indian pharmaceutical firms directed their R&D efforts, surveys of industry participants used in Lanjouw et al. (2001) and Lanjouw et al. (2005) showed that Indian firms dedicated a not insignificant share of their R&D budgets to products for LDC markets and tropical diseases. Lanjouw et al. (2001) reported that approximately 16% of the aggregate R&D expenditures of survey respondents was aimed at products for LDC markets or tropical diseases. In subsequent research, Lanjouw et al. (2005) reported this share was 10%.

Elements of patent systems and their role in promoting innovative medicines

12. The second section also describes how certain elements of the patent system affect or may potentially affect pharmaceutical innovation. While the international legal framework under the TRIPS Agreement requires pharmaceutical products and processes to be patentable subject matter, the legal framework at the national or regional level primarily influences innovation and dissemination of technology in the pharmaceutical sector. One of the elements relevant to pharmaceutical innovation is the question of patentability, especially the patentability of biotechnological inventions. For instance, the determination of what is patentable and what is not under the relevant law may be an important indication for directing pharmaceutical R&D. The Trilateral Study noted that the patentability of first and second medical indications is also an element relevant to the innovation dimension in the pharmaceutical sector. One view on first and secondary medical use patents, for example, is that such patents reward uninventive activities. Another view holds, for example, that additional medical use in itself can be inventive, and development of new medical use also requires incentives.

13. The patentability requirement may also play a role in the pharmaceutical innovation cycle. Because the novelty requirement may bar the patenting of a known molecule, some have held the view that the patent system does not account for extensive development and commercialization costs required to develop a known, and therefore unpatentable, molecule into a market-approved pharmaceutical product (Roin (2009), Basheer (2012)). Additionally, according to a Report prepared by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), the inventive step/non-obviousness requirement impacts incremental innovation, which can play a role in the development of products to meet public health needs. The importance of demarcating the line between incremental innovations with real improvements, and those that offered no therapeutic benefits has been emphasized. The requirement of industrial application/utility, in some literature, has been identified as implicating pharmaceutical innovation, in particular with respect to synthesized compounds for which no applicable result is known (Schacht et al. (2005)) and genes
(UNCTAD (2011)).

14. In relation to claim construction, an UNCTAD study noted that different doctrines of patent infringement might influence medical advances. The term of patent protection, and patent term extensions, may also play a role in pharmaceutical innovation. Different views have been expressed about the impact of patent term extensions on public health. One view holds that such extensions impede access by delaying generic entry (for example, MSF (2013)), whereas another holds that they incentivize research activity (for example, Office of Technology Assessment, US Congress (1981)).

15. A CIPIH Report noted that the experimental use and/or scientific research exception, for example, may influence the extent to which follow-on research may be conducted. Further,

some studies have assessed the relationship between compulsory licensing and changes in pharmaceutical innovation, finding that compulsory licenses may influence pharmaceutical R&D investment in a complex manner. According to them, if broadly used, compulsory licensing undermined incentives for innovation, but it did not necessarily entail a decrease in welfare under certain circumstances (Stavropoulou et al. (2014)) and encouraged innovation in some cases (Tubingen et al. (2014)). Similarly, studies using theoretical models have found that parallel importation influences pharmaceutical R&D investment. Ganslandt et al. (2004) explained that countries with national exhaustion policies, which had a narrow area of exhaustion and therefore a greater scope for price differentiation, might offer stronger incentives to innovate at the expense of higher consumer costs. Using a "North-South country model", Bennato et al. (2014) found that R&D investment increased under parallel trade when the "South" accounted for R&D expenditures, the cost to firms of supplying the "South", and the lack of price regulation. Mantovaniy et al. (2012), using a three-country model, concluded that in an emerging economy with technologically heterogeneous firms (i.e., firms at varying levels of technological advancement), parallel importation resulted in increased pharmaceutical R&D by the more technologically advanced firms. Further, they found that in an emerging economy where trade costs were low, allowing parallel imports of pharmaceuticals would result in less pharmaceutical R&D by firms regardless of the level of technologically sophistication.

16. Additionally, the effects of the patentability of upstream research tools (e.g., gene-based research tools) and certain business strategies (e.g., non-practicing entities and "patent thickets") on pharmaceutical innovation are discussed in the document.

THE ROLE OF PATENT SYSTEMS IN FOSTERING TECHNOLOGY TRANSFER NECESSARY TO MAKE GENERIC AND PATENTED MEDICINES AVAILABLE IN DEVELOPING COUNTRIES AND LDCs

17. The third section of the study reviews empirical studies examining the relationship between patent systems and the transfer or dissemination of pharmaceutical technology. It then proceeds to review literature considering the role of selected elements of the patent system in pharmaceutical technology transfer. The role of patent systems in fostering transfer of technology in general has been extensively addressed elsewhere, and therefore those discussions are not included in this study.

Empirical studies

18. Technology transfer, which may occur through various channels, may take place at each stage of the innovation cycle: from drug discovery to full-scale commercialization. In general, some studies, for example IFPMA (2011), have acknowledged that intellectual property protection is a requisite condition for pharmaceutical technology transfer for research-based pharmaceutical companies. At the same time, studies on pharmaceutical technology transfer and local production, such as UNCTAD (2011), have assessed a country's IP regime as just one component of the framework for technology transfer. Within the context of technology transfer for purposes of local pharmaceutical production, it has been shown that patents had a variable impact on local production. The extent of the impact depended on other factors, including for example the technical capacity of the local pharmaceutical industry.

19. Empirical studies examining the relationship between patent systems and technology transfer necessary to make medicines available in developing countries and LDCs are scarce. Instead, many studies have assessed the relationship between pharmaceutical patent protection and pharmaceutical product launch, the value of pharmaceutical trade, and the general availability of medicines in developing countries and LDCs. Similar to the empirical studies on the role of patent systems as a whole in promoting pharmaceutical innovation, the empirical studies reviewed in the third section explained that factors such as the country's

income level, the distribution of income within a country, among others, influenced any observed effects of pharmaceutical patent protection.

20. Although such studies do not directly explain the role of patent systems in fostering transfer of technology in the pharmaceutical sector, they might be relevant to technology transfer that occurs through various channels. A study by Kyle et al. (2013), for example, examining the results of increased patent protection on the speed of drug launch, quantity sold and price, found that, on average, access to new pharmaceuticals increased with the adoption of the TRIPS Agreement. Further, the study found that the probability of a new pharmaceutical product launch increased, in addition to quantities sold, conditional on price. Additionally, Borrell (2006) found that the patent regime has had a strong positive influence on the availability of HIV/AIDS therapies in developing countries with relatively equally distributed incomes. The study further found that developing countries with relatively large income inequalities did not support the price premiums that incentivize the early launch of patented pharmaceuticals.

21. Lanjouw (2005) found that with respect to high income countries, enhanced patent protection tended to stimulate market entry. However, Lanjouw found that with respect to low and middle income countries, the evidence was mixed. Lanjouw found evidence that high levels of patent protection tended to encourage more frequent entry in the short term, specifically with regard to countries with less production capacity. Conversely, the study found that in the longer term, this may not be the case: countries with local production capacity and extensive patent protection may have fewer new pharmaceutical products enter the market in the longer term. In a study evaluating multilateral and bilateral biopharmaceutical trade subsequent to the implementation of the TRIPS Agreement, Delgado et al. (2010) found that relative to a control group of non-IP products, there was an increase in pharmaceutical exports from developing countries but not a significant increase in imports to those countries. Delgado et al. therefore concluded that the TRIPS Agreement had yet to spur significant changes in the level of biopharmaceutical trade to developing countries and LDCs.

Elements of patent systems and their role in pharmaceutical technology transfer

22. Although it has been acknowledged that a linkage between the patent system and the dissemination of technologies lacks conclusive evidence, certain elements in the patent system could have implications for the transfer of technology in the pharmaceutical sector. As regards the requirement of inventive step/non-obviousness, the European Commission reported a concern that evergreening strategies might impede the development and commercialization of generic versions of a patented product.

23. With respect to the disclosure requirement, it is generally explained that publication of patent applications and patents contribute to the tacit transfer of technology and also to the transfer of technology through licensing agreements and transfer of rights. In this regard, Correa (2007) noted that the disclosure requirement had particular importance in the pharmaceutical sector to enable the reproduction of a pharmaceutical invention during its patent term (e.g., pursuant to a compulsory license) or subsequent to the expiration of the patent. One of the fundamental questions raised with respect to the role of the disclosure requirement is to what extent a patentee must disclose his invention in order to contribute to the transfer of technology and further innovation. The scope of protection (boundary of the right), the owners of the right, information concerning any associated rights and other information relating to the legal status of the patent and patent applications are also made available to the public by patent offices. Determining the legal status, among other aspects, is a key aspect in freedom to operate assessments and used to make decisions on R&D, product launch, commercialization and negotiating licenses.

24. Additionally, Maskus (2001) asserted that the exhaustion of patent rights and parallel importation may be a source of pharmaceutical technology transfer. With regard to compulsory

licensing, instances have been reported in which compulsory licenses were issued to local pharmaceutical producers. The effectiveness of compulsory licensing as a tool for the transfer of technology, however, has been widely debated due to the fact that transfer of know-how not disclosed in patent applications can only be made by concluding voluntary licenses or through reverse engineering (Watal (2001)).

25. Patent licensing is one of the channels for promoting technology transfer to, and the further development of technology by, licensees. In this regard, voluntary licensing agreements have been used to transfer pharmaceutical technology to generic producers in developing countries. A WHO study that looked at trends in initiatives supporting local production and technology transfer of pharmaceuticals to developing countries found that, in general, voluntary licenses incorporating a technology transfer component (i.e., supporting a producer's capacity to produce in addition to licensing the legal right to use the patented invention) had increased since the mid-1990s. Furthermore, a patent pool is seen as an additional tool to transfer technology in the pharmaceutical sector.

26. Additionally, some countries have adopted policies that encourage universities and research institutions to seek patent protection for inventions arising out of government-funded research (for example, the 1980 United States of America Bayh-Dole Act). In the case of pharmaceuticals, the CIPIH report stated that such policies might facilitate the exclusive licensing of a compound from a university, which did not have the skill or resources to engage in clinical trials and mass production, to a pharmaceutical company. Numerous articles have questioned whether such policies, if not tailored to suit the specific context of the R&D environment in a given country, would produce the intended economic benefits. For example, Sampat (2009) explained that if the main objective of Bayh-Dole legislation was to generate licensing revenues, a Bayh-Dole-type of legislation might not produce that intended effect in developing countries where public universities had a limited research base.

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